Concept Report

National Research Council Canada | Conseil national de recherches Canada

National Research Council of Canada

Clinical Trial Manufacturing Facility (CTMF)

Biotechnology Research Institute of the National Research Council of Canada

6100 Royalmount Ave, Montreal, Quebec H4P 2R2, Canada

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1.0 PROJECT OVERVIEW

1.1 Foreword

The Consulting Firm has been retained by the National Research Council of Canada (NRC) to perform a Concept Study to support NRC's business case for a new Clinical Trial Manufacturing Facility (CTMF).

1.2 Executive Summary

1.2.1 General Overview

The Consulting Firm has been requested to complete a concept study of a new greenfield GMP compliant facility at NRC's Royalmount site in Montreal. The facility will be designed for production based on cell culture, purification and bulk filling of biologics such as vaccines, viral vectors and/or monoclonal antibodies.

The facility will be designed to BSL2/CL2 requirements, where required (in accordance with Canadian Biosafety Standard, second edition). The facility will be designed for two processes; one for BSL2/CL2

Figure 1 - 3D Rendering of CTMF Facility

2.0 GOALS AND OBJECTIVES

2.1 Business Mission

NRC is seeking to manufacture vaccines and therapeutics for clinical trials of humans in a new GMP compliant clinical trial manufacturing facility.

2.2 Project Objectives

2.2.1 Business

- Strategic Fit
  - Facility shall be ready for clinical production in Q4 2022
  - Facility design allowing for future process technology implementation
  - Aligned with digital and automation strategies
- Cost
  - Challenge and optimize project concept through value engineering and peer reviews
  - +/- 25% estimate at the end of the concept study
  - +/- 15% estimate at the end of basis of design (BOD)
- Performance
  - Facility is to be designed to accommodate 10 batches per year
  - State-of-the-art facility while maximizing flexibility for manufacturing clinical batches of vaccines, monoclonal antibodies and other therapeutic agents
  - Fill/finish and secondary packaging are not in scope
- Compliance
  - Applicable Canadian Regulations
    - Food and Drug Regulation, Division Part A, Part C (Divisions 1, 2, 4 and 5)
    - Health Canada - Good Manufacturing Practices Guide for Drug Products, 2018, GUI-0001
    - Annex 1 to the Good Manufacturing Practices Guide - Manufacture of Sterile Drugs (GUI-0119)
    - Annex 2 to the Current Edition of Good Manufacturing Practices Guidelines Schedule D Drugs (Biological Drugs) (GUI-0027)
    - Health Products and Food Branch Inspectorate, Guidance Document, Annex 13 to the Current Edition of the Good Manufacturing Practices Guidelines, Drugs Used in Clinical Trials, 2009, GUI-0036
    - Guidelines for Temperature Control of Drug Products during Storage and Transportation, 2011, GUI-0069

- PIC/S Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments 2016 (Referred by Health Canada GUI-0001)
- The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q5 - Viral Safety

2.2.2 Operations

- All production shall use the same unit operations:
  - Cell Amplification
  - Cell Production
  - Clarification using Depth Filtration
  - Purification Chromatography
  - Chemical Inactivation
  - Polishing Chromatography
  - Nanofiltration
  - Ultrafiltration
  - Bulk Filling

2.2.3 Engineering & Maintenance

- Facility
  - Sections of the facility will be designed to meet BSL2/CL2 requirements as defined by the Canadian Biosafety Standard, Edition 2 and to meet GMP compliance to Health Canada guidelines. It will be comprised of cleanroom design for the manufacturing areas with the appropriate airlock strategies to ensure containment and unidirectional flow to eliminate cross-contamination. The facility will also incorporate all necessary support functions including but not limited to:
    - Mud Room
    - Change Rooms
    - Upstream Processing Suite
    - Downstream Processing Suite
    - Media & Buffer Preparation Rooms
    - Washing & Sterilizing Areas
    - Warehouse
    - Cold Storage (2 - 8 C)
    - Weighing & Dispensing Areas
    - In Process QC Laboratory
    - Microbiology Laboratory

- Mechanical Room
- Electrical Room
- IT/Automation Room
- Waste Management (Neutralization & Bio-decontamination) Systems

3.0 PHILOSOPHIES AND DESIGN BASIS

3.1 Product Profile

3.1.1 Product Type

The CTMF shall be designed to be able to produce vaccines, viral vectors from animal cell systems and antibody based therapeutic proteins. The intent of the facility is not to produce a specific or single product, but rather to have the flexibility and adaptability as an inherent feature of its design to produce a limited number of batches of various products as and when required. Therefore, the new CTMF at NRC's campus shall be equipped to use different kinds of biological organisms, such as HEK-293 cells adapted for suspension growth to produce an adenovirus (Ad5-CoV), and CHO cells genetically modified to produce specific monoclonal antibodies.

3.1.2 Markets

The facility design is intended to adhere only to Health Canada requirements to meet the needs of the Canadian market. However, the design will be assessed against FDA and EU requirements to highlight any gaps and acquire recommendations to close those gaps.

3.1.3 Material Characteristics

According to the Health Canada ePATHogen-Risk Group Database and the Centers for Disease Control and Prevention (CDC) Guidelines, the agents that have the potential to be used in this facility are classified as follows:

- HEK-293 Noninfected Cells - Classified as a Risk Group 1 (RG1). These organisms pose a moderate health hazard. CL1 containment is required for work with HEK-293 cell lines.
- Adenovirus in Suspension - Classified as a Risk Group 2 (RG2). These organisms pose a moderate health hazard. CL2 containment is required for work with Adenovirus type-5 vectors.
- CHO Genetically Modified Cells - Classification will depend on the gene modification. NRC chose the assumption to handle maximum Risk Group 2 (RG2). These organisms pose a moderate health hazard. CL2 containment is required for work with GM CHO cells.
- Small volumes of IPA and other solvents may be used for cleaning, sampling, and testing. A strategy to handle solvents within the warehouse and process areas may be required. Based on the production scale, the concept study assumes these volumes to be small enough to be

addressed by a localized solution rather than a centralized solution. This assumption will need to be further evaluated and validated in the next phase of the project.

- Additional hazardous/toxic/corrosive materials may be used in the facility, and impacts of their use need to be understood. The concept study has implemented provisions for the treatment of all - solids, liquids, and gases - bio-hazardous waste and for the treatment of aqueous waste that are not pH neutral. Based on the production scale, the concept study assumes the volumes of all other toxic and corrosive materials and waste to be negligible. This assumption will need to be further evaluated and validated in the next phase of the project.

3.1.4 Forecast Volume

NRC has opted to build the facility to support 500L mAbs bioreactor scale and 50L Viral Vector bioreactor scale. These will be the limiting factors for any future volume forecast. However, The Consulting Firm - as instructed by NRC - has made allowances for space and utility to support a future 500L Viral Vector bioreactor. The Consulting Firm has also considered turndown capacity of the upstream equipment in order to produce volumes that are less than the design capacity of the equipment. Note that some of this critical equipment has already been purchased by NRC prior to The Consulting Firm becoming engaged in this project.

The Equipment List in Process Appendix 8.1 is based on the Recommended Option layout. The equipment selected in the list support the process basis described below.

3.2 Process Basis

The processes described in this section are based on the Recommended Option layout presented in the later sections. While the maximum capacity of this layout is limited by the scale of the production bioreactors - that is, 500L for mAbs and 50L for viral vector - there is opportunity for increasing capacity through intensification of schedule. The current assumption is that approximately 10 batches/year will be processed by each suite. I f there is interest in increasing the output of this facility beyond this assumption while maintaining the processing suites as in Recommended Option, then the utilities and waste management systems will need to be re-evaluated and rescaled as required.

3.2.1 Scope of Operations - mAbs

The scope of operations provides an overview of the major unit operations and support functions required to manufacture mAb cell, and outlines the typical manufacturing sequences. The new manufacturing area is designed to run industry-typical biopharmaceutical manufacturing processes employing single-use equipment for the production of mAb cell cultures. As the facility is designed for maximum flexibility, majority of the process equipment are single-use and portable, thus reconfigurable based on manufacturing and facility requirements. No process equipment is permanently fixed within the core manufacturing area. Clean utilities required for the unit operations shall be assigned in the production areas. Production areas will be clean room, Grade C and not be designed for biocontainment.

Manufacturing and product transfer activities are operated under closed systems to provide product and personnel protection. One upstream suite, which includes a Cell Inoculation room and two downstream suites are designed to operate mAb process unit operations. The two downstream suites will be segregated for pre-viral and post viral step. The suites will be equipped with a single processing train with 500L upstream bioreactor capacity using primarily gamma irradiated & closed single-use systems, to maintain appropriate separation and to employ appropriate procedurally controlled segregation strategies.

Table 1 below summarizes overall process operations for mAb cell production at the Royalmount site. Additional details are provided in the finalized Block Flow Diagrams (BFD) and preliminary Process Flow Diagram (PFD) in Process Appendix 8.1. The Process Flow Diagrams will need to be further developed and detailed in the next phase as a target process is identified.

Table 1 - Summary of Overall Process Operations for mAb Cell Production

UNIT OPERATION	CAPABILITY
VIRAL STOCK PREPARATION	• Part of Upstream Suite Cell Inoculation room #2115 (Grade C) • Viral stock taken out from the refrigerator at ambient room temperature thaws under Bio Safety Cabinet • Batch sizes up to 20L, utilizing 5L shake flasks/bottles • Bench scales for weighing • Closed media additions (liquids) using pump • Biological Safety Cabinet for open media additions • Shaker - Incubator for mixing
CELL THAW & INCUBATION PREPARATION	• Part of Freezer Room #2128 (Grade C) and Upstream Suite Cell Inoculation room #2115 (Grade C) • In Freezer room, staged thawing of seed vials from -80°C freezer to the -20°C freezer to the 2°C - 8°C refrigerator. Then in Cell Inoculation room thawed to ambient room temperature under Bio Safety Cabinet. • Batch sizes up to 10L, utilizing 5L shake flasks • Bench scales • Closed media additions (liquids) using pump

UNIT OPERATION	CAPABILITY
	• Biological Safety Cabinet for open additions including viral substances • Shaker - Incubator for culture growth
INOCULUM PREPARATION & SEED BIOREACTOR TRAIN	• Part of Upstream Suite room # 2116 (Grade C) • Capabilities for batch sizes up to 50L, utilizing single-use bioreactor. • One 50L seed bioreactor • Load cells, bench scales, peristaltic pumps • Closed media additions (liquids) • Closed base, antifoam, and feed additions (liquids) • Utility connections for carbon dioxide gas, oxygen gas, nitrogen gas, and clean compressed air • Utility panels, temperature control unit connections • Automated mixing, pressure and temperature control
PRODUCTION BIOREACTOR TRAIN INCLUDING CELL INFECTION	• Part of Upstream Suite room # 2116 (Grade C) • Capabilities for batch sizes up to 500L, utilizing single-use bioreactor. • One 500L production bioreactor • Load cells, bench scales, peristaltic pumps • Closed media additions (liquids) • Closed base, antifoam and feed additions (liquids) • Utility connections for carbon dioxide gas, oxygen gas, nitrogen gas, and clean compressed air • Utility panels, temperature control unit connections • Automated mixing, pressure and temperature control
HARVEST	• Part of Upstream Suite room # 2116 (Grade C) • Clarification capabilities for batch sizes up to 500L, utilizing Depth filtration skid

UNIT OPERATION	CAPABILITY
	• Closed buffer additions (liquids) • Utility connections for clean steam and Ambient WFI • 500L broth storage tote, post-filtration (broth tote to move into Downstream Suite 1 room # 2135.
AFFINITY CHROMATOGRAPHY	• Part of Downstream Suite 1 room # 2135 (Grade C) • Flexible capabilities for batch sizes up to 500L, utilizing a single-use skid for Protein A chromatography • Closed buffer, acid and Ambient WFI additions (liquids) for chromatography skid • Utility connections for Ambient WFI • Eluate stored in 500L single-use mixer tote
LOW PH VIRAL INACTIVATION, DEPTH FILTRATION, AND PH NEUTRALIZATION	• Part of Downstream Suite 1 room # 2135 (Grade C) • Flexible capabilities for various batch sizes up to 500L, utilizing 100L single-use acid tote and bioburden reduction depth filtration • Closed acid and base additions (liquids) for single-use mixer • Chilled water supply and return connections for single-use mixer • Closed buffer additions (liquid) for bioburden reduction filter • Utility connections for WFI for bioburden reduction filter • Peristaltic pumps
AEX CHROMATOGRAPHY	• Part of Downstream Suite 1 room # 2135 (Grade C) • Flexible capabilities for batch sizes up to 500L, utilizing a 500L single-use mixer (load tote) and an AEX chromatography skid • Chilled water supply and return connections for single-use mixer • Closed buffers, 0.1M NaOH and Ambient WFI additions (liquids) for chromatography skid

UNIT OPERATION	CAPABILITY
	• Utility connections for Ambient WFI • Eluate stored in the 500L single-use mixer/tote
CEX CHROMATOGRAPHY	• Part of Downstream Suite 1 room # 2135 (Grade C) • Flexible capabilities for various batch sizes up to 500L, utilizing a 500L single-use mixer (load tote) and an CEX chromatography skid • Chilled water supply and return connections for single-use mixer • Closed buffer, 0.1M NaOH and 19% ethanol additions (liquids) for chromatography skid • Utility connections for Ambient WFI • Eluate stored in the 500L single-use mixer/tote
NANOFILTRATION	• Part of Downstream Suite 1 room # 2135 and Downstream Suite 2 room # 2139 (Grade C) • Filtration process initiated in Downstream Suite 1 and filtrate passed through via pass-through port and collected in Downstream Suite 2 • Flexible capabilities for various batch sizes up to 500 L, utilizing a 500L single-use mixer (nanofiltration tote) and a nanofiltration skid • Peristaltic pumps • Chilled water supply and return connections for single-use mixer • Closed buffer additions (liquids) for chromatography skid • Utility connections for Ambient WFI
ULTRAFILTRATION - DIAFILTRATION (UF/DF) AND CONCENTRATION ADJUSTMENT	• Downstream Suite 2 room # 2139 (Grade C) • Flexible capabilities for batch sizes up to 500L, utilizing a 500L single-use mixer (UF/DF tote) and a UF/DF skid • Product sampling

UNIT OPERATION	CAPABILITY
	• Product concentration adjustment using Ambient WFI • Chilled water supply and return connections for single-use mixer • Closed buffer, 0.1M NaOH and Ambient WFI additions (liquids) for UF/DF skid • Utility connections for Ambient WFI • Concentrated product stored in 200L single-use mixer
FINAL FILTRATION AND BULK FILLING	• Downstream Suite 2 room # 2139 (Grade C) • Flexible capabilities for batch sizes up to 200 L, utilizing a 0.22-micron filter • Final product filled into 50L single-use bags • Stored in refrigerator at 2-8 °C in warehouse • Peristaltic pumps

3.2.2 Process Description - mAbs

The following section provides a general overview of the major unit operations and outlines the mAb cell manufacturing processing sequences. The process described below represents a "typical" process around which the facility was designed. As NRC's intent is to manufacture clinical materials for various clients not known at this time and various processes which are yet to be identified, the order of the unit operations, volumes, and solutions will differ from client-to-client. Therefore, the facility was designed around a "typical", agreed-to process in order to detail equipment requirements including utility requirements. Additional unit operations, such as buffer exchange using TFF prior to chromatography loading may be required for certain processes. These will need to be evaluated and added as and when needed. The facility is designed to provide the flexibility and adaptability required for this purpose. The volumes presented below are based on the Process Definition document in Process Appendix 8.1. The process definition is based on a typical process and will need to be further defined in the next phase.

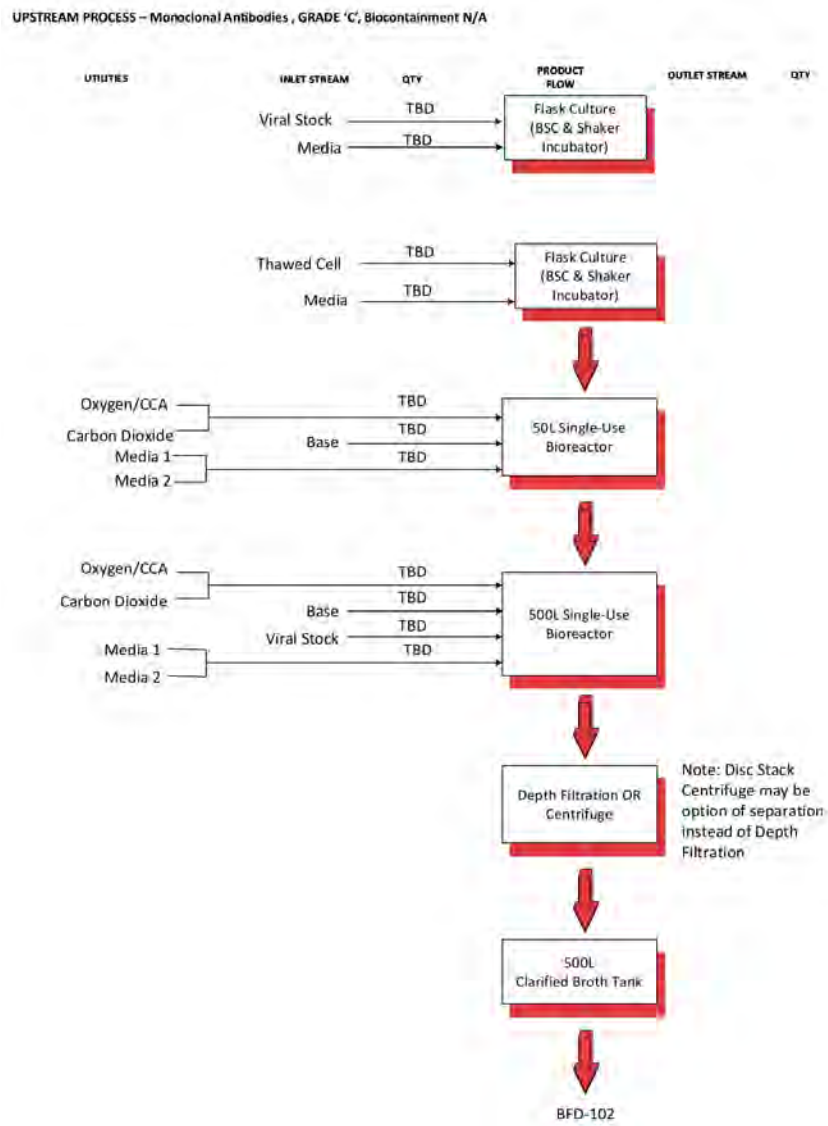


Figure 2 - mAbs Upstream Process Block Flow Diagram

3.2.2.1 Viral Stock Preparation

Viral stocks are taken out from the 2°C to 8°C refrigerator and mixed with prepared media into 5L shake flasks in a Biological Safety Cabinet. The flasks are then loaded into a shaker incubator for mixing.

3.2.2.2 Cell Thaw & Incubation Preparation

Seed vials are taken out from the -80°C freezer and are thawed to ambient room temperature through the -20°C freezer and the 2°C - 8°C refrigerator. Once thawed, the contents within the seed vials and prepared media is combined into 5 L shake flasks in a Biological Safety Cabinet. The flasks are then loaded into a shaker incubator for culture growth.

3.2.2.3 Inoculum Preparation & Seed Bioreactor Train

The 50L single-use seed bioreactor is set up with media at the appropriate temperature and pH with Dissolved Oxygen (DO) control and pH control activated. Approximately, 4L of the incubated culture from the shake flasks is transferred to the 50L single-use bioreactor using peristaltic pump. To achieve the preferred media to inoculum split of 5:1, the seed bio-reactor should initially be set up with 20L of prepared media at the time of inoculation. An additional 16L of media can be added to the bioreactor after 3-4 days of growth to reach the full scale of the bioreactor. Dedicated temperature control units and utility panels provide temperature-controlled water supply and return, ventilation, and blanketing compressed gases necessary for the growth process.

Each single-use bioreactor should also be furnished with appropriate sensors and controller for controlling process parameters such as rpm, conductivity, pH, and temperature.

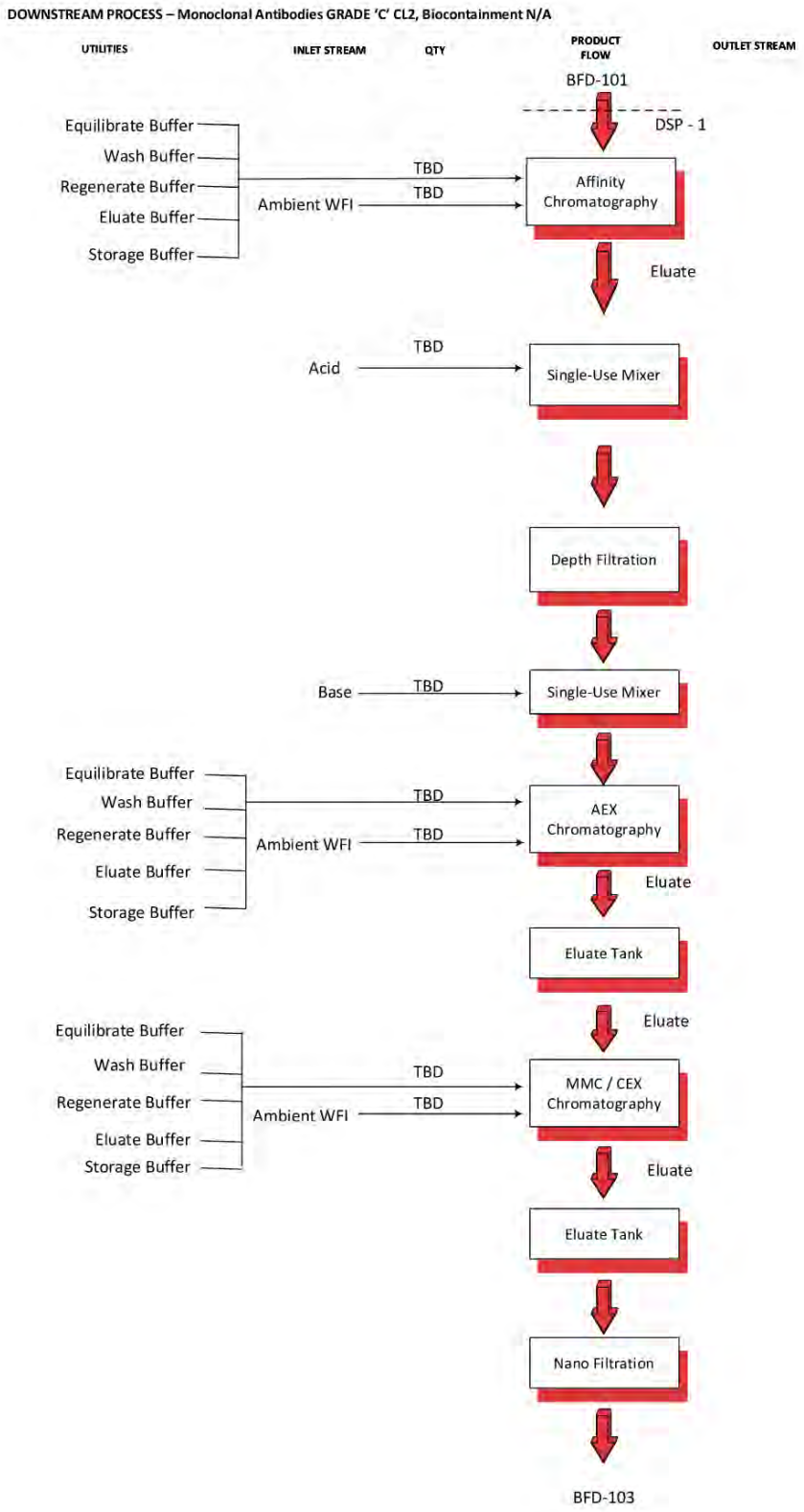
3.2.2.4 Production Bioreactor Train

The 500L single use production bioreactor is set up with media at the appropriate temperature and pH with Dissolved Oxygen (DO) control and pH control activated. Approximately, 40L of inoculate from the 50L single-use bioreactor is then transferred to the 500L single-use bioreactor via a peristaltic pump. To achieve the preferred media to inoculum split of 5:1, the production bioreactor should initially be set up with 200L of prepared media at the time of inoculation. An additional 160L of media can be added to the bioreactor after 3-4 days of growth to reach the full scale of the bioreactor. Dedicated temperature control units and utility panels provide temperature-controlled water supply and return, ventilation, and blanketing compressed gases necessary for the growth process.

Each single-use bioreactor should also be furnished with appropriate sensors and controller for controlling process parameters such as rpm, conductivity, pH, and temperature.

3.2.2.5 Harvest

Once the desired volume and cell density has been reached, the contents within the 500L bioreactor will be transferred for harvest processing through a depth filtration skid. The filters are sanitized with clean steam and then flushed with ambient WFI and buffer solution before contents from the 500L bioreactor is passed through. Approximately 440L of product exiting the depth filtration skid is then transferred to a 500L broth tote (harvest tote) for storage. The depth filtration skid is then chased with buffer to recover product. The filters are then decontaminated with caustic and flushed with WFI prior to breakdown.


DOWNSTREAM PROCESS – Monoclonal Antibodies GRADE 'C' CL2, Biocontainment N/A
UTILITIES
INLET STREAM
QTY
PRODUCT FLOW
OUTLET STREAM
BFD-101
DSP - 1
Equilibrate Buffer
Wash Buffer
Regenerate Buffer
Eluate Buffer
Storage Buffer
TBD
TBD
Ambient WFI
Affinity Chromatography
Eluate
TBD
Acid
Single-Use Mixer
Depth Filtration
Base
TBD
Single-Use Mixer
Equilibrate Buffer
Wash Buffer
Regenerate Buffer
Eluate Buffer
Storage Buffer
TBD
TBD
Ambient WFI
AEX Chromatography
Eluate
Eluate Tank
Eluate
Equilibrate Buffer
Wash Buffer
Regenerate Buffer
Eluate Buffer
Storage Buffer
TBD
TBD
Ambient WFI
MMC / CEX Chromatography
Eluate
Eluate Tank
Nano Filtration
BFD-103

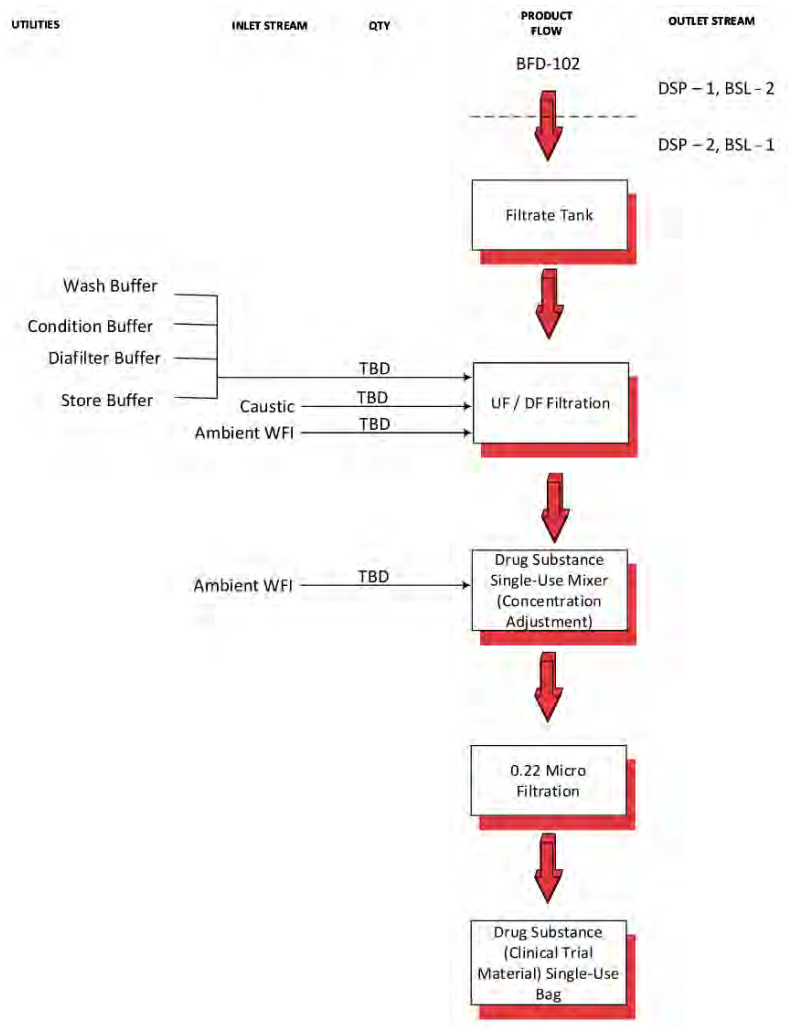


Figure 3 - mAbs Downstream Process Block Flow Diagram

3.2.2.6 Affinity Chromatography

The affinity chromatography column is first cleaned and flushed with 0.1M NaOH solution and ambient WFI respectively. Approximately 400L of buffer solution is passed through the chromatography skid for equilibration before 440L of product from the broth tote are transferred for loading. The chromatography skid then undergoes chase, wash and elution steps before an additional wash step is conducted utilizing buffer solutions. The chromatography column is then sanitized with 0.1M NaOH solution and flushed with ambient WFI before being stored in caustic.

Approximately, 95L of product, eluate exiting the chromatography skid is then stored in a 200L single-use mixer.

3.2.2.7 Viral Inactivation

Approximately, 100L of eluate from the affinity chromatography skid is transferred to a 200L single-use mixer (Eluate tote). Acid solution is added into the single-use mixer and the contents are held in the vessel for approximately 2 hours.

Depth filtration system downstream of the single-use mixer is first flushed with ambient WFI. Approximately 200L of buffer solution is passed through the filter for equilibration before contents from the 200L single-use mixer upstream is transferred. The filter then undergoes chase and flush steps utilizing buffer and ambient WFI solutions respectively.

Approximately, 106L of product exiting the depth filtration system is then stored in a 200L single-use mixer (AEX load tote). Base solution is added into the single-use mixer to adjust pH and the contents are held in the vessel for approximately 2 hours.

Utility panels provide chilled water supply and return for the single-use mixers as well as ambient WFI for the depth filtration system.

3.2.2.8 AEX Chromatography

The AEX chromatography column is first cleaned and flushed with 0.1M NaOH solution and ambient WFI respectively. Approximately 400L of buffer solution is passed through the chromatography skid for equilibration before product from the 200L single-use mixer (AEX load tote) upstream is transferred for loading. The chromatography skid then undergoes wash and elution steps before an additional wash step is conducted utilizing buffer solutions. The chromatography column is then sanitized with 0.1M NaOH solution and flushed with WFI before being stored.

Approximately 75L of product, eluate from AEX chromatography is then stored in a 200L single-use tote (CEX load tote).

Utility panels provide chilled water supply and return for the single-use mixer as well as ambient WFI for the chromatography skid.

3.2.2.9 CEX Chromatography

The CEX chromatography column is first cleaned and flushed with 0.1M NaOH solution and WFI respectively. Approximately 400L of buffer solution is passed through the chromatography skid for equilibration before product from the 200L single-use tote (CEX load tote) upstream is transferred for loading. The chromatography skid then undergoes wash and elution steps before an additional wash step is conducted utilizing buffer solutions. The chromatography column is then sanitized with 0.1M NaOH solution and flushed with WFI before being stored with 19% ethanol solution.

Approximately, 101L of product exiting the chromatography skid is then stored in a 200L eluate tote.

Utility panels provide chilled water supply and return for the single-use mixer as well as ambient WFI for the chromatography skid.

3.2.2.10 Nanofiltration

The nanofiltration assembly consists of a prefilter upstream, a nanofilter, and a bioburden reduction filter downstream. The upstream filter is flushed with ambient WFI. Approximately 200L of buffer solution is passed through the filter for equilibration before contents from the 200L single-use bag upstream is transferred. The filter then undergoes chase and flush steps utilizing buffer and WFI solutions respectively. Filtration process will be initiated in Downstream Suite 1 (pre-viral). The filtrate will be passed through via an actively pressurized pass-through port and collected in Downstream Suite 2 (post-viral) to ensure segregation and containment.

Approximately 130L of product exiting the nanofilter is then stored in a 200L filtrate tote (UF/DF tote).

Utility panels provide chilled water supply and return for the single-use mixers as well as ambient WFI for the Nanofiltration assembly.

3.2.2.11 Ultrafiltration / Diafiltration (UF-DF)

The UF-DF skid is first cleaned and flushed with ambient WFI and 0.5M NaOH solution respectively. Buffer solution and contents from the 200L single-use bag upstream is transferred through the skid for concentration and diafiltration. The skid then undergoes chase and flush steps utilizing buffer and ambient WFI solutions. The filters are then sanitized with 0.5M NaOH solution and flushed with WFI before being stored with 0.1M NaOH solution.

Utility panels provide ambient WFI for the UF-DF skid.

3.2.2.12 Concentration Adjustment

Concentrated product from UF-DF skid is collected in 200L single-use mixer. Product sampling is performed for the concentration. Ambient WFI is used to adjust the product concentration.

Utility panels provide ambient WFI for the concentration adjustment process.

3.2.2.13 Final Filtration

Final filtration assembly consists of a 0.22 micro filter. The filters are first flushed with ambient WFI. Approximately 40L of buffer solution is passed through the filter for equilibration before filtrate from the 200L single-use mixer is transferred. The filter then undergoes chase and flush steps utilizing buffer and ambient WFI solutions respectively.

Utility panels provide ambient WFI for the final filtration assembly.

3.2.2.14 Packaging and Storage

Approximately, 30L of product exiting the final filtration assembly is filled into the single-use bag and is then stored in the 2-8 °C refrigerator.

3.2.3 Scope of Operations - Viral Vector

The scope of operations provides an overview of the major unit operations and support functions required to manufacture viral vector cell, and outlines the typical manufacturing sequences. The new manufacturing area is designed to run a broad range of industry-typical biopharmaceutical manufacturing processes using single-use equipment for the production of viral vector cell cultures. As the facility is designed for maximum flexibility, majority of the process equipment is single-use and portable and thus portable and reconfigurable based on manufacturing and facility requirements. No process equipment is permanently fixed within the core manufacturing area. Clean utilities required for the unit operations shall be assigned in the production areas. Production areas will be clean room, Grade C with the classification of Containment Level 2.

Manufacturing and product transfer activities are operated under closed systems to provide product and personnel protection. One ballroom suite is designed to operate viral vector process unit operations simultaneously using primarily gamma irradiated & closed single-use systems, to maintain appropriate separation and to employ appropriate procedurally controlled segregation strategies. The suite will be equipped with a single processing train with 50L upstream bioreactor capacity.

Table 2 below summarizes overall process operations for viral vector cell production in the Royalmount site. Additional details are provided in the finalized Block Flow Diagrams (BFD) and preliminary Process Flow Diagram (PFD) in Process Appendix 8.1. The Process Flow Diagrams will need to be further developed and detailed in the next phase as and when a target process is identified.

Table 2 - Summary of Overall Process Operations for Viral Vector Cell Production

UNIT OPERATION	CAPABILITY
VIRAL STOCK PREPARATION	Part of Viral Vector ballroom #2108 (Grade C, BSL2/CL2) Viral stock taken out from the refrigerator at ambient room temperature thaws under Bio Safety Cabinet Batch sizes up to 10L, utilizing 5L shake flasks/bottles Bench scales for weighing Closed media additions (liquids) using pump Biological Safety Cabinet for open media additions Shaker - Incubator for mixing

UNIT OPERATION	CAPABILITY
CELL THAW & INCUBATION PREPARATION	Part of Freezer Room #2128 (Grade C) and Viral Vector ballroom Upstream room #2108 (Grade C, BSL2/CL2) In Freezer room, staged thawing of seed vials from -80°C freezer to the -20°C freezer to the 2°C - 8°C refrigerator. Then in Cell Inoculation room thawed to ambient room temperature under Bio Safety Cabinet. Batch sizes up to 10L, utilizing 10L shake flasks Bench scales Closed media additions (liquids) using pump Biological Safety Cabinet for open additions including viral substances Shaker - Incubator for culture growth
INOCULUM PREPARATION & BIOREACTOR TRAIN	Part of Viral Vector ballroom #2108 (Grade C, BSL2/CL2) Capabilities for batch sizes up to 50L, utilizing single-use bioreactor. One 50L production bioreactor Load cells, bench scales, peristaltic pumps Closed media additions (liquids) Closed base, antifoam and feed additions (liquids) Utility connections for carbon dioxide gas, oxygen gas, nitrogen gas and clean compressed air Utility panels, temperature control unit connections Automated mixing, pressure and temperature control
CELL INFECTION	Part of Viral Vector ballroom #2108 (Grade C, BSL2/CL2) Flexible capabilities for batch sizes up to 50L, utilizing single-use bag (viral stock) and bioburden reduction filtration Cell infection hold period: 2 hours Addition of detergent base lysis buffer to release viral vaccine candidate and benzonase to digest nuclease acid

UNIT OPERATION	CAPABILITY
	Peristaltic pumps
HARVEST	Part of Viral Vector ballroom #2108 (Grade C, BSL2/CL2) Clarification capabilities for batch sizes up to 50L, utilizing a Depth filtration skid Closed buffer additions (liquids) Utility connections for clean steam and WFI 50L single-use broth storage bag/tote, post-filtration
AEX CHROMATOGRAPHY	Part of Viral Vector ballroom #2108 (Grade C, BSL2/CL2) Flexible capabilities for batch sizes up to 50L, utilizing an AEX chromatography skid for Protein A chromatography Closed buffer, 0.1M NaOH and Ambient WFI additions (liquids) for chromatography skid Utility connections for Ambient WFI Eluate stored in the 50L single-use bag/tote
MMC CHROMATOGRAPHY	Part of Viral Vector ballroom #2108 (Grade C, BSL2/CL2) Flexible capabilities for batch sizes up to 50L, utilizing a 50L single-use bag/tote (load tote) and MMC chromatography skid Closed buffers, 0.1M NaOH and Ambient WFI additions (liquids) for chromatography skid Utility connections for ambient WFI Eluate stored in the 50L single-use bag/tote
NANOFILTRATION	Part of Viral Vector ballroom #2108 (Grade C, BSL2/CL2) Flexible capabilities for various batch sizes up to 50L, utilizing single-use bag/tote (nanofiltration tote) and a nanofiltration skid Peristaltic pumps Chilled water supply and return connections for single-use mixer Closed buffer additions (liquids)

UNIT OPERATION	CAPABILITY
	Utility connections for Ambient WFI Filtrate stored in the 50L single-use bag/tote
ULTRAFILTRATION - DIAFILTRATION (UF/DF)	Part of Viral Vector ballroom #2108 (Grade C, BSL2/CL2) Flexible capabilities for batch sizes up to 50 L, utilizing a 50L single-use mixer (UF/DF tote) and a UF/DF skid Chilled water supply and return connections for single-use mixer Closed buffer, 0.1M NaOH and Ambient WFI additions (liquids) for UF/DF skid Utility connections for Ambient WFI Concentrated product/filtrate stored in 50L single-use mixer/tote
CONCENTRATION ADJUSTMENT	Part of Viral Vector ballroom #2108 (Grade C, BSL2/CL2) Product stored in the 50L single-use mixer/tote Product sampling Product concentration adjustment using Ambient WFI Chilled water supply and return connections for single-use mixer Utility connections for Ambient WFI Product remain in the 50L single-use mixer
FINAL FILTRATION	Part of Viral Vector ballroom #2108 (Grade C, BSL2/CL2) Flexible capabilities for batch sizes up to 50L, utilizing a 0.22-micron filter Product filled into single-use bags Stored in 2-8 °C refrigerator in warehouse

3.2.4 Process Description - Viral Vector

The following section provides a general overview of the major unit operations and outlines the viral vector cell manufacturing processing sequences. The process described below represents a "typical" process around which the facility was designed. As NRC's intent is to manufacture clinical materials for various clients not known at this time and various processes which are yet to be identified, the order of the unit operations, volumes, and solutions will differ from client-to-client. Therefore, the

facility was designed around a "typical", agreed-to process in order to detail equipment requirements including utility requirements. Additional unit operations, such as buffer exchange using TFF prior to chromatography loading may be required for certain processes. These will need to be evaluated and added as and when needed. The facility is designed to provide the flexibility and adaptability required for this purpose. The volumes presented below are based on the Process Definition document in Process Appendix 8.1. The process definition is based on a typical process and will need to be further defined in the next phase.

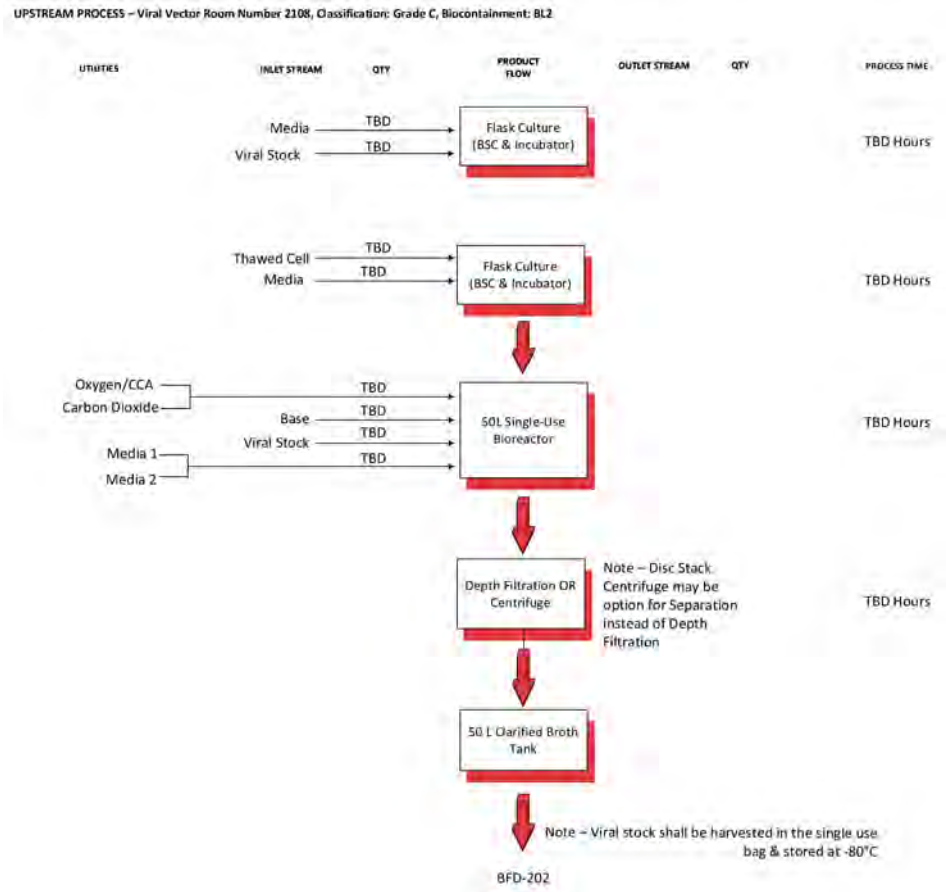


Figure 4 - Viral Vector Upstream Process Block Flow Diagram

3.2.4.1 Viral Stock Preparation

Viral stocks are taken out from the 2°C - 8°C refrigerator and mixed with prepared media into 5L shake flasks in a Biological Safety Cabinet. The flasks are then loaded into a shaker incubator for mixing.

3.2.4.2 Cell Thaw & Incubation Preparation

Seed vials are taken out from the -80°C freezer and are thawed to ambient room temperature through the -20°C freezer and the 2°C - 8°C refrigerator. Once thawed, the contents within

the seed vials and prepared media are combined into 15 L shake flasks in a Biological Safety Cabinet. The flasks are then loaded into a shaker incubator for culture growth.

3.2.4.3 Inoculum Preparation & Bioreactor Train

The 50L single-use seed bioreactor is set up with media at the appropriate temperature and pH with Dissolved Oxygen (DO) control and pH control activated. Approximately 4L of the incubated culture from the shake flasks is transferred to the 50L single-use bioreactor using peristaltic pump. To achieve the preferred media to inoculum split of 5:1, the seed bio-reactor should initially be set up with 20L of prepared media at the time of inoculation. An additional 8L of media can be added to the bio reactor after 3-4 days of growth to reach the full scale of the bioreactor. Dedicated temperature control unit and utility panels provide temperature-controlled water supply and return, ventilation, and blanketing compressed gases necessary for the growth process.

Each single-use bioreactor should also be furnished with appropriate sensors and controller for controlling process parameters such as rpm, conductivity, pH, and temperature.

3.2.4.4 Cell Infection

Approximately, 5 L of viral stock from the single-use bag is transferred to a 50L single-use bioreactor and the contents are held in the vessel for approximately 2 hours.

Lysis of the cells is initiated by the addition of detergent-based lysis buffer into the single-use bioreactor to release the Ad5-nCoV (viral vaccine candidate). Along with lysis buffer, benzonase (nuclease) will be added into the bioreactor to digest the released nucleic acids.

3.2.4.5 Harvest

Once the desired volume and cell density has been reached, the contents within the 50L bioreactor will be transferred for harvest processing through a depth filtration skid. The filters are sanitized with clean steam and then flushed with ambient WFI and buffer solution before contents from the 50L bioreactor is passed through. Approximately 40L of product exiting the depth filtration skid is then transferred to 50L broth tote (harvest tote) for storage. The depth filtration skid is then chased with buffer to recover product. The filters are then decontaminated with caustic and flushed with WFI prior to breakdown.

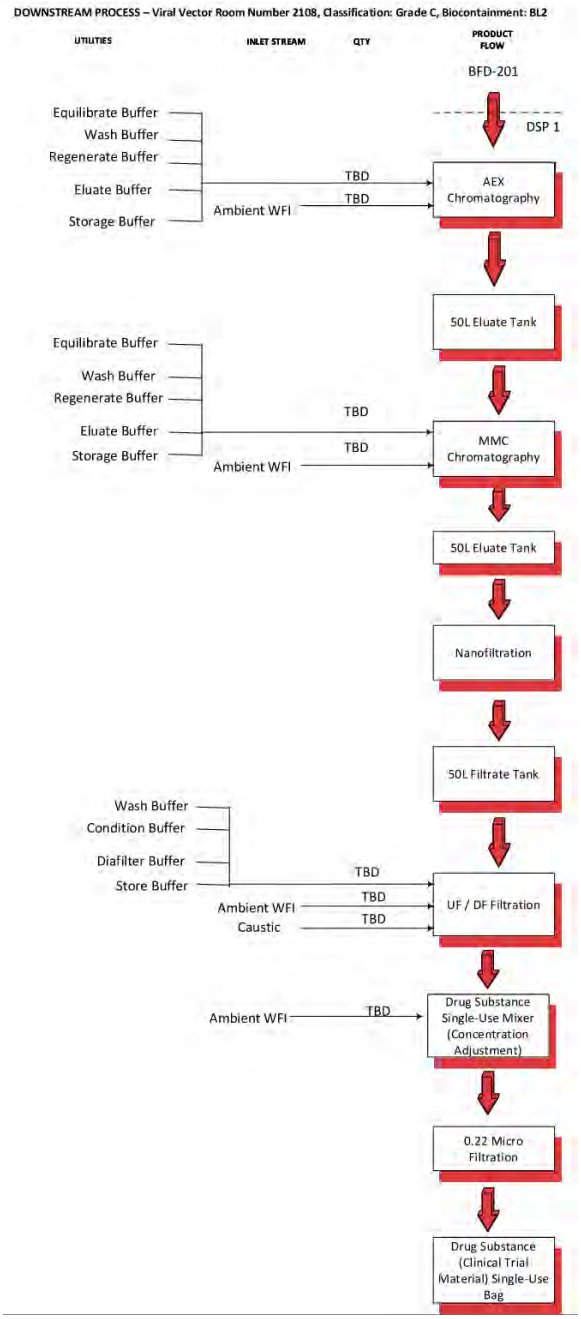


Figure 5 - Viral Vector Downstream Process Block Flow Diagram

3.2.4.6 AEX Chromatography

The AEX chromatography column is first cleaned and flushed with 0.1M NaOH solution and ambient WFI respectively. Approximately 100L of buffer solution is passed through the chromatography skid for equilibration before 40L of product from the broth tote is transferred for loading. Eluate is received in the load tote. The chromatography skid then

undergoes chase, wash, and elution steps before an additional wash step is conducted utilizing buffer solutions. The chromatography column is then sanitized with 0.1M NaOH solution and flushed with ambient WFI before being stored in caustic.

Approximately, 75L of product, eluate from AEX chromatography is then stored in 100L eluate tote.

Utility panels provide ambient WFI for the AEX Chromatography skid.

3.2.4.7 MMC Chromatography

The MMC chromatography column is first cleaned and flushed with 0.1M NaOH solution and ambient WFI respectively. Approximately 100 L of buffer solution is passed through the chromatography skid for equilibration before product from the 100L eluate tote (MMC load tote) upstream is transferred for loading. The chromatography skid then undergoes wash and elution steps before an additional wash step is conducted utilizing buffer solution. The chromatography column is then sanitized with 0.1M NaOH solution and flushed with WFI before being stored.

Approximately, 75L of product, eluate exiting the chromatography skid is then stored in 100L eluate tote.

Utility panels provide ambient WFI for the MMC chromatography skid.

3.2.4.8 Nanofiltration

The nanofiltration assembly consists of a prefilter upstream, a nanofilter, and a bioburden reduction filter downstream. The filter assembly is flushed with ambient WFI. Approximately 100L of buffer solution is passed through the filter for equilibration before eluate from the 100L eluate tote upstream is transferred. The filter then undergoes chase and flush steps utilizing buffer and ambient WFI solutions respectively.

Approximately, 84L of product exiting the nanofilter is then stored in 100 L filtrate tote (UF/DF tote).

Utility panels provide ambient WFI for the nanofiltration assembly.

3.2.4.9 Ultrafiltration / Diafiltration (UF-DF)

The UF-DF skid is first cleaned and flushed with ambient WFI and 0.5M NaOH solutions respectively. Buffer solution and contents from the 100 L filtrate tote upstream is transferred through the skid for concentration and diafiltration. The skid then undergoes chase and flush steps utilizing buffer and ambient WFI solutions. The filters are then sanitized with 0.5M NaOH solution and flushed with WFI before being stored with 0.1M NaOH solution.

Concentrated product is stored in the 50L single-use mixer.

Utility panels provide ambient WFI for the UF-DF skid.

3.2.4.10 Concentration Adjustment

Concentrated product from UF-DF skid is collected in 5L single-use mixer. Product sampling is performed for the concentration. Ambient WFI is used to adjust the product concentration.

Utility panels provide ambient WFI for the concentration adjustment process.

3.2.4.11 Final Filtration

Final filtration assembly consists of a 0.22-micron filter. The filters are first flushed with ambient WFI. Approximately 20L of buffer solution is passed through the filter for equilibration before filtrates from the 50L single-use mixer is transferred. The filter then undergoes chase and flush steps utilizing buffer and ambient WFI solutions respectively.

Utility panels provide ambient WFI for the final filtration assembly.

3.2.4.12 Packaging and Storage

Approximately, 22L of product exiting the final filtration assembly is filled into the single-use bags and then transported to the warehouse for storage at 2-8 °C.

3.2.5 Assumptions and Open Issues

- Facility to be used for manufacturing of clinical materials for various clients not known at this time and various processes which are yet to be identified, the order of the unit operations, volumes, and solutions will differ from client-to-client
- Approximately 10 batches/year/suite will be processed by each suite. If there is interest in increasing the output of this facility beyond this assumption then the utilities and waste management systems will need to be reevaluated and rescaled as required
- Viral Vector suite will require BSL2/CL2 biocontainment. mAbs suite will not require biocontainment
- Batch volume in the single use bioreactor assumed to be 80% of total volume
- Process equipment shall be single-use and portable
- Any use of solvents will be small enough in volume to be handled with a localized solution and will not require a centralized solution
- Decontamination of the viral vector suite using VHP will be provided by a service contractor as and when required

3.2.6 Technologies

This section discusses technologies that were considered and implemented in the design to provide solutions that represent current best practices and enhance the flexibility of the facility. Significant

alternate technologies that were considered but were not selected are also discussed for the purpose of future consideration.

3.2.6.1 Closed Transfer, Single-Use, and Ready-to-Use Technologies

Operations will utilize closed transfer, single-use, and ready-to-use technologies throughout the facility. The emphasis is on single-use technology, which allows for the maximum flexibility of the processing suites. Single-use systems also reduce risk of contamination and improved sterility assurance when compared to ready-to-use systems.

Closed transfers consist of sterile connectors and single-use tubing for liquid transfer between process equipment and their respective supply equipment or drop.

Single-use and ready-to-use systems will be utilized in conjunction with the transfer technologies mentioned above. The bioreactors used in the process will employ single-use bioreactors (SUBs) only. In both the downstream and the formulation processes, the chromatography and TFF (tangential flow filtration) systems will utilize single-use flow paths and pre-packed columns.

Pre-assembled tubing sets for formulation operations will include sterile connectors to enable sterile transfers in pooling steps. SUMs will be connected to the final filtration product path. This product path typically consists of sterile connector, final filtration, tubing, final bioprocess container and arranged for ergonomic setup. Where required, tube welders and sealers will be used to maintain closed systems and aseptic transfers.

Although parts washing and autoclaving may be required in some cases, the technologies mentioned above will eliminate the majority of the component prep activities for the suites. The extent to which parts washing and autoclaving will be required will be evaluated and finalized in the next phase.

3.2.6.2 Filter and Bag Integrity

With the use of single-use technology, the assurance and quality of those systems are a vital part of the systems that needs to be routinely verified.

Filters elements can wear overtime from a number of factors such as: particle load, pressure fluctuations, temperature, etc. Damage to the filter element can be in the form of blockages, cracks or changes in the membrane structure. Although blockages in the filter element can be discovered easily, cracks or changes to the membrane do require a filter integrity test to be discovered.

Single-use bioprocessing containers or bags are a vital part of the process, as it contains all the materials, including the media, product and buffers. As the bags are used in all stages of the process, a bag failure or leak can be detrimental to the process causing a loss of resources, product and time. Test methodology can differ but are usually in the form of a pressure decay test. The bag will be pressurized and once equilibrium has been reached, the

pressure will be monitored over time. The pressure decay over time will be compared to an acceptable standard determined through validation and leak-rate specifications of the bag film.

As both filters and single-use bags play a critical part in ensuring closure of single-use systems, the technologies to test and confirm their integrity have been included in the scope of the project.

3.2.6.3 Alternate Technologies

Single-use and disc-stack centrifugation was considered for the purpose of clarification of bioreactor broth. However, depth filtration was favoured and selected owing to its lower capital cost, simplicity of design, easy adaptability to different processes (i.e.: different membranes) and different batch sizes (i.e.: different surface areas). Though, allowances will be made in the facility design for the future incorporation of centrifugation. If materials with higher than anticipated cell densities are to be processed in this facility in the future, centrifugation may be seen as the preferred option.

The Media Buffer Prep area also employs single-use mixers. NRC has confirmed that formulations that require elevated temperatures that are incompatible with single-use mixers will not be required for this facility. Pasteurization systems that heat the media to a temperature range of 62 - 100ºC for certain amount of time such as Vat Pasteurization, High-Temperature-Short-Time (HTST), and High-Heat-Short-Time (HHST) were considered but are not part of the design based on NRC's input.

A decontamination option for the Viral Vector suite that will be integrated into the facility design was discussed. However, considering how infrequently a decontamination and changeover of the Viral Vector suite will be required, the capital cost required for implementing such a system and the operating cost involved in maintaining and operating such a system was not palatable to the design team. Therefore, the design assumes that a VHP decontamination service provider - such as Steris or Bioquell - will be contracted to perform this function as and when required.

3.2.6.4 Designing for Flexibility and Adaptability

As stated above, heavy emphasis was placed on selecting single-use technology for all possible processing applications in order to provide maximum flexibility for the processing suites. These single-use systems will be portable and none of the equipment in the processing suites will be hard-piped. Equipment will be able to be moved up to utility panels at each station and be connected to the required utilities. This will allow for the reconfiguration of the suites to provide different sequences of unit operations as required for different processes. This will be especially useful for the downstream purification process, since the sequences of downstream unit operations can be highly product specific. This approach will also allow the ability to introduce additional unit operations that are not

currently in design, such as a buffer exchange step prior to each chromatography step or a centrifugation step for clarification.

In selecting the single-use equipment, the systems that have already been purchased by NRC were considered and the new systems were chosen as much as possible from the same vendors. This approach will not only provide synergies between all the systems but also will be beneficial to the validation effort allowing for employing leveraging strategies.

The Recommended Option layout also provides additional flexibility by allowing concurrent processing of viral vectors and mAbs in the two separate suites. The strategies employed for segregation and containment required for concurrent processing is discussed in Section 3.4.4 of this report. Section 3.4.4 also discusses ways in which the viral vector suite can be switched over for mAbs production and the constraints associated with it.

3.2.6.5 Automation

Increased automation and validation will improve process robustness of process steps and support functions. Utilization of appropriate automation will achieve repeatable, validated manufacturing processes and support processes that are significantly less reliant on procedures and less prone to operator-dependent variations.

3.2.7 Production Capacity

The number of batches that will be processed per year in this facility is unknown at this time but is anticipated to be around 10 batches/year per suite. The maximum production capacity of the mAbs suite will be based on the 500L mAbs bioreactor. The maximum production capacity of the Viral Vector suite will be based on the 50L Viral Vector bioreactor. The Viral Vector suite may be utilized, after proper decontamination and line-clearance, for non-viral activities such as mAbs cell line propagation. However, the mAbs suite may not be used for Viral Vector production activities since the mAbs suites lack the required biocontainment features.

NRC does not intend to use this facility for running sustained production campaigns. Rather, its intent is to use this facility for the manufacturing of one-off or limited number of batches required for testing and trials. Therefore, it is foreseeable that specific line-clearance and turn-over activities will need to be performed after each such batch or batches. Thus, the true capacity of this facility cannot be estimated at this time and will be evaluated in the next phase.

3.2.8 Material Management

The design incorporates a warehouse for raw material and final product storage, a sampling area for material sampling, a weigh and dispense area for staging and kitting materials required for media and buffer making, and a Media Buffer Prep room for formulation of required buffers, media, and solutions such as 0.1N NaOH. The design also incorporates component prep, sterile prep, and clean storage areas. The programming of these areas will be further developed in the next phase.

3.2.8.1 Media and Buffers

The Media Buffer Prep room has three 500 L single-use mixers and two 50 L single-use mixers that will be used to perform the required formulations. Formulated solutions will be transferred into final use containers at required volumes and moved to required processing rooms for use. The formulations will be performed-to-order as much as possible in order to limit the space requirements for storage. Since the facility is not intended to run sustained campaigns, this approach is feasible and desirable to minimize wastages. Pre-preparing and storing solutions will also prove challenging in terms of establishing and validating hold-times and hold-conditions, especially when transitioning from client to client.

However, at the request of NRC, some allowances have also been made in the warehouse for storage of prepared solutions at refrigerated conditions. These allowances will need to be reviewed and validated in the next phase.

3.2.8.2 Washing and Sterilizing

The component prep room has a pass-through parts washer that will unload clean parts into the sterile prep room. The sterile prep room has a pass-through sterilizing autoclave that will unload sterilized components into the clean storage room.

Though models have been selected for the parts washer and the sterilizing autoclave, and have been included in the equipment list to assist with the layout and cost estimation; the programming for this equipment will need to be further evaluated and the required capacity of these equipment adjusted accordingly in the next phase. As stated before, the design intent is to minimize the number of components that will require washing and sterilizing by driving towards single-use technology. However, it is unlikely that the design will be able to fully eliminate the requirement for a washer and a sterilizer.

3.2.9 Labs

The design incorporates a QC lab and a microbial lab. The Consulting Firm has identified and selected equipment and instruments for these two labs in close collaboration with NRC. However, this exercise was only intended to facilitate a proposed layout and cost estimation for the labs and was not intended to be the finalized list. Many of the identified instruments offer multiple features as options and their prices are heavily dependent on the options selected. Therefore, a deeper dive will be required in the next phase to value-engineer what is truly essential and optimize the available budget and space.

The QC lab is also equipped with support equipment such as sterilizing autoclave, de-pyrogenation oven, biosafety cabinet, and incubator.

3.2.10 Utility Requirements

NRC's intent is to use this facility for the manufacturing of one-off or limited number of batches required for testing and trials. The facility is not intended for running sustained production

campaigns. Therefore, there is expected to be considerable flexibility in the scheduling of these batches. This allows the design team to take a cost-conscious approach to sizing and sourcing the required utilities. The required capacities of these utilities will need to be evaluated and validated in the next phase of the project.

3.2.10.1 Clean Utilities

- Clean Steam: A Clean Steam generation system with the capacity of 300kgs/hr. at 45psig is included in the design. The capacity for this system is based on the assumption that the two pass-through autoclaves in the facility will be the largest users of clean steam.
- WFI: A vapour-compression WFI generation system with a capacity of 1000 lbs./hr. is included in the design together with a WFI distribution system consisting of 2000L Storage Tank and a pumping capacity of 100gpm at 70psig. This capacity is based on the assumptions made for the buffer volumes required for the larger downstream skids.
- The WFI distribution will be at ambient temperature which will be required for the single-use systems in the facility. The system will have the ability for routine automated heat sanitization.
- Clean Compressed Air: Clean Compressed air generation is not included in the design. It is assumed that the site will be able to provide the required compressed air. A filtration station will be included in the design to transition from instrument air to clean compressed air.
- Purified Water: Purified water generation is not included in the design. It is assumed that WFI will be used for all processing applications requiring compendial grade clean water.
- Adding a separate purified water generation system and distribution system will add to the capital cost of equipment and facility foot print. When considering the expected low and infrequent usage of water in this facility, the maintenance of two separate compendial water systems will not be favourable in terms of operating cost either. Therefore, PW generation is not included in the design.
- The QC lab will be equipped with a lab scale system to supply the required small volumes of purified water for lab use only.

3.2.10.2 Medical Gasses

Medical gasses such as Carbon Dioxide, Nitrogen, and Oxygen will be required for the process. The design approach is to purchase the medical gasses in cylinders, hold them in a centralized location outside the production suites, and distribute them to the production suites via utility panels. Therefore, only medical distribution is included in the design.

3.2.10.3 Black Utilities

The facility will require plant steam including condensate return, chilled water supply and return, instrument air, and non-potable water.

- Plant Steam: Plant steam will be required primarily for the generation of clean steam, the generation of WFI through vapour compression, heat sanitization of the WFI distribution, and for the operation of the bio-kill system. The design includes plant steam generation, distributions, and condensate return.
- Chilled Water: Chilled water will be required primarily for the WFI generation system, the post-heat sanitization cooling of the WFI distribution system, the post-kill cooling operation of the bio-kill system, the cooling operation of the autoclaves, and the cooling operation of single-use systems requiring cooling. The design assumes the required chilled water will be supplied by the site.
- Instrument air will be required for the operation of all systems and for the clean compressed air. The design assumes the required compressed air will be supplied by the site.
- Non-potable water will be required primarily for the WFI generation system (vapour compression), and the clean steam generation system. It may also be required for quenching the drains at the autoclave and at the bio-kill system. Potable water may also be used for these purposes if readily available. The design assumes the required non-potable water will be supplied by the site.

3.3 Automation

3.3.1 Scope of Work

The automation scope is to implement the appropriate level of automation and information systems in the facility to ensure operational reliability, process repeatability, and provide data collection of process information and GMP reporting. The systems will be validated in accordance with NRC standards.

The automation scope includes process automation, facility automation, network and telecommunications requirements. Building Management Systems is covered under Engineering in Section 3.10.4.2.2.16.

The following are in project scope:

- Implementation of a new facility SCADA (Supervisory Control and Data Acquisition) system
- Implementation of an EMS (Environmental Monitoring System)
- Implementation of an MES (Manufacturing Execution System)
- Integration of new PLC-based OEM control systems with the new SCADA system
- Install new network infrastructure components to support Manufacturing Network, BAS Network, Device/Field IO Isolated Networks (as required), Laboratory Networks
- Implement GMP reporting using both centrally stored data and from on-board reporting services on OEM equipment (where available)

- Integration of ERP/CMMS/QMS/WMS/LIMS

3.3.1.1 Level of Automation

The automation solution for this project consists of a combination of manual operations, and OEM automated equipment systems which are networked and integrated into the SCADA.

A list of major integrated equipment systems with quantities and their associated proposed controls and integration strategy can be seen in the following table. List and quantity were generated based on project Equipment List (Rev. B) at time of report creation. The Lab Equipment List will be incorporated in the next design phase.

Table 3 - List of Major Integrated Equipment Systems

PROCESSING AREA	EQUIPMENT NAME	CONTROLS & INTEGRATION
MABS CELL INOCULATION	Biosafety Cabinet	Equipment status/data wired for data collection and monitoring at SCADA
	Shaker Incubator	Equipment status/data wired for data collection and monitoring at SCADA
	-20ºC Freezer	Process data wired for data collection and monitoring at EMS/SCADA
	-80ºC Freezer	Process data wired for data collection and monitoring at EMS/SCADA
	2 to 8ºC Lab Freezer	Process data wired for data collection and monitoring at EMS/SCADA
MABS UPSTREAM	Cryogenic Tank	Process data wired for data collection and monitoring at EMS/SCADA
	50L Bioreactor	OEM Controls, data to SCADA
	500L Bioreactor	OEM Controls, data to SCADA
MABS DOWNSTREAM 1	500L Single Use Mixer	OEM Controls, data to SCADA
	Chromatography System - Affinity	OEM Controls, data to SCADA
	500L Single Use Mixer (Qty. 2)	OEM Controls, data to SCADA

PROCESSING AREA	EQUIPMENT NAME	CONTROLS & INTEGRATION
	Chromatography System - AEX	OEM Controls, data to SCADA
MABS DOWNSTREAM 2	Chromatography System - MMC/CEX	OEM Controls, data to SCADA
	Tangential Flow Filtration - Single Use	OEM Controls, data to SCADA
VIRAL VECTOR	200L Single Use Mixer	OEM Controls, data to SCADA
	Biosafety Cabinet	Equipment status/data wired for data collection and monitoring at SCADA
	Shaker Incubator	Equipment status/data wired for data collection and monitoring at SCADA
	-80ºC Freezer	Process data wired for data collection and monitoring at EMS/SCADA
	50L Bioreactor	OEM Controls, data to SCADA
	Cryogenic Tank	Process data wired for data collection and monitoring at EMS/SCADA
	Chromatography System - AEX	OEM Controls, data to SCADA
	Chromatography System - MMC	OEM Controls, data to SCADA
	50L Single Use Mixer (Qty. 2)	OEM Controls, data to SCADA
MEDIA / WASHING / STERILIZATION	AKTA Flux 6	OEM Controls, Interface TBD
	Fume Hood	Equipment status/data wired for data collection and monitoring at SCADA
	Parts Washer	OEM Controls, data to SCADA
	Sterilization Autoclave	OEM Controls, data to SCADA

PROCESSING AREA	EQUIPMENT NAME	CONTROLS & INTEGRATION
	Decon Autoclave	OEM Controls, data to SCADA
	50L Single Use Mixer (Qty. 2)	OEM Controls, data to SCADA
UTILITIES	500L Single Use Mixer (Qty. 3)	OEM Controls, data to SCADA
	WFI Generation	OEM Controls, data to SCADA
	WI Distribution	OEM Controls, data to SCADA
	Clean Steam Generation	OEM Controls, data to SCADA
	Neutralization	OEM Controls, data to SCADA
ACCESSORIES	Bio-Kill	OEM Controls, data to SCADA
	Bag Integrity Tester (Qty. TBD)	Data Backup onto network
	Filter Integrity Tester (Qty. TBD)	Data Backup onto network
	EM Particulate Monitor (Qty. TBD)	Wireless Access Interface TBD
LABS	EM Viable Monitors (Qty TBD)	Wireless Access Interface TBD

3.3.1.2 OEM Systems

The automation platform associated with each piece of OEM process equipment will be the standard solution provided by the vendor, subject to approval by NRC.

OEM systems require integration into the site SCADA for data monitoring and collection. Where required, simple SCADA operator graphics displaying connected OEM equipment system status (e.g. system running, idle, in alarm) will be developed by the SCADA integrator.

OEM systems will be able to be both operated 1) locally, where system control, recipes and settings will be conducted at the machine level via the local HMI; and 2) remotely, where system control, recipe configuration and settings may be performed remotely from the SCADA and/or MES. The extent of remote functionality will be explored and designed during Detailed Design.

The data to be collected from each piece of OEM equipment will be identified during Detailed Design; this list will be provided to the OEM vendor to facilitate the organization of pertinent data into contiguous blocks for data acquisition, if necessary. Data may include:

- Alarms and Events
- Recipe Information
- Equipment status
- Cycle commands (Start, Hold, Abort, Restart, etc.)
- Cycle status (Running, Complete, Held, Aborted, Restarting, etc.)

User authentication via a site domain controller shall be used, where possible for OEM systems. In general, Ethernet communications for field level devices or I/O will be segregated from the manufacturing network, either via physical segregation or VLAN configuration.

Time clock synchronization to a network time source will be implemented where possible for OEM control systems.

OEM systems are to generate reports locally if required, provided that all data integrity standards are satisfied. Reports are to be transferred and stored on a network location. The possibility of generating reports with batch context as supplied by the SCADA/MES system will be further explored during DD.

3.3.1.3 SCADA

The new SCADA's primary functions are as follows:

- Facilitate permissives/interlocking with OEM equipment
- Facilitate utilities marshalling with clean utilities systems (WFI)
- Perform as a data aggregator to collect data from OEM-supplied control systems
- Provide non-OEM, off-skid equipment control (such as WFI Point-of-use drops), monitoring and notification

No SCADA platform has been chosen yet. Some platforms that may be appropriate include Rockwell FactoryTalk View Site Edition, Wonderware, GE iFIX or Inductive Ignition.

The new SCADA (with associated PLC) will be used to facilitate communications with the new WFI distribution system for the purposes of water marshalling and POU coordination. This communication may be via hardwire signals or via communication bus; this will be determined during the next project phase.

The selected SCADA should allow for industry-standard integration with MES modules or systems.

Data collection from OEM equipment systems will be via Ethernet on the Manufacturing Network. The protocol to be used will be determined in the next project phase, and may depend on the chosen SCADA platform.

The SCADA will be connected to a client domain controller for user authentication. SCADA system time will be synchronized against a time server.

SCADA workstation locations will be determined in the next project phase.

3.3.1.4 Environmental Monitoring System (EMS)

A new EMS is within project scope. The EMS will perform the following functionality:

- Monitor GMP environments for temperature / relative humidity / differential pressure conditions, and particle monitoring
- Alarm and display monitored points
- Facilitate data collection of monitored points

The EMS will be incorporated as part of the SCADA system described above. Since both the SCADA and EMS are GMP systems, a combined system platform would allow for joint design, procurement, implementation and validation.

The EMS system will be separate from the BMS system due to validation/maintainability concerns and complications.

3.3.1.5 Manufacturing Execution System (MES)

A new MES system is within project scope; the platform has not yet been determined. The MES will perform the following functionality:

- ERP-MES integration for scheduling/coordination of manufacturing
- LIMS-MES integration for product lab results
- EMS -MES integration for room status tracking
- SCADA-MES integration for equipment status tracking
- QMS-MES integration for product release
- Historian-MES integration to provide batch/production reports outside the scope of OEM equipment reports

The extent of MES integration (heavy vs. light) with the SCADA and OEM systems will be explored during Detailed Design.

3.3.1.6 Database/Historian

New high-availability databases/historians will be installed as part of the project scope for the purposes of long-term GMP data storage and to be used as a data source for SCADA-generated reports. The database platforms to be used (e.g. Ignition Tag Historian Module,

Wonderware Historian, Rockwell FactoryTalk Historian, GE Proficy Historian etc.) will be determined based on considerations of the SCADA to be selected.

3.3.1.7 Other Systems and Standards:

The following major systems to be integrated, as suggested by NRC, are as follows:

- Computerized Maintenance Management System (CMMS)
- Quality Management System (QMS)
- Enterprise Management System (ERP)
- Warehouse Management System (WMS)
- Laboratory Information Systems (LIMS)

It is assumed that these systems will be scoped and procured by NRC directly.

Process Analytical Technology (PAT) applications are to be explored in the next project phase.

3.3.2 System Architecture

3.3.2.1 Network Architecture

The facility is expected to use the following networks:

- SCADA/Manufacturing network - this network will be used for the SCADA, communication to OEM equipment, communication to databases/historians, and other manufacturing support servers. This network will be segregated from field device/IO communications' traffic.
- BMS network - this network will be used for the BMS application, communication to field controllers, servers and workstations.
- Isolated field networks required for OEM equipment, or off-skid remote I/O modules will be installed.
- Laboratory network - this network will be used for Ethernet based connections to lab equipment and servers as required.

NRC has expressed that Cisco hardware shall be used for network infrastructure where possible. A network closet will be on the second floor and a server room will be on the first floor; Ethernet devices will be cabled back to these spaces.

A preliminary network architecture can be seen in 21090-DES-AIC-DIA-001.

3.3.2.2 Servers and Virtualization

Required servers to support manufacturing will be hosted on server clusters managed by the NRC IT group.

3.3.2.3 Field Controllers and I/O

An Allen Bradley controller (ControlLogix/CompactLogix) is planned for the following functionality:

- Controls/monitoring of stick-built equipment, OEM provided equipment without controllers
- Facilitate communications (messaging or hardwire) with external systems, such as the WFI distribution system
- Field I/O will utilize Allen Bradley Point I/O modules where appropriate

A second Allen Bradley controller is planned for the EMS functionality.

OEM control systems will use their standard controller and field I/O implementation, subject to NRC review.

3.3.2.4 Operator Interfaces

SCADA workstations shall utilize thin clients, housed in enclosures appropriate to the room environment. OEM system workstations shall be the vendor standard, subject to NRC review.

3.3.2.5 Control System Software

Development of the SCADA application will be performed by a system integrator, experienced with the chosen software platform. Configuration of any centrally generated reports will be by a system integrator, potentially the same as the SCADA system integrator. Report generation software will be subject to data integrity requirements (e.g. 21 CFR P11)

OEM systems will be controlled using vendor standard control applications. Integration of data and controls into the SCADA application will be performed by the SCADA system integrator.

3.3.3 Open Issues

The following items require greater definition during the next project phase:

- SCADA platform selection is required.
- MES platform selection is required.
- QMS/ERP/CMMS/WMS/LIMS - integration definition is required.
- The level of MES integration with SCADA/OEM equipment is required to be defined.

3.3.4 Assumptions and Qualifications

The following assumptions and qualifications apply:

- Data storage must be on Canada-based servers.

3.4 Containment and Segregation

The process design and facility design has taken into account the level of containment and segregation required for the safe and successful operation of this facility.

3.4.1 Risk Overview

The Material Characteristics section (Section 3.1.3) above provides the known biological risks associated with biohazardous agents that may be potentially used within this facility. As discussed in that section, other hazards such as respiratory risks or adsorption risks are not known at this time and will need to be evaluated in the next phase. Based on the biological risks known, the design has implemented strategies to mitigate against cross-contamination risk and to allow for biological containment.

3.4.2 Containment Basis

The highest expected risk level of the biohazardous agents that will be handled in this facility is Risk Group 2 requiring BSL2/CL2 level containment. Two levels of containment have been considered in the design to mitigate this risk.

3.4.2.1 Primary Containment

The primary containment shall be by means of process closure. The only open manipulations intended in the facility will be the activities related to the shake flask additions and sampling. These activities are designed to be carried out in a Class II Type A2 Biological Safety Cabinet (BSC) for containment. In order to further enhance containment and protect against contamination risk, the BSC is located in a separate inoculation room of the mAbs upstream suite. Owing to the ballroom design concept of the Viral Vector suite, locating the BSC in a separate room is not possible. The risk related to this can be further evaluated in the next phase. If deemed necessary, an isolator or Closed Restricted Access Barrier System (cRABS) technology may be implemented in place of the BSC.

All additions and transfers downstream of the shake flasks shall be by closed systems. Single use tubing and connections will be made utilizing sterile connection technologies that can be validated. See images below for examples.

Figure 6 - Lynx Connectors by Millipore Sigma

Figure 7 - Lynx Connectors by Millipore Sigma

Figure 8 - AseptiQuik Connectors by CPC

In the mAbs production area, product transfer from Downstream 1 to Downstream 2 will be carried out using single-use tubing and connections through an active pass-through port. The nanofiltration skid for viral clearance will be situated in Downstream 1 and the filtrate will be collected in Downstream 2. The design takes this precaution in order to mitigate the risk of contaminating the nanofiltered product by handling it in the same suite as the pre-filtered product. See image below for an example of an active pass-through.

Figure 9 - AdvantaPass by AdvantaPure (Wall Pass-through)

Only waste generated by the Viral Vector process are considered for biocontainment of waste. The solid waste generated by this suite will be decontaminated using a moist heat autoclave prior to being removed from the containment boundary. The decontamination autoclave will be of a design similar to a passthrough to facilitate this transition from contaminated to decontaminated. The liquid waste from the Viral Vector suite will be collected via a segregated process drain and directed to the biowaste collection tank for decontamination. The biowaste collection tank will be at atmospheric pressure but will be vented through two sterilizing grade filters in series. The redundancy in filters is intended to provide additional protection against the risk of a containment breach. The filters will have the ability to be independently isolated and steamed prior to removal or replacement.

3.4.2.2 Secondary Containment

The secondary containment shall be by facility design and procedural measures. Facility design aspects include segregation of manufacturing areas, HVAC design and allocations, and pressurization schemes. Procedural measures include aspects such as personnel flow, material flow, cleaning and gowning requirements.

The Viral Vector suite is independent of the mAbs suites. The mAbs suite is further divided into independent rooms for upstream processing, pre-viral downstream processing, and post-viral downstream processing. Other design aspects are discussed in the sections below.

The design proposes material and personnel flows to maintain containment in the sections below. Gowning, cleaning and other procedural measures will need to be evaluated and finalized in the next phase.

The biowaste treatment system is located in a segregated and dedicated room with the pressurization of the room designed for containment within the BSL2/CL2 boundary. The QC and Microbial labs are also located in dedicated rooms with the pressurization designed for containment within the BSL2/CL2 boundary.

3.4.3 Segregation Basis

The facility design provides the primary basis for segregation. As discussed above, the facility is divided into dedicated rooms for the following activities:

- Viral Vector manufacturing
- mAbs upstream processing
- mAbs pre-viral downstream processing
- mAbs post-viral downstream processing
- Media and buffer prep area
- Controlled classified supply corridor, sterile prep and clean storage areas
- Controlled classified return corridor and component prep area
- Only waste generated by the Viral Vector process are considered for biocontainment of waste. The solid waste generated by this suite will be decontaminated using a moist heat autoclave prior to Each of the above areas will be serviced by an independent Air Handling Unit (AHU). Waste streams from Viral Vector suite and other areas will also be segregated. Other aspects of facility design are discussed in the sections below

The processing equipment may be used interchangeably between the various suites in order to allow for the high level of flexibility and adaptability required for this facility. Therefore, equipment dedication was not considered as a strategy for segregation. However, appropriate cleaning and sanitization methodologies and procedures will need to be developed in the next phase to mitigate cross-contamination risks and risks related to segregation breach.

3.4.4 Switchover and Alternate Layout

The viral vector suite has the potential to be switched over to carry out mAbs processes if required. The suite will first have to be cleaned and decontaminated - using a technology such as VHP - and the efficacy of the decontamination process established before switching over. This can be achieved by contracting out the VHP process as discussed in the section above. The additional constraints related to processing mAbs in the viral vector suite are related to containment and segregation. The viral vector suite is a ballroom and does not have the upstream/pre-viral downstream/post-viral downstream segregation like the mAbs processing suite. Therefore, in order to carry out a mAbs process that involves viral infection and viral clearance in the viral vector suite, complete process closure will have to be implemented. However, demonstrating or proving complete process closure can be challenging.

Alternately, the viral vector suite - once decontaminated - may be used to carry out only the cell propagation steps of the mAbs process. This activity can be carried out in the ballroom since there is no viral infection or viral clearance involved. Note that viral vector cannot be processed in the mAbs suite as it is presented in Recommended Option layout, because this layout does not provide biocontainment of the mAbs suite.

Even though the User Requirement Brief approved by NRC requires two separate suites for viral vector and mAbs processing, an alternate layout of a single suite where both the viral vector process and mAbs process can be carried out was also considered as an option. This single suite layout will have to be designed with segregated rooms for upstream, pre-viral downstream, and post-viral downstream. The suite will also have to be designed for BSL2/CL2 containment. This layout will be advantageous in terms capital cost and foot print of the facility. However, this layout will have the following disadvantages and thus not recommended.

- Line clearance and decontamination will be required every time switchover between mAbs and viral vector is performed leading to increased downtime and operating costs
- Facility will lose the ability to run two different processes concurrently leading to reduced capacity
- Waste management systems will need to be designed to treat all waste as BSL2/CL2 leading to larger systems and higher operating cost

3.5 GMP Area Classifications

The viral vector and mAbs suites will be classified as Grade C. The supply corridor to all of these suites will be Grade C and the return corridors will be Grade D. Transitions from the Grade D to Grade C rooms will be by means of airlocks.

3.5.1 Environmental Cleanliness Levels

A full list of rooms with classifications is shown on the Facility Program (Section 3.10.3.1) section below.

Please see below table for typical ECL showing maximum number of particles permitted per cubic meter.

FDA Maximum number of particles permitted /m³		COFEPRIS Maximum number of particles permitted /m3					EMA & WHO Maximum number of particles permitted /m³					ANVISA Maximum number of particles permitted /m³				
	In operation		At rest		In operation			At rest		In operation			At rest		In operation	
Class	≥.5 µm	Class	≥.5µm	≥5µm	≥.5µm	≥5µm	GR	≥.5 µm	≥5 µm	≥.5 µm	≥5 µm	GR	≥.5µm	≥5µm	≥.5µm	≥5µm
ISO 5	3,520	ISO 5	3,520	29	3,520	29	A	3,520	20	3,520	20	A	3,520	20	3,520	20
ISO 6	35,200	ISO 6*	35,200	293	3,520,000	293	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ISO 7	352,000	NA	NA	NA	NA	NA	B	3,520	29	352,000	2,900	B	3,520	29	352,000	2,900
ISO 8	3,520,000	ISO 7	352,000	2,930	3,520,000	29,300	C	352,000	2,900	3,520,000	29,000	C	352,000	2,900	3,520,000	29,000
NA	NA	ISO 8	3,520,000	29,300	Not defined	Not defined	D	3,520,000	29,000	Not defined	Not defined	D	3,520,000	29,000	Not defined	Not defined

* For products that are not terminally sterilized. ISO Class 5 dressing rooms also required.

FDA Microbiological Active Air Action Levels Air Sample		COFEPRIS Recommended Limits for Microbial Contamination Air Sample		EMA & WHO Recommended Limits for Microbial Contamination Air Sample		ANVISA Recommended Limits for Microbial Contamination Air Sample	
Class	cfu/m3	Class	cfu/m3	Grade	cfu/m3	Grade	cfu/m3
ISO 5	1	ISO 5	<1	A	<1	A	<1
ISO 6	7	ISO 6	<10	NA	NA	NA	NA
ISO 7	10	ISO 7	<100	B	10	B	10
ISO 8	100	NA	NA	C	100	C	100
		ISO 8	<200	D	200	D	200

Figure 10 - Typical Environmental Cleanliness Levels for Cleanrooms

3.5.2 ECL for Manufacturing Functions

Use of the ECL designations minimizes the risk of microbial, particulate, and/or pyrogen contamination in the respective areas.

3.6 Transition & Gowning Strategy

3.6.1 Overall Transition Basis

The facility will be designed to EMA - Annex1.

The Viral Vector and mAbs suites will be classified as Grade C. The supply corridor to all of these suites will be Grade C and the return corridors will be Grade D. Transitions from the Grade D to Grade C rooms will be by means of airlocks. Addition airlocks are provided for the Viral Vector suite to accommodate the containment risk as the suite is designated BSL2/CL2.

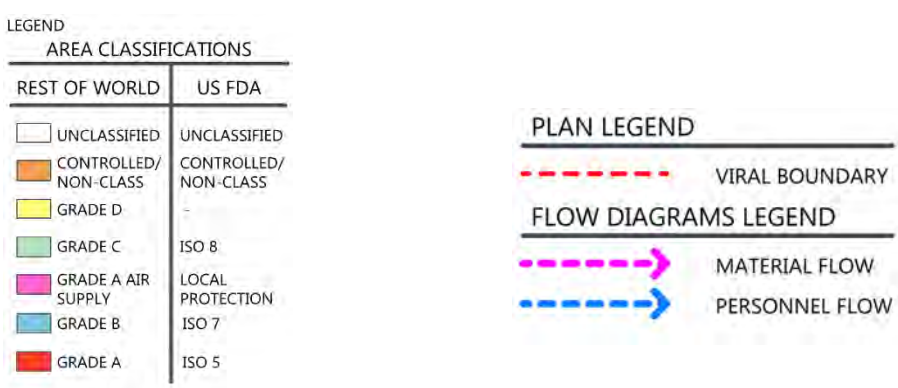


Figure 11 - Area Classification Legend and Drawing Legend

3.6.2 Personnel Transitions

Personnel will enter the facility and can go directly to the lockers in the mud room/corridor and access the external lockers there. To access the second floor, personnel can enter the Viral Vector locker area or the general access locker area and use the stairs to access level 2. The Viral vector suite is classified as a BSL2/CL2 area and requires separation from the non BSL2/CL2 area. In the gown rooms, operatives will don plant uniforms and plant shoes before entering the clean non-classified stairways to access level 2.

3.6.3 Material Transitions

Materials entering into the new facility, will utilize the existing dock in building 4. This can be used for raw materials and finished goods. A new connection door will be provided to move materials to the new facility warehouse. Here, materials will be stored on racks or within the Cold room provided. For moving materials to the manufacturing floor, an elevator is available. The elevator is designed to carry people and materials.

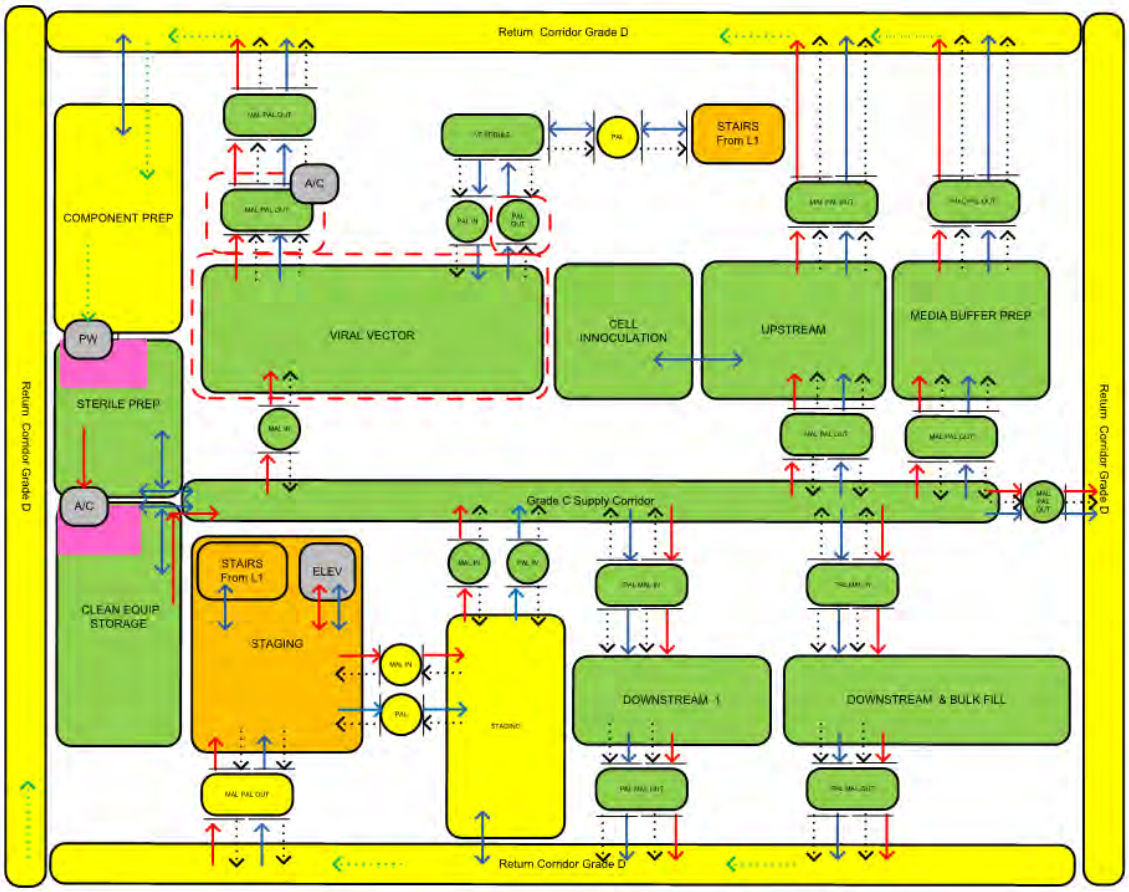


Figure 12 - CTMF Zoning and Transition Diagram

3.7 Cleaning Philosophy

3.7.1 Facility

A program for cleaning in the facility shall be determined at a later date.

3.7.2 Equipment

The facility design primarily uses single-use system which will not require cleaning. The only parts of the single-use systems that require cleaning will be the hardware such as the bag holders, the motors for agitators, and control towers. These will undergo the same cleaning regiment as the facility which typically involves manual wipe downs with approved cleaning chemicals.

Process equipment components that are multi-use - such as TFF membranes and chromatography columns - will be cleaned in place with their system after every use using sanitization solutions. These will not require an external cleaning system.

The design does not include a clean in place system as it is the design's intent not to utilize any stainless-steel systems or process piping that will require cleaning.

The design assumed that pre-packed columns will be utilized for chromatography and does not currently have a column packing area. This assumption will need to be validated in the next phase. If column packing is required, provisions for it will need to be made in the component prep area.

The design includes a part washer that can be used to clean reused components such as glassware and lab equipment. The components that will require washing will need to be further evaluated in the next phase.

The design also includes a sterilizing autoclave for steam sterilizing cleaned components.

3.8 Waste Management

The operation of the facility is expected to generate bio-contaminated solid wastes, uncontaminated solid wastes, bio-contaminated liquid waste that will also require neutralization, and uncontaminated liquid waste that will require neutralization.

3.8.1 Solid Waste

- The bio-contaminated solid waste, such as single-use bags and filters will be generated by the viral vector ballroom which is BSL2/CL2. This waste will be thermally decontaminated via the pass-through decontamination autoclave before being removed from the suites.
- Other solid waste such as single-use bags that have not been exposed to the BSL2/CL2 materials can be removed from the facility without decontamination. Strategy and logistics for their disposal off-site will need to be developed in the next phase.

3.8.2 Liquid Waste

- Bio-contaminated liquid waste will be generated by the viral vector ball room which is BSL2/CL2. This waste stream will need to be segregated from the rest of the waste streams and directed to a bio-kill system for treatment. The design includes a single-pass thermal bio-kill system with a capacity of 9000 lph and a holding tank with the capacity of 2000 L. The treated effluent from this system will need to be directed to a neutralization system for pH adjustment.
- Other liquid waste that have not come in contact with BSL2/CL2 materials will be directed to the neutralization system. The design includes a neutralization system with 50 gpm capacity and a 2000-gallon equalization hold tank. The liquid waste will be pH and temperature adjusted before being released to the city's waste system.

3.8.3 Additional Liquid Waste Treatment

The design does not include any provisions for any other liquid waste treatments such as for phosphate removal or Kjeldahl nitrogen removal. Any requirements related to this should be further evaluated in the next phase.

3.9 Process Architecture

3.9.1 Blocking and Stacking

The new build facility (Recommended Option) will consist of 2 working floors and a Penthouse/Interstitial level. Level 1 will be designed as the support floor and will consist of Gown rooms, restrooms, warehouse, QC labs, Mechanical and Electrical/IT. Level 2 will support the manufacturing process and will include a Viral Vector suite, a mAbs Upstream and Downstream process, a Media and Buffer prep room and a Component prep area.

The building is located to the South East of the existing site and is connected to the existing Building L4 at the existing loading dock. The building will sit in between the extended office and the site boundary. Please see site plan below. A number of options were produced to evaluate the best location for the expansion.

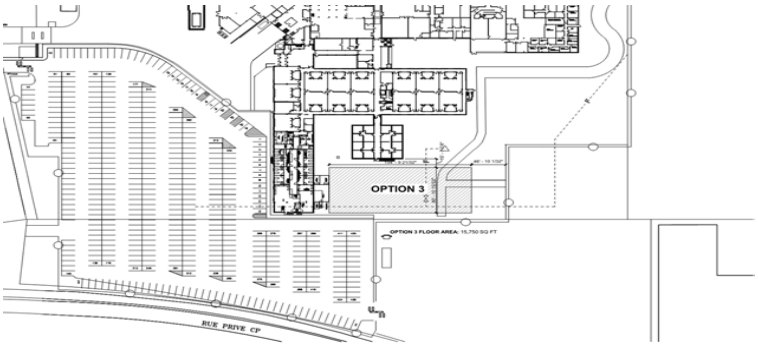


Figure 13 - Recommended Option Site Plan

3.9.2 Facility Flows

The manufacturing area on Level 2 is designed to support unidirectional flow. To achieve this concept a Central Clean supply Corridor (Grade C) is used for access for Personnel and materials to the individual rooms. The design is a 'one-way' system, personnel and materials exiting the suites will use the Exit Airlocks to the Return Corridor (Grade D). People, Materials and equipment to be washed can exit the MAL's directly to the Grade D corridor and make their way either to the staging area to transfer back to level 1 or to the Component prep area for washing and Autoclaving. A decon Autoclave is located at the exit of the Viral Vector suite as part of the BSL2/CL2 boundary requirement.

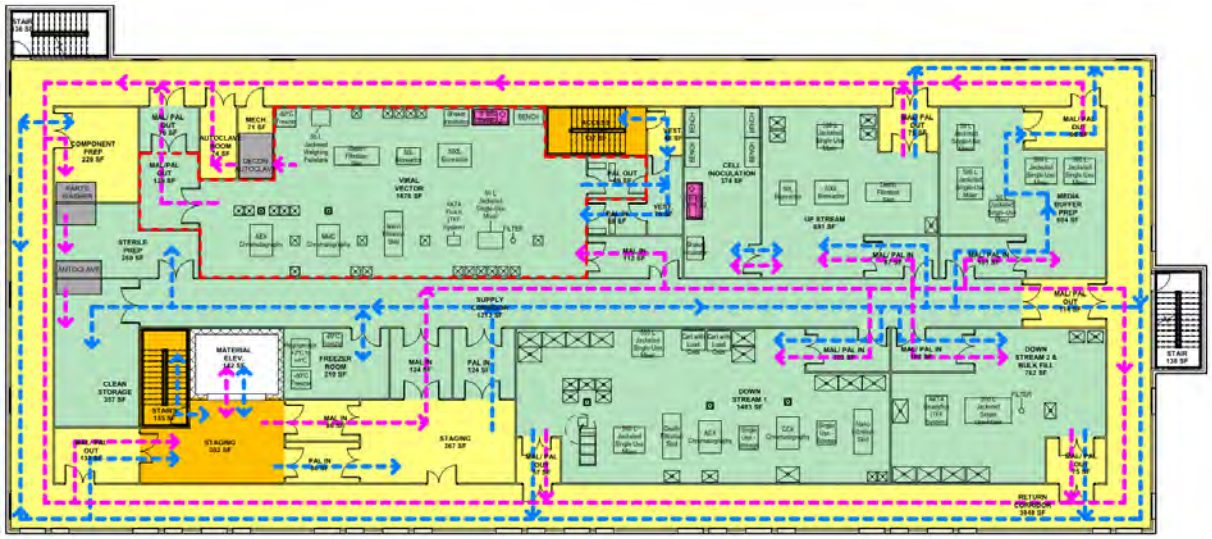
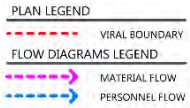


Figure 14 - Flow Plan for Recommended Option Layout



3.9.3 Adjacencies

Level 1 will be the primary connection to the Existing facility for Personnel and materials entering the new facility. Personnel entering the new building extension will enter through the existing main entrance. They will then proceed through Building L4 and enter the new facility at a new entrance provided. The existing dock located to the South of Building 4 will be utilized for the transport of new materials in to the new facility.

Once staff enter the facility, they can go directly to the lockers in the mud room/corridor and access the external lockers there. To access the second floor, personnel can enter the Viral Vector locker area or the general access locker area and use the stairs to access Level 2. The Viral Vector suite is classified as a BSL2/CL2 area requires separation from the non BSL2/CL2 area. In the gown rooms, staff will don plant uniforms and plant shoes before entering the clean non-classified stairways to access level 2.

To distribute materials to the new facility, the existing dock in Building 4 will be utilized. This can be used for raw materials and finished goods. A new connection door will be provided to move materials to the new facility warehouse. Here materials will be stored on racks or within the cold room provided. For moving materials to the manufacturing floor, an Elevator is available. The elevator is designed to carry people and materials.

3.9.4 Access & Visibility

In terms of access and visibility, the new expansion leverages off the existing L4 building in terms of access for personnel and for materials. The new building is directly connected to it and separate access will be provides for personnel and materials to transfer between the two.

The external façade of the new building will be designed to blend in with the existing.

Figure 15 - Site Plan Showing Recommended Option Connections to Existing Building

3.9.5 Expandability

The concept does not look at future expansion as there was a not a requirement to do so at this point.

3.9.6 Flexibility

The facility has been designed with a certain amount of flexibility in mind. The mAbs and the Viral suites are designed to receive future equipment based on future Client needs. The corridors, elevator and the airlocks doors are sized to accommodate the installation of any future equipment.

3.9.7 Master Plan Integration

As part of the concept process a review of the overall site was conducted to understand the existing material and personnel flow plus site entrances. The existing loading dock and Warehouse located to the north of Building L4 and as a consequence it was designed that the new manufacturing building should utilize the existing loading dock to the south of building L4.

The site boundary was also established and provided the design team with the set-out limits.

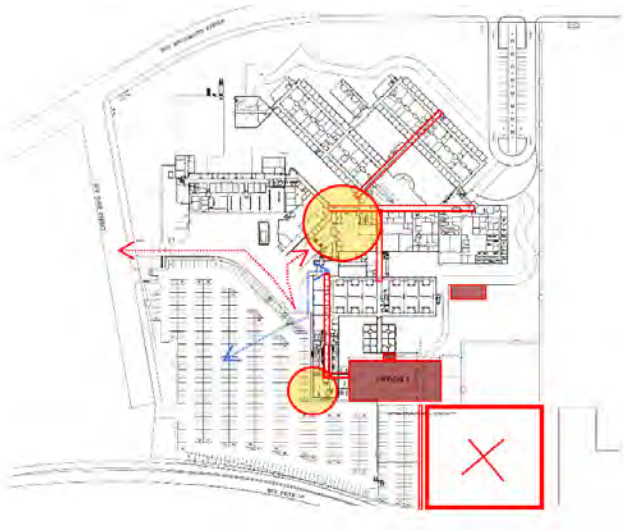


Figure 16 - Site Plan Showing Recommended Option and Site Boundary

3.9.8 Phasing

Construction phasing and sequencing will be examined in more detail during the next phase.

3.10 Architecture & Engineering

3.10.1 Building Code Analysis

The National Research Council (NRC) located at 6100 Royalmount Ave, Montreal wishes to build a greenfield Clinical Trial Manufacturing Facility (CTMF) at this campus.

There is currently an addition for a bio-manufacturing (BMC project) under construction at the north-west part of the site. The existing complex of buildings is generally 2-storeys in height with some mechanical penthouses. The building cladding is generally insulated metal siding with punched window fenestration.

The CTMF project proposes a greenfield addition of approximately 31,500 SF (2,928 m2) designed for production based on cell culture, purification of biologics such as vaccines, viral vectors and monoclonal antibodies. The CTMF is placed on the site connected to the L4 loading dock and is adjacent to the office block directly to the north.

During the Detailed Design phase, the space between the office block and the CTMF needs to be examined for code issues regarding "limiting distance" as defined by the building code.

This addition will be connected to the existing complex of buildings at the south portion of Lab Wing 4 (L4). The point of connection for the CTMF will be the south loading dock at L4 wing.

Initial Zoning review has been completed and there is currently a building height restriction of 12.5 m. Other zoning issues will be examined during the Detailed Design phase of the project.

The CTMF will be constructed as a steel frame and will be designed with fire separations on the floor slabs and on vertical risers such as the stair towers and elevators shafts.

There are 2 options proposed for the Mechanical Penthouse and both options propose a walkable ceiling over the process floor (Refer to section 6.0 for comparison of cost):

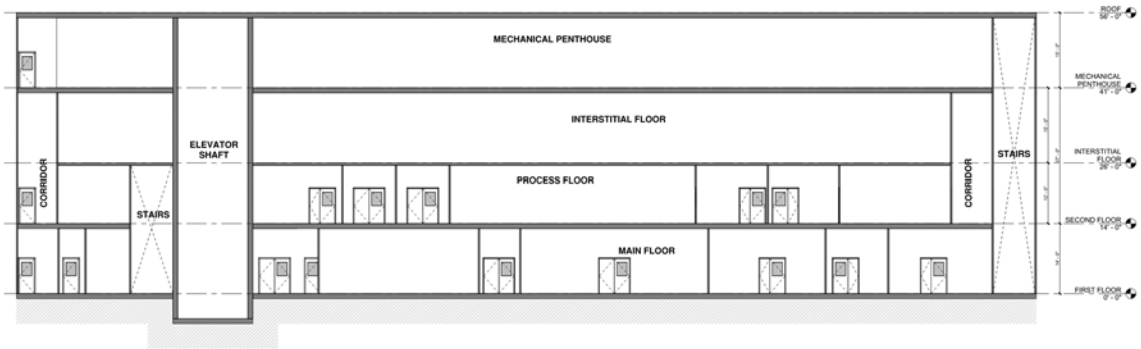


Figure 17 - Option 1 Schematic Sections for CTMF

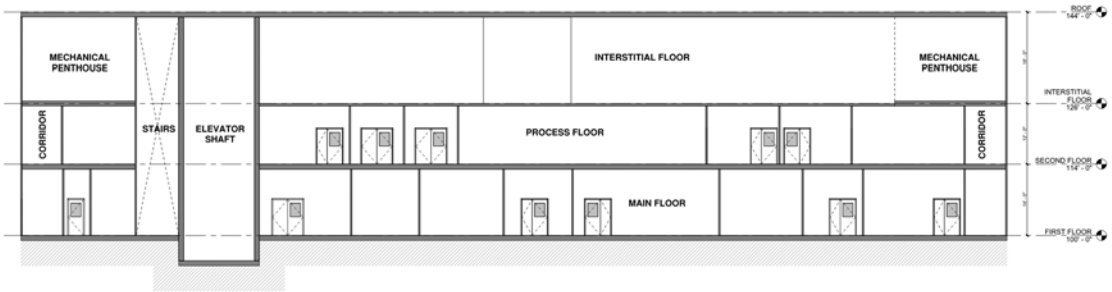


Figure 18 - Option 2 Schematic Sections for CTMF

- The first is a full penthouse floor for air handling units and duct distribution through an interstitial space to connect with diffusers at walkable ceiling above the process floor. This is the option that is recommended for this project.

  - Pros:
    - Provide a space for the installation of dedicated air handling units (AHU's)
    - Continuous louvres around the perimeter of the penthouse will allow air intake for the AHU's
    - Space for removing coils and filters
    - Space for maintenance of the AHU's
    - Safe exiting for the penthouse
    - Space for future equipment and replacement of fan motors, coils and filters
    - Space for duct distribution
  - Cons:
    - Higher capital cost
    - Height of the building exceeds the zoning requirements which would require a zoning variance
- The second option is for an interstitial space which is shared with the mechanical space and has the air handling units suspended from the steel which frames the roof. This option would reduce the height of the building and is expected to reduce cost. This option, if selected will be designed during the Detailed Design phase of the project.
  - Pros:
    - Results in a smaller footprint for the CTMF facility because this option will yield a 3-storey building, compared to a 4-storey building
    - Height of the building is lower, compared to option-1, however, height may still exceed zoning requirements and require a zoning variance
  - Cons:
    - This option would require that the AHU's be mounted on platforms suspended from the roof steel (advantage of lower building height and less cost);
    - Results in less space for duct distribution
    - More difficult access to service equipment from suspended platforms
    - Getting replacement parts to AHU's is more difficult; more difficult to install new equipment

Exiting will be provided by 2 exit stairs at either end of the CTMF. The building will be sprinklered and the base building fire alarm system will be extended to the CTMF.

3.10.2 Sustainability

In discussions with Sirak Ogbaghebriel (Site Manager) on 4 March 2021, he indicated that all new federal buildings have a mandate to be 'net zero' by 2022. Jim Johnston (Project Manager) said we will not be pursuing a net zero strategy for the CTMF.

We understand that the intent for energy conservation is to use electrical power as the preferred energy source.

3.10.3 Architecture

3.10.3.1 Facility Program

OPTION 3 - ROOM LIST WITH AREAS			
ROOM NO	**ROOM CLASSIFICATION**	**ROOM NAME**	**AREA**
FIRST FLOOR			
1100	UNCLASSIFIED	STAIR	136 SF
1101	UNCLASSIFIED	MUDROOM/ CORRIDOR	914 SF
1102	CONTROLLED NON CLASSIFIED	AIR LOCK	80 SF
1103	GRADE C	SAMPLING	277 SF
1104	GRADE C	PAL IN	52 SF
1105	GRADE D	PAL IN	52 SF
1106	GRADE D	MAL/ PAL OUT	64 SF
1107	GRADE C	WEIGH DESPENSE	346 SF
1108	GRADE D	MAL/ PAL OUT	66 SF
1109	GRADE C	PAL IN	52 SF
1110	GRADE D	PAL IN	52 SF
1111	UNCLASSIFIED	MENS	250 SF
1112	UNCLASSIFIED	WOMENS	250 SF
1113	UNCLASSIFIED	VIRAL VECTOR FEMALE LOCKERS	289 SF
1114	CONTROLLED NON CLASSIFIED	STAIRS	137 SF
1115	UNCLASSIFIED	VEST.	88 SF
1116	UNCLASSIFIED	VIRAL VECTOR MALE LOCKERS	289 SF
1117	CONTROLLED NON CLASSIFIED	QC LAB	705 SF
1118	GRADE D	MICRO LAB	197 SF
1119	UNCLASSIFIED	ELECTRICAL	1007 SF
1120	UNCLASSIFIED	IT	135 SF
1121	UNCLASSIFIED	MECHANICAL	1317 SF
1122	CONTROLLED NON CLASSIFIED	CNC CORRIDOR	712 SF
1123	UNCLASSIFIED	WASTE HANDLING	122 SF
1124	UNCLASSIFIED	JANITOR STORAGE	80 SF
1125	UNCLASSIFIED	CORRIDOR	1012 SF
1126	CONTROLLED NON CLASSIFIED	VEST.	35 SF
1127	UNCLASSIFIED	MALE LOCKER ROOM	269 SF

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1125	UNCLASSIFIED	CORRIDOR	1012 SF
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1127	UNCLASSIFIED	MALE LOCKER ROOM	269 SF

Figure 19 - Recommended Option Room List with Classification and Areas

3.10.3.2 Head Count/Staffing

Headcount Summary - 25 staff at one time. Total staff count to be determined when the number of shifts per week have been finalized.

3.10.3.3 Existing Building Description

Complex of buildings incorporating labs, bio-manufacturing and offices; currently an addition for a bio-manufacturing facility is under construction at the north-west part of the site. The existing complex of buildings is generally 2-storey in height with some mechanical penthouses. The building cladding is generally insulated metal siding with punched window fenestration.

Proposing a greenfield addition of 31,500 SF (2,928 SM) designed for production based on cell culture, purification of biologics such as vaccines, viral vectors and monoclonal antibodies.

3.10.3.4 Exterior Design and Finishes

The existing complex of buildings at this site are of a similar height and are generally 2 story plus a mechanical penthouse. The exterior cladding of the complex is insulated metal siding and the CTMF will use similar cladding materials to match the appearance of the existing buildings on the site.

3.10.3.5 Interior Finishes

- Flooring

Floors shall be coated with the appropriate finishes as outlined below:

- Manufacturing:

Concrete slab shall be prepped and covered with a rolled monolithic epoxy flooring system with an integral coved base.

- Manufacturing Support Areas:

Concrete slab shall be prepped and covered with a rolled monolithic epoxy flooring system with an integral coved base.

Figure 20 - Rolled Monolithic Epoxy Flooring System with Integral Coved Base

- Mechanical Space:

Concrete slab shall be covered with a gray epoxy paint over concrete slab.

- Walls

Walls shall be constructed as outlined below:

- Interior

Manufacturing Areas – Grade C & D Only

Walls will be prefabricated sandwich panels with corrugated aluminum cores with aluminum face with a PVC finish or powder-coated metallic insulated panels. Adjacent PVC panels are chemically welded to form a seamless monolithic surface. Vertical and horizontal corners will have pre-molded coved welded surfaces.

Figure 21 - Grade C and D Cleanrooms Sandwich Panels

Non-GMP Areas (Unclassified)

Walls will be paperless 5/8" gypsum wall board on metal studs with paperless tape (fiberglass mesh).

- Ceilings

Ceilings shall be constructed as outlined below:

Manufacturing Areas – Grade C, D and CNC Only

Ceilings in Production Areas will be prefabricated, walkable, sandwich panels with corrugated aluminum cores with aluminum face with a PVC finish or powder-coated metallic insulated panels. Adjacent panels are chemically welded to form a seamless monolithic surface. Vertical and horizontal corners will have pre-molded coved welded surfaces. The panels will be supported from the structure above and be designed for light load access (20 pounds per square foot), allowing Mechanical or Electrical service.

Figure 22 - Ceiling in Production Areas Showing Mechanical and Electrical Services

Manufacturing Support Areas – Unclassified Only

All ceilings in in Manufacturing Support Areas will be 2' x 4' acoustic clean room ceiling tile with a clipped and gasketed suspended grid (with the exception of the BSL-2 areas which will be built with a hard ceiling).

Mechanical Penthouse:

There are no ceilings; it will be open to the structure above.

3.10.4 Engineering

3.10.4.1 Electrical

3.10.4.1.1 Introduction / Overview / Scope of Work

The intent of this section is to convey the Electrical design philosophies and concepts to support the Clinical Trial Manufacturing Facility (CTMF) project to be located at the NRC facility in Montreal, Quebec.

The existing NRC site is fed from two 2000kVA 25kV-347/600Y Hydro-Quebec transformers located in the annex room of the Main Electrical Room. They feed a 6000A switchgear (rated at 80%) through a bus duct.

At the moment a new addition BMC is being added to the NRC Main facility, this is to be fed from the Main NRC Electrical Room.

CTMF building will be a new addition to the NRC facility.

3.10.4.1.2 Primary Electrical System

The scope of the electrical services is based on certain assumptions (outlined below) from information in the previous drawings and communications provided by NRC.

The main Electrical Room in the main building has a 6000A switchgear rated at 80% capacity (4800A).

The historical peak load of the existing facility not including the BMC building is 2600A.

The BMC building (currently under construction) is fed via a 2000A breaker from the main electrical room. Its projected load is 1600A.

This leaves us with a 600A capacity, but the projected load for the CTMF building is 1400A. This would mean getting a new service for the CTMF facility.

To reduce the carbon footprint of the site, NRC is planning to convert the existing gas fired boiler in the main building to the electric boiler, the projected load of this boiler would be 1875A.

If the BMC building gets a new feed from Hydro Quebec and the existing boiler in the main building is kept as gas-fired, then the CTMF building can use the existing electrical capacity, eliminating the need for a new service.

Below are the two options to get electric power for CTMF building:

Option 1:

New Electrical Service for CTMF Building:

Hydro Quebec Service Entrance is located at the Northwest corner of the site. In order to get a new service to the CTMF building, a trenching path is proposed from the Hydro Quebec service entrance to the 2500kVA pad mount transformer located on the south side of the CTMF building, as shown in the Electrical Site Plan E1.02 - Option 1 (Refer to the Appendix).

This path includes routing through an existing manhole and two new manholes. The first new manhole is proposed at the end of the trenching path along the Rue Pare Street before the elbow turn and the second one is located in the middle of the parking lot on the trenching path before heading to the utility transformer respectively. Manholes are proposed for service access and to reduce stress on the underground cabling runs.

Option 2:

New Electrical Service for BMC building:

Hydro Quebec Service Entrance is located at the Northwest corner of the site. In order to get a new service to the BMC building, a trenching path is proposed from the Hydro Quebec service entrance to the 2500kVA pad mount transformer located on the south side of the BMC building, as shown in the Electrical Site Plan E1.03 - Option 2 (Refer to the Appendix)

CTMF building would tap into the existing NRC building feed via a 2000A breaker located in the Main Electrical Room. Cables would be run from the Main Electrical Room to the CTMF building via Aluminum Cable Tray on the roof as shown in the Electrical Site Plan E1.03 - Option 2 (Refer to the Appendix)

3.10.4.1.3 Electrical Load Estimate

The estimated demand load for the new renovation is 1400 kVA as shown in the Electrical Load Estimate NRC (Refer to the Appendix). This includes a 25% safety factor. On the right are summary tables for the estimated electrical calculations. The tables include breakdown for Process rooms, Clean corridors, Clean storage, Air locks, Normal corridors, Mechanical/Electrical rooms, Locker rooms, Warehouse and other areas. Diversity, watts per square foot, and connected and demand loads are also included in the table.

3.10.4.1.4 Power Distribution System

The main switchboard lineup to be provided in the main electrical room will feed many of the large breakers for mechanical and process equipment located on the first floor and penthouse floor, as well as core distribution equipment located in the same electrical room. The single line Diagram E5.01 illustrates the distribution design intent (Refer to the Appendix).

Many of the motors in Air Handlers, Boilers, Pumps and the like will have starters or breakers located in Motor Control Centers. These motor control centers will be centralized where needed near the mechanical equipment. Phasing of this equipment will be developed in the next design phase.

Lighting and Receptacle Panels will be located in the central electrical rooms, or on corridors for distribution to local power needs. For many lab designs, having local lab panels provides shorter cable runs, saves money, and provides a safer environment when circuits need to be disconnected for service.

Many motors are to be Variable Frequency Control (VFC) controlled, with the controller at the local equipment or located in a Motor Control Center. All VFCs to be provided with 5%-line side reactors and will be evaluated for bypass in the next phase of design.

Transformer Characteristics: All transformers will be designed to be high efficiency, low heat rejection transformers to provide low losses.

The main switchboard equipment is to be provided with a local Surge Protective Device (SPD). Additional SPDs shall be provided at the Distribution panels located in the central Electrical Rooms.

3.10.4.1.5 Emergency/Stand-by Power System

The building will be provided with a Diesel generator initially sized for 600KW (750KVA). The generator will be located on grade adjacent to the utility transformer.

There is an Automatic Transfer Switch (ATS) to switch power between Normal and Emergency power. The genset will parallel with the building power, or can provide complete standby power to the critical process and mechanical loads in the event of utility loss as shown in the Single Line Diagram E5.01 (Refer to the appendix)

3.10.4.1.6 Special Power

Heat Trace System – This scope will be identified during the Detailed Design Phase.

3.10.4.1.7 Airlocks

A door interlock system will be provided at each personnel Airlock, Material Airlock, and Gown/De-gown Rooms to avoid simultaneous opening of the doors in the Airlock to maintain proper pressure and cleanness inside the Process suites. This will be achieved through red and green lights to inform staff of an occupied maglock.

The interlock system will include door operators, door status switches, and door actuators (hands free or pushbutton type where indicated). All wiring from devices related to a particular door will be run in conduit to a door junction box and wired back to the system controller. Controllers will be installed in the ceiling space.

Activation of the building fire alarm system will automatically release all interlocked doors to allow free passage through the Airlocks for personnel evacuation from the building. Fire alarm pull stations will be installed at each Maglock to meet Ontario Building Code.

3.10.4.1.8 Lighting System

Energy efficient lighting will be provided throughout the building using appropriate Light-Emitting Diode (LED) light fixtures. Normal lighting fixtures will be powered from 120/208

panelboards. Below is a table of acceptable average lighting levels for different areas in the building. Note that the illuminance calculated is 36 inches above the floor.

Table 4 - Typical Rooms with Average Lux and Light Type

SPACE	LIGHT TYPE	AVERAGE (LUX)
PROCESS ROOMS	LED	753 - 861
CORRIDORS	LED	161 - 215
CLEAN STORAGE	LED	215-323
AIR LOCKS	LED	161-215
MECHANICAL/ELECTRICAL/IT ROOMS	LED	215 - 323
LOCKER ROOMS	LED	215-323
WAREHOUSE	LED	215 - 323
VESTIBULE	LED	215 - 323
STAIRS	LED	108
MENS/WOMENS ROOMS	LED	161-215

3.10.4.1.9 Emergency Lighting System

The NRC building will be provided with lighting circuits and industrial lighting per floor, with some emergency coverage if temporarily occupied.

Exit signage will be provided at stair towers and elevator core.

Exterior lighting is to be provided at egress doors and exterior areas to provide areas for mustering.

The new lighting fixtures will be high efficiency LED fixtures with a low wattage per SF to allow for lower ambient lighting.

All emergency lighting throughout the building will be backed up via emergency generator.

Exit signage is to be LED, long life fixtures powered from the Generator.

3.10.4.1.10 Uninterruptible Power System

The building will be provided with a 250KW UPS system to provide uninterruptible power to critical systems and data equipment.

The system shall be provided at 600V, and through a stepdown transformer, will provide 208/120V to multiple distribution panels in the building.

The system is expected to be sized at 200KVA (250KW).

The system shall be backed up by generator power, so the typical outage time is expected to not exceed 15 seconds.

Battery Cabinet: VRLA batteries, arranged in battery strings, will provide the DC power to keep the system running, and shall be sized for a 15-minute runtime in the case of a loss of normal power.

UPS Distribution shall be run separately than normal power, and lab, office and production receptacles will be provided as a different color device with an indicator of UPS power.

3.10.4.1.11 Grounding System

The Core Building will be provided with a grounding ring of 3/O buried copper, with bonding jumpers to vertical building steel (exothermically welded).

Test wells are to be provided at opposing building corners, to ensure proper minimal resistance to an adjacent test conductor.

Grounding of the following systems shall be considered part of the Grounding System: Electrical Equipment, IT Equipment, Tanks, Vessels, Electrostatic dissipative floors, Lighting Protection.

3.10.4.1.12 Lightning Protection System

The building will be provided with a lighting protections system, designed to applicable standards.

The perimeter of the building shall have air terminals, with horizontal conductors bonded to building steel through vertical roof penetrations.

All down conductors are to terminate into the building grounding system.

3.10.4.1.13 Electrical Devices

Switches, Receptacles and Special Purpose devices are to be hospital-grade, high quality devices.

Most locations will require cover plates with electrical circuit marking.

Exterior receptacles and devices shall be provided with NEMA 3R protective covers.

Lab or production areas will be provided with divided surface raceway, with recessed devices integral to the raceway. Each will be marked with circuit numbers accordingly.

Special purpose receptacles shall follow NEMA standards, and will be provided for the power system and current ratings required.

Exterior receptacles, or those within 6' if a water source, shall be provided a GFCI type. Kitchen receptacles will be fed from GFCI circuit breakers.

3.10.4.1.14 Security

The security system will have multiple systems integrated into a single security solution.

Door Access Control: An access control system will be used for securing the main entrances to the building, utilizing RFID cards and existing access groups.

Assumption: The system will be integrated into the existing access control system on the NRC site.

The door access system will be used for controlling access to processing spaces (as needed), support areas, storage, security rooms and other areas that require special authorization for entry.

CCTV cameras will be provided at various entrances, stair towers, and access-controlled doors. The CCTV system will augment the existing CCTV system, and the location of Network Video Recorders (NVR) and other monitoring equipment will be developed at the next phase of the project.

The CCTV devices shall be 360deg dome cameras (solid state) or travelling PTZ cameras to cover multiple areas.

Where the building will have interlocked airlock doors, an Interlocking Controller will be utilized to provide single use of airlock doors, to ensure there is not a pathway for controlled particulates to exit the processing spaces. The Interlocking controllers will integrate with the Access Control system to ensure the proper credentials are provided for each door accessed (as necessary).

The entire Security system will be integrated with the fire alarm, to release egress doors a needed in the event of a fire or security issue.

3.10.4.1.15 Tele/Data

Assumption: Existing voice and data can be run into a 24-strand fiber from the existing building to CTMF IT Room.

All cabling will be provided as CAT6A based on the required speed of the connections.

All data jacks provide in office spaces, lab benches and other equipment will be provided with a CA6A jack and associated cabling, as per TIA standards.

3.10.4.1.16 Fire Alarm

The CTMF building will be developed with a base building digital, addressable fire alarm system.

The system shall be designed to meet all applicable codes.

The system will employ standard, addressable fire alarm initiation devices such as heat and smoke detectors, and will utilize fire speakers and strobes. The fire speaker system will allow evacuation announcements to be played in the event of a fire or security event.

The main FA panel will be located in the entrance vestibule and will integrate with the existing site fire alarm system to allow communication between buildings when there is a trouble or fire event.

The entrance vestibule room will contain the Fire Alarm Control Panel, a complete set of building drawings, an elevator control panel for recall and shutdown, as well as a communication console for announcements.

All elevator lobbies, fire alarm areas, electrical rooms and large storage areas will be designed with smoke detectors. The Elevator shafts will employ smoke and heat detectors as per code.

Duct detectors are to be employed on supply and return of air handlers, and on each floor when broken into smoke zones or fire containment areas.

The system shall be designed to be generator powered, but will also have a 12 hours battery installed for continuous use, as per code.

The final battery calculations utilized for permitting are to be completed by the selected Fire Alarm Vendor.

3.10.4.1.17 Materials of Construction

All wire to be copper. THHN wire used under #4 AWG, and XHHW-2 wire is to be used for #4AWG and higher. Solid THHN wire under 8AWG, all stranded wire for any size 8AWG and over.

Interior conduits and raceways shall be Electrical Metallic Tubing (EMT) for any concealed spaces or areas where the conduit is not prone to hard or high traffic environments. Rigid Metal Conduit (RMC) is to be used for areas where conduit is exposed to hazard our high traffic.

Exterior conduits and raceways shall be Aluminum conduit or coated rigid metallic conduit as necessary.

Conduits as part of a duct bank shall be PVC on supports, and concrete encased. This applies for transformer feeds and generator feeds.

Site lighting and low voltage power conduits shall be PVC in grade, with handholes no more than 150' or after three 90-degree bends.

Lightning Protection shall be copper conductors and tin-plated aluminum air terminals.

Cable Trays shall be utilized for low voltage power distribution. The tray shall be basket trays where used in the building for bundled cable distribution. Ladder rack shall be used in computer rooms or IDFs.

3.10.4.2 Mechanical

3.10.4.2.1 Introduction

The intent of this section is to convey the HVAC/Utilities design philosophies and concepts to support the Clinical Trial Manufacturing Facility project to be located at the NRC facility in Montreal, Quebec. Items covered are general design requirements for the supply, return and exhaust air handling systems that maintain the room environments, chilled water system, hydronic and steam systems supporting the process users and air handling systems as well as the compressed air system.

3.10.4.2.2 Design Criteria

The following outdoor (ambient) conditions shall be used for the design (peak load) of the Mechanical HVAC systems:

SUMMER[1]	WINTER[2]
86.1°F DB / 71.4°F WB (30.1°C DB / 21.8°C WB)	-12°F DB / -12.9 °F WB (-24.4°C DB / -24.9°C WB.)

Table 5 - Outdoor Design Conditions – GMP Areas

Notes:

1. American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE), 2017 Fundamentals, 0.4% wet bulb with mean coincident dry bulb for Montreal, Quebec, Canada.

2. American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE), 2017 Fundamentals, 99.6% dry bulb for Montreal, Quebec, Canada. The Consulting Firm will use a more conservative value than ASHRAE for the purposes of this design - due to extreme cold conditions.

Table 6 - Outdoor Design Conditions – Warehouse and Support Spaces

SUMMER[1]	WINTER[2]
83.3°F DB / 69.8°F WB (28.5°C DB / 21.0°C WB)	-7.24°F DB (-21.8°C DB)/ 0 gr/lb.

Notes:

1. American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE), 2017 Fundamentals, 1.0% wet bulb with mean coincident dry bulb for Montreal, Quebec, Canada.

2. American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE), 2017 Fundamentals, 99.0% dry bulb for Montreal, Quebec, Canada.

3.10.4.2.2.1 Indoor Design Conditions

The indoor design conditions (temperature and humidity) for typical areas are listed below. Indoor design conditions for specific rooms/areas may be developed further during the Detailed Design Phase.

Table 7 - Indoor Design Conditions

CLASSIFICATION R0W/FDA	ROOM TEMPERATURE DESIGN	ROOM TEMPERATURE RANGE1	ROOM % DESIGN 2,3
GRADE C / ISO 8	20°C +/- 2°C 68°F +/- 4°F	18°C / 22°C 64°F / 72°F	50% + 5% Dehumidification 35% - 5% Humidification
GRADE D / CONTROLLED NON-CLASSIFIED	20°C +/- 2°C 68°F +/- 4°F	18°C / 22°C 64°F / 72°F	50% + 5% Dehumidification 35% - 5% Humidification
CONTROLLED NOT CLASSIFIED	22°C +/- 5°C 72°F +/- 8°F	17°C / 27°C 62°F / 80°F	50% + 5% Dehumidification 35% - 5% Humidification
UNCLASSIFIED	22°C +/- 5°C 72°F +/- 8°F	17°C / 27°C 62°F - 80°F	55% + 5% Dehumidification 35% - 5% Humidification
MECHANICAL	24°C 75°F	16°C (Min) 29°C (Max)	Uncontrolled

		61°F (Min) 84°F (Max)	

Notes:

1. Room temperature alarm setpoints. Alert setpoints to be defined during the detailed design.

2. Alarm setpoints – 60% RH Maximum; 30% RH minimum. Alert setpoints shall be 55% for dehumidification and 32% RH for humidification.

3. Soften Water converted to steam will be provided for humidification for all required GMP and non-GMP areas.

Room alert and alarm setpoints will be reviewed during the Detailed Design phase. Also, if there are specific products that require specific relative humidity ranges, NRC will identify the acceptable limits and the affected areas.

3.10.4.2.2.2 Room Classifications

The room cleanliness classifications will be indicated on the area classification plan drawings. Refer to Architectural drawings ASK-007 and ASK-008 in the appendix.

3.10.4.2.2.3 Minimum Airflow Criteria

Design supply airflow rates will be based on the minimum ventilation requirements for occupant comfort, occupant density, equipment loads, pressurization criteria, contamination control, and/or exhaust air requirements. The recommended minimum air change per hour (ACH) to each space shall be as follows:

Table 8 - Design Supply Airflow Rates

SPACE DESIGNATION	DESIGN AIR CHANGES PER HOUR[1,2,3]
Zone C /ISO 8	30
Grade C Material and Personnel Airlocks	40
Zone D / Controlled Non-Classified	20
Grade D Material and Personnel Airlocks	30
BSL2 Space	12

Controlled Not Classified	As required for cooling or ventilation
Unclassified	As required for cooling or ventilation
Washrooms / Locker Rooms	As required for cooling or ventilation
Mechanical	As required for cooling or ventilation

Notes:

1. The above air changes rates are design levels based on room classification. In the case of a classification change for a room, the air change rate will need to be revised accordingly.

2. All gown/de-gown airlocks and airlocks transitioning from one grade to another shall be 10 ACPH greater than the space design ACPH.

3. All air change rates are based on HEPA filtered supply air only; not return/exhaust or transfer.

3.10.4.2.2.4 Pressurization

Airflow and room pressures must cascade from the area of greatest product risk (Grade C / ISO 8) to the area of least risk. Rooms with a higher cleanliness classification must be held at a higher pressure relative to adjacent lower classification rooms. The BSL2 rooms, however, will be kept at a negative pressure relative to their surrounding airlocks in order to ensure containment.

The design pressure shall be a minimum of 15.0 Pa (0.06”) between classifications and will alarm at 8 Pa (0.033”).

The design differential pressure across each door of airlocks that transition between different ISO level environments shall be a minimum of 7.5 Pa (0.03") with all doors in their normal closed positions.

3.10.4.2.2.5 Ventilation Air

The minimum design ventilation air quantity in all cases will be as required by the Quebec Building Code and ASHRAE 62.1-2016, or as required for pressurization and makeup air to replenish exhaust air. For calculation purposes, units were assumed to have a minimum outside air as follows:

- The BSL2 area HVAC units were assumed to have 30% outside air.

All other GMP and Non-GMP units were assumed to have 10% outside air.

The following rooms will be 100% exhausted:

- Wash Rooms
- Locker Rooms

3.10.4.2.2.6 Filtration

Supply air filtration will be as follows:

Table 9 - Supply Air Filtration

SPACE DESIGNATION	TERMINAL AIR FILTRATION EFFICIENCY[2]	SUPPLY AIR FILTRATION EFFICIENCY AT AIR HANDLING UNITS
Grade C / ISO 8	H14 (HEPA)	F5 (MERV 9 – 50-55%)/F6 (MERV 11 – 65%) and F9 (MERV 15 - >95%)1
Grade D / ISO 9	NA	F5 (MERV 9 – 50-55%)/F6 (MERV 11 – 65%) and F9 (MERV 15 - >95%)1
Controlled Non-Classified	NA	F5 (MERV 9 – 50-55%)/F6 (MERV 11 – 65%) and F9 (MERV 15 - >95%)1,3
Controlled Non-Classified (BSL2)	NA	F5 (MERV 9 – 50-55%)/F6 (MERV 11 – 65%) and F9 (MERV 15 - >95%)1,3 – BIBO HEPA Return Filter4
Unclassified	NA	F5 (MERV 9 – 50-55%) and F7 (MERV 13 - 85%)

Notes:

1. F5 (MERV 9 – 50-55%)/F6 (MERV 11 – 65%) filters will be located upstream of the heating and cooling coils in the air handling unit(s). F9 (MERV 15 - >95%) filters will be located downstream of the heating and cooling coils in the air handling unit(s).

2. Terminal supply HEPA filters for Grade C areas will have a minimum efficiency of 99.995% on 0.1 micron tested in accordance with IES-RP-CC-001-86.

3. Level of filtration for Controlled Non-Classified (CNC) areas will be reviewed during the next phase.

3.10.4.2.2.7 Air Handling System and Zoning

The air-handling units will be separated based on one or more of the following criteria:

- Areas of different products.
- Areas of different process stages.
- Similar cleanliness levels (cGMP vs. non-cGMP areas).
- Areas of different load characteristics.

Air handling systems will be designed to minimize the risk of contamination between areas handling different products, activities performed in different area classifications, and different levels of manufacturing and non-process operations.

Separate systems will be used for each production area to minimize risk and provide flexibility from a maintenance perspective. There will be a total of 10 air handling units serving the new Clinical Trial Manufacturing Facility.

The second-floor production areas will be served by 7 individual air handling units with one unit serving each of the production suites (5 total). As well as, 2 units serving the grade C corridor/storage spaces and grade D corridor/storage spaces respectively.

The first-floor graded areas and the BSL2/CL2 spaces will each be served by their own handler. The remaining first floor CNC/NC area will all be served by one air handler.

The individualized approach of having each production room have its own air handler provides the client with the flexibility of performing maintenance on the HVAC system of a particular room without affecting the operation of adjacent rooms. More importantly, this approach protects the process from potential cross contamination between the production suites.

Grade C areas shall be designed with ceiling mounted terminal HEPAs and low wall return grilles.

Grade D areas shall be designed with ceiling mounted return grilles and HEPAs located in the air handling units (no terminal HEPA filtration). Grade D Production areas would be evaluated for best application regarding return grille location.

cGMP and Non-cGMP air handlers will utilize steam for preheat, chilled water for cooling and soften water for humidification for cGMP and non-cGMP areas.

Air handling units will be sized to include 10% spare capacity.

Ductwork will be specified, designed and tested for a maximum of 1% duct leakage.

Stairwells will not be directly supplied with supply air from any air handlers, however, every stairwell will have electric unit heaters to ensure comfortable space temperatures are achieved during the winter.

Proposed zoning for recirculation/air handling units is indicated on drawings M5.01 and M5.02 that can be found in the appendix.

All air handling units will be on emergency power in order to prevent freezing within the building as well as to maintain building pressurization in the event of a power failure.

3.10.4.2.2.8 cGMP Air Handling Units

The cGMP air handling units will be constant volume, semi-custom grade air-handling units. The air handling unit casing will be double wall, insulated construction and consist of the following components:

- Return Plenum
- Return Fan Section
- Return/Relief Air
- Mixing Box Section
- F5 (MERV 9)/F6 (MERV 11) Pre-filter Section
- Access Section
- Steam Preheat Coil Section.
- Access Section
- Steam Humidifier Section
- Access Section
- Chilled Water-Cooling Coil/Access Section
- Supply Fan Section
- F9 (MERV 15) Filter Sections
- Discharge Section

3.10.4.2.2.9 Distribution

Supply air will be distributed via externally insulated galvanized sheet metal ductwork incorporating variable volume air valves (similar to Price VAV units), SCR equipped electric reheat coils, and ceiling mounted Terminal HEPA diffusers. Temperature sensors located in the return/exhaust air ducts will modulate the associated electric reheat coil to maintain space temperature. Humidity sensors located in the unit return/exhaust air ducts will modulate the air handling unit humidifier coil control valve to maintain system relative humidity.

The return/exhaust air valve will modulate to maintain constant space pressure setpoint. Variable frequency drives on exhaust and return fans will modulate to maintain constant duct pressure setpoint for the air valves to operate. The space pressures will be referenced to a common point (large area, such as a technical space) as a base line. Direct differential pressure air measurement will occur for monitoring/alarm. Discussion will take place during the BOD phase regarding differential pressure qualification.

For Grade C Classified Areas return air will incorporate low wall exhaust/return with stainless steel grilles, and will be returned back to the air handling unit via externally insulated galvanized sheet metal ductwork incorporating return/exhaust air valves.

3.10.4.2.2.10 Non- cGMP Air Handling Units

The non-cGMP air handling units will be constant volume, semi-custom grade air-handling units. The air handling unit casing will be double wall, insulated construction and consist of the following components:

- Return Plenum
- Return Fan Section
- Return/Relief Air
- OA Intake Section
- Access Section
- F5 (MERV 9) Pre-filter Section
- Access Section
- Plant Steam Humidifier Section
- Access Section
- Chilled Glycol Cooling Coil/Access Section
- Supply Fan Section
- F7 (MERV 13) Filter Sections
- Discharge Section

3.10.4.2.2.11 Distribution

Supply air will be distributed via externally insulated galvanized sheet metal ductwork incorporating variable volume air valves (similar to Price VAV units), SCR equipped electric reheat coils, and ceiling mounted Terminal HEPA diffusers. Temperature sensors located in the return/exhaust air ducts will modulate the associated electric reheat coil to maintain space temperature. Humidity sensors located in the unit return/exhaust air ducts will modulate the air handling unit humidifier coil control valve to maintain system relative humidity.

Air will be returned back to the air handling unit via externally insulated galvanized sheet metal ductwork incorporating manual balancing dampers.

3.10.4.2.2.12 Mechanical Equipment Rooms

Mechanical equipment rooms will be conditioned using either fan coil units to provide tempering, or ventilation and unit heaters will be provided. Further analysis of the various mechanical equipment rooms will be performed during the next phase.

3.10.4.2.2.13 Plant Utilities

This section covers Chilled Water, Steam and Hot Water Generation and Distribution for HVAC Systems. The utility loads and equipment are estimated and sized based on block load calculations performed by using the gross areas.

3.10.4.2.2.14 HVAC Chilled Water System Description

Chilled water to the new CTMF will be provided from the central facility chilled water system. An existing 350-ton centrifugal chiller located in the main facility boiler room is not functional. This non-functional chiller will be replaced with a new YORK 350-ton centrifugal chiller. It is assumed that the existing chilled water piping header and distribution has sufficient capacity to support the operation of this new chiller. It is also assumed that the existing cooling tower for this chiller is in operating condition and will be functional.

The estimated chilled water load for the new CTMF building is 300 tons. Since the existing non-functional chiller is rated for 350 tons, the design intent is to replace it with a new chiller of similar capacity, even though it exceeds the needs of the CTMF building. This approach provides the campus with additional capacity for use in future projects/upgrades.

The existing central chilled water system is of the primary-secondary type. The secondary pumps will be upsized to provide chilled water to the new CTMF building. Chilled water piping to the CTMF mechanical penthouse will be brought from the existing L3 mechanical penthouse.

The central chilled water system will be used to serve both, HVAC and process applications. Peak load: The anticipated peak chilled water demands for the project area are as follows:

- HVAC load: 550 GPM and 230 tons.
- Process load: 170 GPM and 70 tons.

It is assumed that the existing central chilled water system is not currently supported on back-up power. Therefore, in the event of a power failure, the CTMF building will lose chilled water capability.

3.10.4.2.2.15 Steam System Description

Steam and Condensate Requirements

It is assumed that the site currently does not have adequate capacity to support the steam load for CTMF. Therefore, steam will be produced by one (1) new gas-fired, high-pressure (150 psig) nominal 200 HP boiler located in the new CTMF mechanical penthouse. The boiler will be the packaged flexible water tube type, including a forced draft, natural gas fired burner and control panel. This system will be on emergency power. Combustion air makeup louvers will be provided in the mechanical penthouse for the boiler.

Condensate from the HVAC and process equipment will be returned to the deaerator/condensate tank via a new steam-powered condensate receiver tank/pump.

The estimated steam load for the CTMF is 2700 Kg/hr.

Natural gas supply for the boiler will be taken from building L3's mechanical penthouse and brought over to the new CTMF mechanical penthouse. A PRV station will be used to reduce the natural gas pressure from 35Kpa to the required boiler input pressure.

Plant steam will be supplied to all air handling unit preheat coils, the humidification generator and process equipment. In order to minimize the floor cross-section taken up by mechanical piping travelling between floors, high pressure steam piping will run from the penthouse to the first floor. PRV stations will be used on the first floor for all equipment as required.

All air handling units will utilize steam coils supplied by plant steam for preheating. The new steam generation system (natural gas) will be supported on emergency power in order to prevent freezing in the building in the event of a power failure.

Humidification

A humidification generator will be used to provide humidification steam to all air handling units. Plant steam will be the source of heat and soften water will be used for the humidification application. A new water softener system will be located in the mechanical room on the first floor. The softened water will be pumped up to the mechanical penthouse to feed the humidification generator.

3.10.4.2.2.16 Building Management System

The NRC site's existing Honeywell BMS system will be expanded to incorporate the new CTMF building. The BMS shall control and monitor the HVAC, utility, and energy management systems. All new BMS devices in the scope of this project will be on emergency power.

3.10.4.2.2.17 Parking Lot Items to be addressed in next Design Phase

1. Room alert and alarm setpoints will be reviewed during the Basis of Design (BOD) phase. Also, if there are specific products that require specific relative humidity ranges, NRC will identify the acceptable limits and the affected areas.

2. Venturi air valves will allow for reduced mode (reduced air change rates for non-production hours). Reduced air change rates may be incorporated into the design for nonproduction hours (reduced mode).

3.10.4.3 Plumbing

3.10.4.3.1 Introduction

This section is dedicated to the description of the proposed Plumbing systems and the design criteria required for constructing the new facility which will comply with current Good Manufacturing Practice (cGMP) Standards.

3.10.4.3.2 Scope of Work

The Plumbing scope of work includes equipment layout and distribution of the following plumbing systems. See mechanical and process sections for all other utilities.

- Domestic Cold Water
- Domestic Hot Water
- Domestic Hot Water Recirculation
- Non-Potable Water
- Sanitary Waste and Vent

3.10.4.3.3 Fixtures and Equipment

All Plumbing fixtures will be selected in accordance with Water Conservation Codes and ADA Standards. Exposed fixtures and floor drains in the Manufacturing Areas will have a stainless-steel finish. Safety showers will be located throughout the building in potentially hazardous areas. The following fixtures will be a part of this Conceptual Engineering effort, but are subject to change based on owner review comments:

- Water closets and urinals will be wall mounted vitreous china elongated bowl, with manually operated flush valves for the water closets and hard-wired electric sensor operated flush valves for the urinals.
- Lavatories will be self-riming vitreous china, with hard wired electric sensor operated faucet.
- Janitor's Closets will have a floor mounted one-piece molded stone mop receptor with domestic hot and cold water.

- Sinks within graded spaces to support process procedures will be stainless steel with stainless steel faucets.
- Safety Showers/eyewashes will be provided at intervals per code and will be supplied from the domestic water system via a thermostatic mixing valve. Safety Showers will be free standing type.

3.10.4.3.4 Service Piping Design Guidelines

3.10.4.3.4.1 Water Service

The new CTMF building will require a new water service line. A 3" (102 GPM) line will be brought to the building's ground floor mechanical room from Rue Pare Street. It is assumed that city pressure will be adequate to supply water to the new building. However, this assumption shall be further examined in the next phase through the use of a city water test report. A booster pump will be provided if required, in the 1st floor mechanical room to ensure adequate water pressure is delivered to all fixtures.

A new water softener will be used in the first-floor mechanical room of CTMF to provide Non-potable water which shall be supplied to all Mechanical and Process equipment. A backflow preventer will be installed before any connection to equipment.

3.10.4.3.4.2 Domestic Hot Waters and Tepid Water

Domestic hot water will be generated by using an electric water heater which will be located in the first floor Mechanical Room. Hot water will be recirculated via redundant hot water return pumps located in the first floor Mechanical Room.

Domestic hot water will be generated at 140°F and will be blended with cold water via mixing valves at the domestic fixtures.

Tepid water will be supplied locally from thermostatic mixing valves adjacent to safety fixture. Domestic hot and cold water will feed the mixing valves. Tepid water will be delivered at the temperature set forth by the Owner’s safety department.

The type of safety shower/eyewash stations and their locations shall be set forth by the Owner’s Safety Department.

3.10.4.3.5 Drainage Design Guidelines

3.10.4.3.5.1 Sanitary Waste Drainage and Vent System

The current design assumption is that the new CTMF building's sanitary main will be connected to the existing building L3's sanitary main as there are no other sanitary connections nearby. This assumption will need to be confirmed during the DD phase.

CTMF's storm water drainage will be connected to a nearby storm water manhole. However, further invert information and site survey on the existing line is required to confirm this assumption during the DD phase.

Current estimations, based on building, size show that control flow roof drains can be utilized and a storm water retention tank will not be required. However, storm water retention design will be based on the site's storm water management report which has yet to be reviewed/provided. Storm water system design will need to be reviewed during the DD phase.

The design of process drainage/treatment systems will be explored in the next phase of the project.

3.10.4.4 Fire Protection

3.10.4.4.1 Introduction

This section is dedicated to the description of the proposed Fire Protection systems and the design criteria required in accordance with the Fire Code, requirements of local authorities having jurisdiction, governing NFPA standards, Factory Mutual (FM) and the Owner's Design Guidelines.

3.10.4.4.2 Scope of Work

This project will consist of modifications to the existing fire protection system and provisions of new fire protection systems as determined to be required.

A new fire service line will be required for the new CTMF building's fire protection service. A 6" take-off can be taken from the fire ring main that runs right beside the new CTMF. The fire line will enter the mechanical room in the first floor, go through a double check valve assembly and then be distributed to the building sprinklers. It is currently assumed that a fire pump will not be required as none of the other campus building utilize a fire pump. However, a city pressure and flowrate test will be required to confirm this assumption.

3.10.4.4.3 Fire Protection Design Guidelines

The complete fire protection system will be hydraulically sized using densities as set forth by Owner's insurance carrier and be installed in accordance with NFPA 13. Fire protection systems will be designed to maintain two levels of protection, underside of roof structure and ceilings of new rooms.

Maximum coverage per sprinkler head will be 225 square feet for light hazard and 130 square feet for ordinary hazard. Existing Hazardous storage areas to remain with the hazard classifications to be retained.

Sprinklers will be installed to include protection of the interstitial space above the first floor and below the Penthouse where walkable ceilings are installed as these areas will be viewed as occupied spaces.

Type and characteristics of sprinkler heads will be determined. Storage Areas will be sized based on commodity class.

Preliminary sprinkler head K-Factors will be as follows and are subject to change throughout the Detailed Design:

- Light and Ordinary Hazard:
  - K-Factor 8.0
- ESFR Sprinklers for Storage Areas:
  - K-Factors ranging from 11.2 to 16.8
- 2-8°C Cold Storage:
  - K-Factor 8.0

3.10.4.5 Civil

The existing fire ring main underneath Recommended Option will need to be relocated. The fire hydrant will probably be retained in the same location.

3.11 Validation Strategy

3.11.1 High Level Validation Strategy

This strategy is assuming that The Consulting Firm shall be retained to provide CQV services for NRC. The same strategy is followed to fully CQV the BMC facility on the other side of the complex.

The approach for the validation activities will include the CQV SMEs from the start of the project to ensure that quality requirements have been addressed into the concept, system and equipment.

A System-Level Impact Assessment (SLIA) will allow for appropriate effort to be concentrated on the critical systems and equipment. The SLIA will be executed at the early stages of the design activities and performed following ISPE risk-based methodology. The Project Validation Plan will be prepared based on the SLIA.

Whenever possible, Commissioning activities (FAT, SAT) will be leveraged into qualification, in order to avoid repeating tests and verifications. IQs, OQs and PQs will be performed when required, for critical systems and equipment.

3.11.2 System Qualification

- System Qualification will encompass:
  - Facility and controlled environments
  - Critical Utilities: WFI, PW, Medical gasses, etc.
  - Computerized Systems: SCADA, Historian, BAS, EMS, etc.
  - Upstream Process Equipment: Bioreactors, TFFs, etc.

- Downstream Process Equipment: washers, sterilizers, fillers, isolators, etc.
- Secondary Packaging equipment: labelers, palletizers, etc.
- Cleaning Validation
- Process Validation

4.0 CONCEPT OPTIONS

4.1 Recommended Option

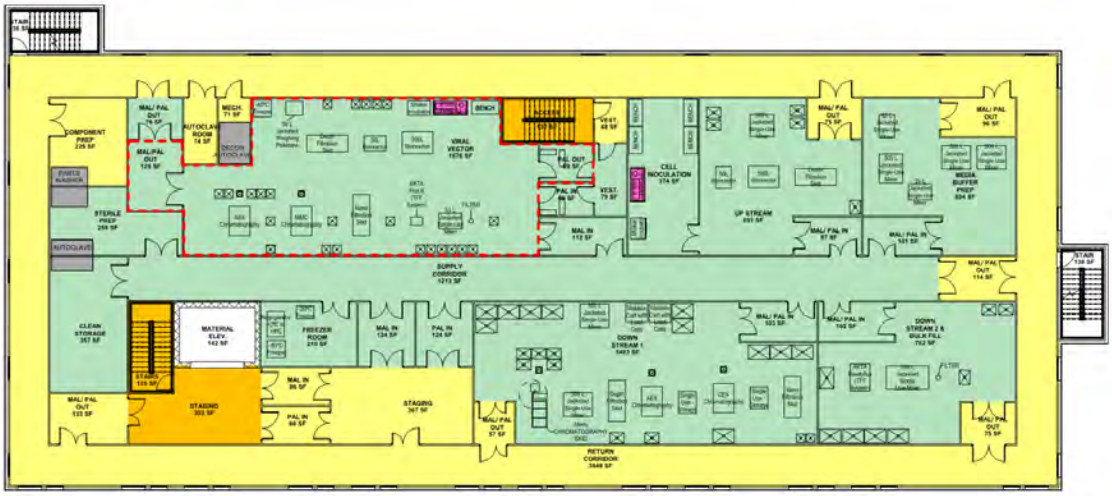

Figure 23 - Recommended Option Second Floor Classification Plan

4.1.1 Site Plan

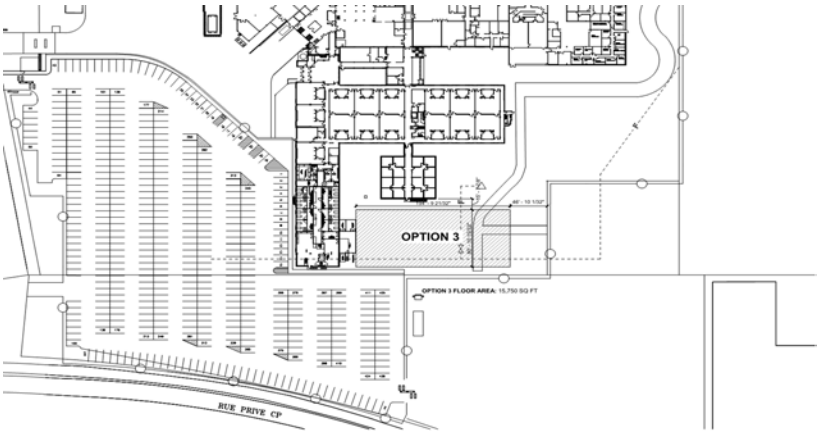

Figure 27 - Recommended Option Site Plan 1

4.1.2 Option Description

Recommended Option follows a similar design strategy to previous design iterations, with measures applied to conserve space and footprint, while keeping the integrity of the unidirectional flows. It consists of 2 working floors and a penthouse/interstitial level. Level 1 will be designed as the support floor and will consist of gowning rooms, restrooms, warehouse, QC labs, mechanical and electrical/IT rooms. Level 2 program was adjusted by allowing for 1 BSL2/CL2 level containment for the Viral Vectors suite only. Cell inoculation, upstream, downstream 1 and downstream 2 were designed to a

BSL1/CL1 Level containment standard. This has allowed for a downsize of the support spaces, eliminated the need for multiple access stairs, eliminate the need for multiple decontamination autoclaves and eliminate the separate locker rooms on the ground floor. Level 2 will also support a solution prep room, and a component prep area. This option is recommended as it offers a good level flexibility while maintaining the smallest foot print of 15,570 Sq. Ft. which will adhere to the existing site restrictions.

- Pros
  - Space and footprint are conserved
  - Good level of flexibility
  - Adheres to existing site restrictions
- Cons
  - Level 2 program was adjusted by allowing for 1 BSL2/CL2 level containment for viral vectors only
  - Does not match initial intent of URB as the design needed to be reduced in size and cost

5.0 SCHEDULE

5.1 Schedule Summary and Assumptions

- A schedule is attached in the appendix. Please see appendix 8.5.
- A summary of the schedule is as follows:
  - Conceptual study - March to April 2021
  - Detailed design (DD) - May to September 2021
  - Early construction work packages - May to September 2021
  - Procurement of long lead equipment - June 2021 to March 2022
  - Procurement of balance of equipment - July 2021 to March 2022
  - Construction - July 2021 to April 2022
  - Commissioning - March to July 2022
  - Qualification and validation (QV) - June to December 2022
  - Ready for production - December 2022
- Assumptions made are as follows:
  - The Consulting Firm shall proceed to DD right after concept study.
  - Permit shall be applied for but construction may proceed without permit.

6.0 CONCEPTUAL COST ESTIMATE (+25%/-15%)

The following table outline the cost estimate for recommended option at 4 levels (Schematic Option 1) and 3 levels (Schematic Option 2). The values are all in **Canadian dollars**.

A summary of the estimated costs is presented below, the variance of the ROM Estimate is +25%/-15%:

DESCRIPTION	4 LEVEL (SCHEMATIC OPTION 1)	3 LEVEL (SCHEMATIC OPTION 2)
E.01 - Site Conditions, Site Utilities, Demolition	$2,062,250	$2,018,750
E.02 - Building Shell Construction and Building Envelope	$9,634,625	$8,543,375
E.03 - Miscellaneous Structural Work	$638,750	$638,750
E.04 - Interior Fit Outs	$19,406,294	$18,164,419
E.05 - Facility Cost (E.01, E.02, E.03, E.04)	$31,741,919	$29,365,294
E.06 - Plant and Central Utilities	$2,866,375	$2,863,875
E.07 - Process Utilities	$3,363,011	$3,363,011
E.08 - Total Utilities Cost (E.06, E.07)	$6,229,386	$6,226,886
E.09A - Process Equipment and Installation	$11,771,129	$11,771,129
E.09B - Other Miscellaneous Items	$552,125	$552,125
E.10 - Total Process and Miscellaneous Items (E.09A, E.09B)	$12,323,254	$12,323,254
E.11 - Hard Costs (E.04, E.08, E.10)	$50,294,559	$47,915,434
E.12 - Soft Costs	$18,402,650	$17,530,005
E.13 - Grand Total	**$68,697,209**	**$65,445,440**

DESCRIPTION	4 LEVEL (SCHEMATIC OPTION 1)	3 LEVEL (SCHEMATIC OPTION 2)
Lower End Cost (-15%)	$58,392,628	$55,628,624
Higher End Cost (+25%)	$85,871,511	$81,806,799

7.0 TOPICS FOR DEVELOPMENT

7.1 Introduction

The following items are topics that shall be discussed and developed further during the next phase.

7.1.1 Electrical Feed

There are two options proposed to send power to CTMF. The first option is that CTMF will be fed directly from a new feed at Royalmount Avenue. The second option which would reduce trenching and cabling costs is that the BMC facility will receive a new feed from Royalmount Avenue and CTMF can tie-in to the existing Annex in the main building. More details are found in the Electrical Section 3.10.4.1.2.

7.1.2 Parking Options

The assumptions currently made are as follows:

- Pre-COVID - the NRC facility is at full parking capacity
- BMC is currently developing their own parking plan
- CTMF will need to develop a plan for parking before parking application during the next phase. This assessment requires an understanding on GFA, zoning bylaws, how this affects business requirements etc.

7.1.3 Schematic Sections Options

The Consulting Firm proposed two options for schematic sections. The Consulting Firm prefers Option 1 from a safety and operational point of view. However, option 1 will create a taller building and exceeds zoning which will require a variance. More details are found in the Architectural Section 3.10.1.

- Option 1 - Separate mechanical penthouse and interstitial space
- Option 2 - Mechanical penthouse and interstitial space are in the same level, AHU's shall be hung in underside of roof steel

7.1.4 Stormwater Retention/Piping

The Consulting Firm did not receive a stormwater retention report from NRC. The Consulting Firm assumes that there are piping underneath the parking lot which would need to be evaluated further during the next phase. Please see Plumbing Section 3.10.4.3.5.1 for more details.

8.0 APPENDICES

8.1 Process Section

- 21090 - Equipment List_B - Equipment List for mAbs and Viral Vectors
- 21090 - Equipment List_B_Labs - Equipment List for QC and Microbiology Labs
- mAb BFD - Block Flow Diagram (Rev C) - Block Flow Diagram - mAbs
- mAb PFD Rev B - Process Flow Diagram - mAbs
- Viral Vector BFD - Block Flow Diagram (Rev C) - Block Flow Diagram - Viral Vector
- VV PFD Rev B - Process Flow Diagram - Viral Vector
- 21090 - Process Definition mAbs
- 21090 - Process Definition Viral Vector

8.2 Automation Section

- 21090-DES-AIC-DIA-001 - Preliminary Manufacturing Network Architecture

8.3 Architectural and Process Architecture Section

- Room List with Classification and Areas
- ASK-007 - Classification Plan - First Floor - Recommended Option
- ASK-008 - Classification Plan - Second Floor - Recommended Option
- ASK-009 - Flow Plan - Second Floor - Recommended Option
- ASK-010 - Mechanical Penthouse Plan - Recommended Option
- ASK-011 - Site Plan - Recommended Option
- ASK-012 - Schematic Sections
- ASK-013 - Axonometric Views - First and Second Floor
- ASK-014 - Axonometric Views - Mechanical Penthouse
- CTMF Exterior Perspective 1 3D Rendering
- CTMF Exterior Perspective 2 3D Rendering
- CTMF Exterior Perspective 3 3D Rendering
- CTMF Overhead View 3D Rendering

8.4 Engineering Section

- Electrical Load Estimate
- E1.02 - Site Power Plan - Option 1

- E1.03 - Site Power Plan - Option 2
- E5.01 - Single Line Diagram
- M5.01 - HVAC Zoning Plan - First Floor
- M5.02 - HVAC Zoning Plan - Second Floor
- M5.10 - Pressurization Plan - First Floor
- M5.11 - Pressurization Plan - Second Floor

8.5 Schedule

- NRC CTMF Project Schedule

EQUIPMENT INFORMATION

REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	Area	ROOM	NEW / EXISTING	MFG.	MODEL NUMBER	SPECIFICATION NO.	BID PACKAGE NO.	DIMENSIONS	MAX Weight	FURNISHED BY	INSTALLED BY	FIXED OR PORTABLE
Cell Innoculation mAbs																	
B	-	PFD-102	BFD-101	-20°C Freezer	-20°C Manual Defrost Freezer	Freezer Room	2128	EXISTING	Fisher Scientific	TSX2320FA	-	-	711 mm W x 990 mm D x 1994 mm H	208 kg	-	-	-
B	-	PFD-102	BFD-101	-80°C Freezer - 1	-80°C Ultra-Low Freezer	Freezer Room	2128	EXISTING	Fisher Scientific	TSX60086A	-	-	1006 mm W x 955 mm D x 1981 mm H	358 kg	-	-	-
B	-	PFD-101 PFD-102	BFD-101	Regrigerator +2°C to +8°C	+2°C to +8°C High Perf. Lab Refrigerators	Freezer Room	2128	EXISTING	Fisher Scientific	TSX5005SA	-	-	1435 mm W x 962 mm D x 1994 mm H	282 kg	-	-	-
B	-	PFD-101 PFD-102	BFD-101	Biosafety Cabinet - 1	Class II, Type A2 6 ft Biological Safety Cabinet	Cell Innoculation	2115	EXISTING	Fisher Scientific	Model - 1377 Catalog - 13261223	-	-	1900 mm W x 800 mm D x 1568 mm H	280 kg (Cabinet) 30.0 kg (Stand)	-	-	-
B	-	PFD-101 PFD-102	BFD-101	Shaker Incubator	ISF1-Z-Shaker Incubator	Cell Innoculation	2115	NEW	Kuhner Shaker	SMZ1500	-	-	1288 mm W x 854 mm D x 771 mm H	200 kg	-	-	-
B	-	PFD-101 PFD-102	BFD-101	Cryogenic Tank	Cryogenic Tank - Cryoplus 3 340 L Load	Cell Innoculation	2115	NEW	Fisher Scientific	7404	-	-	876 mm W x 1054 mm D x 1041 mm H	249 kg (550 lbs)	-	-	-
USP mAbs																	
B	-	PFD-103	BFD-101	50 L Bioreactor	XDR50 GRAV Bioreactor RePurpos, TCU Included - Single Use	Up Stream	2116	EXISTING	Cytiva	Model - XDR50L Catalog - 29649820	-	-	1466 mm W x 1070 mm D x 2210 mm H Weight X-Station: 601 mm W x 797 mm D x 1466 mm H TCU: 483 mm W x 661 mm D x 775 mm H	468 kg (empty) X-Station: 146 kg TCU: 146 kg	-	-	-
B	-	PFD-103	BFD-101	100 L Storage Tote	100 L Storage Tote - Flex Station PN	Up Stream	2116	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-103	BFD-101	500 L Bioreactor	XDR500 Bioreator DP RePurpos, TCU Included - Single Use	Up Stream	2116	EXISTING	Cytiva	Model - XDR500L Catalog - 29653172	-	-	1466 mm W x 1070 mm D x 2210 mm H Weight X-Station: 601 mm W x 797 mm D x 1466 mm H TCU: 483 mm W x 661 mm D x 775 mm H	669 kg (empty) X-Station: 146 kg TCU: 146 kg	-	-	-
B	-	PFD-103	BFD-101	200 L Storage Tote - Base	200 L Storage Tote - Flex Station PN (Base)	Up Stream	2116	NEW	Meissner Filtration	FSB0200TD	-	-	609 mm W x 809 mm D x 833 mm H	20 kg (empty)	-	-	-
B	-	PFD-103	BFD-101	200 L Storage Tote - Media 1	200 L Storage Tote - Flex Station PN (Media 1)	Up Stream	2116	NEW	Meissner Filtration	FSB0200TD	-	-	609 mm W x 809 mm D x 833 mm H	20 kg (empty)	-	-	-
B	-	PFD-103	BFD-101	200 L Storage Tote - Media 2	200 L Storage Tote - Flex Station PN (Media 2)	Up Stream	2116	NEW	Meissner Filtration	FSB0200TD	-	-	609 mm W x 809 mm D x 833 mm H	20 kg (empty)	-	-	-
B	-	PFD-103	BFD-101	Depth Filtration Skid	Depth Filtration Skid - SartoClear Depth Filters	Up Stream	2116	NEW	Sartorius	2ZGL--0006	-	-	2300 mm W x 930 mm D x 910 mm H	50 kg	-	-	-
B	-	PFD-103	BFD-101	500 L Jacketed Single-Use Mixer - Clarified Broth	500 L Xcellerx XDM Single-Use Mixer - Clarified Broth	Up Stream	2116	NEW	Cytiva	29054862	-	-	1350 mm W x 1200 mm D x 1480 mm H (with I/O Panel)	315 kg (690 lbs)	-	-	-
B	-	PFD-103	BFD-101	Peristaltic Pump (50 L)	Peristaltic Pump	Up Stream	2116	NEW	Watson Marlow	TBD	-	-	TBD	TBD	-	-	-
B	-	PFD-103	BFD-101	Peristaltic Pump (200 L)	Peristaltic Pump	Up Stream	2116	NEW	Watson Marlow	TBD	-	-	TBD	TBD	-	-	-
DSP - 1 mAbs																	
B	-	PFD-104	BFD-102	Single-Use Chromatogrraphy - Affinity	AKTA Ready Gradient Chromatography System - Single Use (including Column Trolley) - Affinity	Down Stream 1	2135	EXISTING	Cytiva	29032038	-	-	1160 mm W x 800 mm D x 1650 mm H	250 kg	-	-	-
B	-	PFD-104	BFD-102	200 L Storage Tote - Equilibrate Buffer	200 L Storage Tote - Flex Station PN (Equilbrate Buffer)	Down Stream 1	2135	NEW	Meissner Filtration	FSB0200TD	-	-	609 mm W x 809 mm D x 833 mm H	20 kg (empty)	-	-	-
B	-	PFD-104	BFD-102	500 L Storage Tote - Wash Buffer	500 L Storage Tote - Flex Station PN (Wash Buffer)	Down Stream 1	2135	NEW	Meissner Filtration	FSB0500TD	-	-	915 mm W x 1200 mm D x 1260 mm H	70 kg (empty)	-	-	-
B	-	PFD-104	BFD-102	500 L Storage Tote - Regenerate Buffer	500 L Storage Tote - Flex Station PN (Regenerate Buffer)	Down Stream 1	2135	NEW	Meissner Filtration	FSB0500TD	-	-	915 mm W x 1200 mm D x 1260 mm H	70 kg (empty)	-	-	-
B	-	PFD-104	BFD-102	500 L Storage Tote - Eluate Buffer	500 L Storage Tote - Flex Station PN (Eluate Buffer)	Down Stream 1	2135	NEW	Meissner Filtration	FSB0500TD	-	-	915 mm W x 1200 mm D x 1260 mm H	70 kg (empty)	-	-	-
B	-	PFD-104	BFD-102	200 L Storage Tote - Storage Buffer	200 L Storage Tote - Flex Station PN (Storage Buffer)	Down Stream 1	2135	NEW	Meissner Filtration	FSB0200TD	-	-	609 mm W x 809 mm D x 833 mm H	20 kg (empty)	-	-	-
B	-	PFD-104	BFD-102	1000 L Storage Tote - WFI	1000 L Storage Tote - Flex Station PN (WFI)	Down Stream 1	2135	EXISTING	Meissner Filtration	Model - Flex Station 'IND331' FSB1000TD	-	-	1000 mm W x 1200 mm L x 1260 mm H	125 kg (empty)	-	-	-
B	-	PFD-104	BFD-102	1000 L Storage Mobile Cart with load cells.	1000 L Storage Tote - Flex Station Mobile Cart	Down Stream 1	2135	EXISTING	Meissner Filtration	FSC11A-LC	-	-	1031 mm W x 1229 mm L x 185 mm H	34 kg	-	-	-
B	-	PFD-104	BFD-102	200 L Jacketed Single-Use Mixer	200 L Xcellerx XDM Single-Use Mixer	Down Stream 1	2135	NEW	Cytiva	29054862	-	-	1140 mm W x 1000 mm D x 1120 mm H (with I/O Panel)	200 kg (440 lbs)	-	-	-
B	-	PFD-104	BFD-102	100 L Storage Tote - Acid	100 L Storage Tote - Flex Station PN (Acid)	Down Stream 1	2135	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-104	BFD-102	Depth Filtration Skid	Depth Filtration Skid - SartoClear Depth Filters	Down Stream 1	2135	NEW	Sartorius	2ZGL--0006	-	-	2300 mm W x 930 mm D x 910 mm H	50 kg	-	-	-
B	-	PFD-104	BFD-102	Peristaltic Pump (200 L)	Peristaltic Pump	Down Stream 1	2135	NEW	Watson Marlow	TBD	-	-	TBD	TBD	-	-	-
B	-	PFD-104	BFD-102	200 L Jacketed Single-Use Mixer	200 L Xcellerx XDM Single-Use Mixer	Down Stream 1	2135	NEW	Cytiva	29054862	-	-	1140 mm W x 1000 mm D x 1120 mm H (with I/O Panel)	200 kg (440 lbs)	-	-	-
B	-	PFD-104	BFD-102	100 L Storage Tote - Base	100 L Storage Tote - Flex Station PN (Base)	Down Stream 1	2135	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-105	BFD-102	Single Use - Storage	Flex Station PN - 1000 L	Down Stream 1	2135	NEW	Meissner Filtration	Model - Flex Station 'IND331' FSB1000TD	-	-	1000 mm W x 1200 mm L x 1260 mm H	125 kg (empty)	-	-	-
B	-	PFD-105	BFD-102	Mobile Cart with load cells.	Flex Station Mobile Cart - 1000 L	Down Stream 1	2135	NEW	Meissner Filtration	FSC11A-LC	-	-	1031 mm W x 1229 mm L x 185 mm H	34 kg	-	-	-
B	-	PFD-105	BFD-102	Single-Use Chromatogrraphy - AEX	AKTA Ready Gradient Chromatography System - Single Use (including Column Trolley) - AEX	Down Stream 1	2135	EXISTING	Cytiva	29032038	-	-	1160 mm W x 1650 mm D x 800 mm H	250 kg	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote - Equilibrate Buffer	200 L Storage Tote - Flex Station PN (Equilbrate Buffer)	Down Stream 1	2135	NEW	Meissner Filtration	FSB0200TD	-	-	609 mm W x 809 mm D x 833 mm H	20 kg (empty)	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote - Wash Buffer	500 L Storage Tote - Flex Station PN (Wash Buffer)	Down Stream 1	2135	NEW	Meissner Filtration	FSB0500TD	-	-	915 mm W x 1200 mm D x 1260 mm H	70 kg (empty)	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote - Regenerate Buffer	500 L Storage Tote - Flex Station PN (Regenerate Buffer)	Down Stream 1	2135	NEW	Meissner Filtration	FSB0500TD	-	-	915 mm W x 1200 mm D x 1260 mm H	70 kg (empty)	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote - Eluate Buffer	500 L Storage Tote - Flex Station PN (Eluate Buffer)	Down Stream 1	2135	NEW	Meissner Filtration	FSB0500TD	-	-	915 mm W x 1200 mm D x 1260 mm H	70 kg (empty)	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote - Storage Buffer	200 L Storage Tote - Flex Station PN (Storage Buffer)	Down Stream 1	2135	NEW	Meissner Filtration	FSB0200TD	-	-	609 mm W x 809 mm D x 833 mm H	20 kg (empty)	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote - AWFI	200 L Storage Tote - Flex Station PN (Storage Buffer)	Down Stream 1	2135	NEW	Meissner Filtration	FSB0200TD	-	-	609 mm W x 809 mm D x 833 mm H	20 kg (empty)	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote	200 L Storage Tote - Flex Station PN	Down Stream 1	2135	NEW	Meissner Filtration	FSB0200TD	-	-	609 mm W x 809 mm D x 833 mm H	20 kg (empty)	-	-	-
B	-	PFD-105	BFD-102	Single-Use Chromatography- MMC / CEX	AKTA Ready Gradient Chromatography System - Single Use (including Column Trolley) - MMC / CEX	Down Stream 1	2135	NEW	Cytiva	29032038	-	-	1160 mm W x 1650 mm D x 800 mm H	250 kg	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote - Equilibrate Buffer	200 L Storage Tote - Flex Station PN (Equilbrate Buffer)	Down Stream 1	2135	NEW	Meissner Filtration	FSB0200TD	-	-	609 mm W x 809 mm D x 833 mm H	20 kg (empty)	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote - Wash Buffer	500 L Storage Tote - Flex Station PN (Wash Buffer)	Down Stream 1	2135	NEW	Meissner Filtration		-	-	915 mm W x 1200 mm D x 1260 mm H	70 kg (empty)	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote - Regenerate Buffer	500 L Storage Tote - Flex Station PN (Regenerate Buffer)	Down Stream 1	2135	NEW	Meissner Filtration	FSB0500TD	-	-	915 mm W x 1200 mm D x 1260 mm H	70 kg (empty)	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote - Eluate Buffer	500 L Storage Tote - Flex Station PN (Eluate Buffer)	Down Stream 1	2135	NEW	Meissner Filtration	FSB0500TD	-	-	915 mm W x 1200 mm D x 1260 mm H	70 kg (empty)	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote - Storage Buffer	200 L Storage Tote - Flex Station PN (Storage Buffer)	Down Stream 1	2135	NEW	Meissner Filtration	FSB0200TD	-	-	609 mm W x 809 mm D x 833 mm H	20 kg (empty)	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote - AWFI	200 L Storage Tote - Flex Station PN (Storage Buffer)	Down Stream 1	2135	NEW	Meissner Filtration	FSB0200TD	-	-	609 mm W x 809 mm D x 833 mm H	20 kg (empty)	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote - Eluate Buffer	200 L Storage Tote - Flex Station PN Eluate Buffer	Down Stream 1	2135	NEW	Meissner Filtration	FSB0200TD	-	-	609 mm W x 809 mm D x 833 mm H	20 kg (empty)	-	-	-
B	-	PFD-105	BFD-102	Peristaltic Pump (200 L)	Peristaltic Pump	Up Stream	2116	NEW	Watson Marlow	TBD	-	-	TBD	TBD	-	-	-
B	-	PFD-105	BFD-102	Nano Filter	Nano Filter	Down Stream 1	2135	NEW	Millipore	TBD	-	-	TBD	TBD	-	-	-
DSP - 2 mAbs																	
B	-	PFD-106	BFD-103	200 L Storage Tote - Filtrate	200 L Storage Tote - Flex Station PN (Filtrate)	Down Stream 2 & Bulk Fill	2139	NEW	Meissner Filtration	FSB0200TD	-	-	609 mm W x 809 mm D x 833 mm H	20 kg (empty)	-	-	-
B	-	PFD-106	BFD-103	AKTA Readyflux	Tangential Flow Filtration System - Single Use	Down Stream 2 & Bulk Fill	2139	EXISTING	Cytiva	29151000	-	-	1100 mm W x 880 mm D x 1520 mm H	280 kg	-	-	-
B	-	PFD-106	BFD-103	500 L Storage Tote - Wash Buffer	500 L Storage Tote - Flex Station PN (Wash Buffer)	Down Stream 2 & Bulk Fill	2139	NEW	Meissner Filtration	FSB0500TD	-	-	915 mm W x 1200 mm D x 1260 mm H	70 kg (empty)	-	-	-
B	-	PFD-106	BFD-103	200 L Storage Tote - Condition Buffer	200 L Storage Tote - Flex Station PN (Condition Buffer)	Down Stream 2 & Bulk Fill	2139	NEW	Meissner Filtration	FSB0200TD	-	-	609 mm W x 809 mm D x 833 mm H	20 kg (empty)	-	-	-
B	-	PFD-106	BFD-103	500 L Storage Tote - Diafilter Buffer	500 L Storage Tote - Flex Station PN (Diafilter Buffer)	Down Stream 2 & Bulk Fill	2139	NEW	Meissner Filtration	FSB0500TD	-	-	915 mm W x 1200 mm D x 1260 mm H	70 kg (empty)	-	-	-
B	-	PFD-106	BFD-103	200 L Storage Tote - Storage Buffer	200 L Storage Tote - Flex Station PN (Storage Buffer)	Down Stream 2 & Bulk Fill	2139	NEW	Meissner Filtration	FSB0200TD	-	-	609 mm W x 809 mm D x 833 mm H	20 kg (empty)	-	-	-
B	-	PFD-106	BFD-103	500 L Storage Tote - Caustic	500 L Storage Tote - Flex Station PN (Caustic)	Down Stream 2 & Bulk Fill	2139	NEW	Meissner Filtration	FSB0500TD	-	-	915 mm W x 1200 mm D x 1260 mm H	70 kg (empty)	-	-	-
B	-	PFD-106	BFD-103	500 L Storage Tote - AWFI	500 L Storage Tote - Flex Station PN (AWFI)	Down Stream 2 & Bulk Fill	2139	NEW	Meissner Filtration	FSB0500TD	-	-	915 mm W x 1200 mm D x 1260 mm H	70 kg (empty)	-	-	-
B	-	PFD-106	BFD-103	200 L Jacketed Single-Use Mixer	200 L Xcellerx XDM Single-Use Mixer - Concentration Adjustment	Down Stream 2 & Bulk Fill	2139	NEW	Cytiva	29054862	-	-	1140 mm W x 1000 mm D x 1120 mm H (with I/O Panel)	200 kg (440 lbs)	-	-	-
B	-	PFD-106	BFD-103	200 L Storage Tote - AWFI	200 L Storage Tote - Flex Station PN (AWFI)	Down Stream 2 & Bulk Fill	2139	NEW	Meissner Filtration	FSB0500TD	-	-	915 mm W x 1200 mm D x 1260 mm H	70 kg (empty)	-	-	-
B	-	PFD-107	BFD-103	0.2 Micron Filter	0.2 Micron Filter	Down Stream 2 & Bulk Fill	2139	NEW	Pall	TBD	-	-	TBD	TBD	-	-	-
B	-	PFD-107	BFD-103	Peristaltic Pump (200 L)	Peristaltic Pump	Down Stream 2 & Bulk Fill	2139	NEW	Watson Marlow	TBD	-	-	TBD	TBD	-	-	-

PROCESS UTILITIES

EQUIPMENT NAME	HOT WFI HWFI LPM	HWFI PSIG	PURIFIED WATER PW LPM	PW PSIG	CIP LPM	CIP PSIG	CLEAN STEAM CS kg/h	CS PSIG	CLEAN STEAM CONDENSATE CSC kg/h	CSC PSIG	NITROGEN N_2 SCFM	N_2 CFM	N_2 PSIG	OXYGEN O_2 SCFM	O_2 CFM	O_2 PSIG	CABRON DIOXIDE CO_2 SCFM	CO_2 CFM	CO_2 PSIG	PROCESS AIR CCA SCFM	CCA CFM	CCA PSIG	INSTRUMENT AIR IA SCFM	IA CFM	IA PSIG	HEAT XFER FLUID (S/R) GPM	(S/R) PSIG
Cell Innoculation mAbs																											
-20°C Freezer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
-80°C Freezer - 1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Regrigerator +2°C to +8°C	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Biosafety Cabinet - 1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Shaker Incubator	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	8.9	-	29 max	-	-	-	-	-	-	-	-
Cryogenic Tank	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
USP mAbs																											
50 L Bioreactor	-	-	-	-	-	-	-	-	-	-	-	-	-	11.96	-	44	11.96	-	44	11.96	-	44	11.96	-	44	-	-
100 L Storage Tote	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Bioreactor	-	-	-	-	-	-	-	-	-	-	-	-	-	11.96	-	44	11.96	-	44	11.96	-	44	11.96	-	44	-	-
200 L Storage Tote - Base	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Media 1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Media 2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Depth Filtration Skid	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Jacketed Single-Use Mixer - Clarified Broth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Peristaltic Pump (50 L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Peristaltic Pump (200 L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DSP - 1 mAbs																											
Single-Use Chromatogrraphy - Affinity	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1.77	79.8 - 101.5	-	-
200 L Storage Tote - Equilibrate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Wash Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Regenerate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Storage Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
1000 L Storage Tote - WFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
1000 L Storage Mobile Cart with load cells.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Jacketed Single-Use Mixer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Acid	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Depth Filtration Skid	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Peristaltic Pump (200 L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Jacketed Single-Use Mixer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Base	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Single Use - Storage	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Mobile Cart with load cells.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Single-Use Chromatogrraphy - AEX	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1.77	79.8 - 101.5	-	-
200 L Storage Tote - Equilibrate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Wash Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Regenerate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Storage Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Single-Use Chromatography- MMC / CEX	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1.77	79.8 - 101.5	-	-
200 L Storage Tote - Equilibrate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Wash Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Regenerate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Storage Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Peristaltic Pump (200 L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Nano Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DSP - 2 mAbs																											
200 L Storage Tote - Filtrate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
AKTA Readyflux	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1.77	79.8 - 101.5	-	-
500 L Storage Tote - Wash Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Condition Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Diafilter Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Storage Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Caustic	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Jacketed Single-Use Mixer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
0.2 Micron Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Peristaltic Pump (200 L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

PLANT UTILITES

EQUIPMENT NAME	PLANT STEAM PS kg/h	PS PSIG	PLANT STEAM CONDENSATE kg/h	CONDENSATE PSIG	DOMESTIC COLD WATER (T=60°F) CW LPM	CW PSIG	PROCESS CHILLED WATER PCHWS/R LPM	PCHWS/R PSIG	RELIEF VENT PV SCFM	PV CFM	PV PSIG	INTAKE AIR SCFM	EXHAUST SCFM	EXHAUST CFM	EXHAUST PSIG	SANITARY SEWER SAN LPM	SAN PSIG	PROCESS WASTE PW LPM	PW PSIG	BIOWASTE BIOD LPM	BIOD PSIG	HEAT LOAD kW
Cell Innoculation mAbs																						
-20°C Freezer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
-80°C Freezer - 1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Regrigerator +2°C to +8°C	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Biosafety Cabinet - 1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Shaker Incubator	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Cryogenic Tank	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
USP mAbs																						
50 L Bioreactor	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Bioreactor	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Base	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Media 1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Media 2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Depth Filtration Skid	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Jacketed Single-Use Mixer - Clarified Broth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Peristaltic Pump (50 L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Peristaltic Pump (200 L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DSP - 1 mAbs																						
Single-Use Chromatogrraphy - Affinity	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Equilibrate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Wash Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Regenerate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Storage Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
1000 L Storage Tote - WFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
1000 L Storage Mobile Cart with load cells.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Jacketed Single-Use Mixer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Acid	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Depth Filtration Skid	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Peristaltic Pump (200 L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Jacketed Single-Use Mixer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Base	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Single Use - Storage	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Mobile Cart with load cells.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Single-Use Chromatogrraphy - AEX	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Equilibrate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Wash Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Regenerate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Storage Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Single-Use Chromatography- MMC / CEX	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Equilibrate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Wash Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Regenerate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Storage Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Peristaltic Pump (200 L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Nano Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DSP - 2 mAbs																						
200 L Storage Tote - Filtrate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
AKTA Readyflux	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Wash Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Condition Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Diafilter Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - Storage Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - Caustic	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Jacketed Single-Use Mixer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
200 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
0.2 Micron Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Peristaltic Pump (200 L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

AUTOMATION / ELECTRICAL / COST

EQUIPMENT NAME	CONTROL (OEM, PCS, BAS, N/A)	QUANTITY	BMS or SCADA	ELECTRICAL DESCRIPTION	HP	VOLTAGE	PHASE	AMPS	KVA	FIELD CONNECTION	CLASS OF POWER	BACK-UP POWER / UPS	DATA INTEGRATION (PCS, MES, BAS, EMS, N/A)	UNIT COST	QUANTITY	INSTALLATION FACTOR	ESTIMATED TOTAL COST	LEAD TIME (WEEKS ARO)	ESTIMATION SOURCE	NOTES
Cell Innoculation mAbs																				
-20°C Freezer	-	-	-	-	-	115 @ 60 Hz	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$8,069	4-6	Vendor	
-80°C Freezer - 1	-	-	-	-	-	115 @ 60 Hz	-	9.5	-	-	-	BACK-UP POWER	-	-	-	-	$23,190	4-6	Vendor	
Regrigerator +2°C to +8°C	-	-	-	-	-	115 @ 60 Hz	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$10,293	4-6	Vendor	
Biosafety Cabinet - 1	-	-	-	-	-	120 @ 60 Hz	-	-	-	-	-	UPS	-	-	-	-	$17,500	18-24	Vendor	Updated Utility Requirements
Shaker Incubator	-	-	-	-	-	120 @ 60 Hz	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$29,700	13-17	Vendor	Updated Model and Utility Requirements
Cryogenic Tank	-	-	-	-	-	115 @ 60 Hz	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$20,000	25-29	Vendor	Added
USP mAbs																				
50 L Bioreactor	-	-	-		-	110 ± 10% @ 60Hz TCU: 460 V @ 60 Hz	1 3	14 18	-	-	-	Back-Up + UPS: X-Station: 110 ± 10% @ 60Hz 1 Ph, 2.9A	-	-	-	-	$270,000	20-24	Vendor	Updated Utility requirements, dimensions and weight. These do NOT include TCY requirements. Price is base unit price. Total with TCU, SAT, Commissioning, IQOQ, etc. is 368,000. No results when looking for this specific catalog number.
100 L Storage Tote	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$8,000	18-22	HISTORY - Consultant estimate	Added
500 L Bioreactor	-	-	-	-	-	110 ± 10% @ 60Hz TCU: 460 V @ 60 Hz	1 3	14 18	-	-	-	Back-Up + UPS: X-Station: 110 ± 10% @ 60Hz 1 Ph, 2.9A	-	-	-	-	$460,000	20-24	Vendor	Updated Utility requirements, dimensions and weight. These do NOT include TCY requirements. Price is base unit price. Total with TCU, SAT, Commissioning, IQOQ, etc. is 565,000. No results when looking for this specific catalog number.
200 L Storage Tote - Base	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant estimate	Updated volume, model, dimensions, etc.
200 L Storage Tote - Media 1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY -	Updated volume, model, dimensions, etc.
200 L Storage Tote - Media 2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
Depth Filtration Skid	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$42,000	14-16	Vendor	
500 L Jacketed Single-Use Mixer - Clarified Broth	-	-	-	-	-	120 @ 60 Hz	3	4.5A (Max)	-	-	-	BACK-UP POWER	-	-	-	-	$155,000	14-16	Vendor	Updated volume, model, dimensions, utility requirements, etc. Total Cost including Kits, SAT, Commissioning, IQOQ, etc. is $245,000.
Peristaltic Pump (50 L)	-	-	-	-	-	TBD	TBD	-	-	-	-	BACK-UP POWER	-	-	-	-	$10,500	-	HISTORY - Consultant Estimate	
Peristaltic Pump (200 L)	-	-	-	-	-	TBD	TBD	-	-	-	-	BACK-UP POWER	-	-	-	-	$10,500	-	HISTORY - Consultant Estimate	
DSP - 1 mAbs																				
Single-Use Chromatogrraphy - Affinity	-	-	-	-	-	100, 120, 200-208, 220-230 or 240 ± 10% @ 60Hz	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$213,500	4-6	Vendor	Added - Details to equipment name and description Updated utility requirements
200 L Storage Tote - Equilibrate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
500 L Storage Tote - Wash Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
500 L Storage Tote - Regenerate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
500 L Storage Tote - Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
200 L Storage Tote - Storage Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Added Details to equipment name
1000 L Storage Tote - WFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	No results when looking for this specific catalog number. Used the model number 'FSB1000TD' as basis. Moved from UPS mAbs and updated name and description
1000 L Storage Mobile Cart with load cells.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Accessory to the above unit Moved from UPS mAbs and updated name and description.
200 L Jacketed Single-Use Mixer	-	-	-	-	-	120 @ 60 Hz	3	4.5A (Max)	-	-	-	BACK-UP POWER	-	-	-	-	$145,400	14-16	Vendor	Updated volume, model, dimensions, utility requirements, etc. Total Cost including Kits, SAT, Commissioning, IQOQ, etc. is $245,000.
100 L Storage Tote - Acid	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$8,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
Depth Filtration Skid	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$42,000	14-16	Vendor	
Peristaltic Pump (200 L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$10,500	-	HISTORY - Consultant Estimate	Added
200 L Jacketed Single-Use Mixer	-	-	-	-	-	120 @ 60 Hz	3	4.5A (Max)	-	-	-	BACK-UP POWER	-	-	-	-	$145,400	14-16	Vendor	Updated volume, model, dimensions, utility requirements, etc. Total Cost including Kits, SAT, Commissioning, IQOQ, etc. is $245,000.
100 L Storage Tote - Base	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$8,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
Single Use - Storage	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	No results when looking for this specific catalog number. Used the model number 'FSB1000TD' as basis. Added
Mobile Cart with load cells.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		Accessory to the above unit. Added
Single-Use Chromatogrraphy - AEX	-	-	-	-	-	100, 120, 200-208, 220-230 or 240 ± 10% @ 60Hz	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$213,500	4-6	Vendor	Added Details to equipment name and description
200 L Storage Tote - Equilibrate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
500 L Storage Tote - Wash Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
500 L Storage Tote - Regenerate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
500 L Storage Tote - Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
200 L Storage Tote - Storage Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Added Details to equipment name
200 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Added Details to equipment name
200 L Storage Tote	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Added
Single-Use Chromatography- MMC / CEX	-	-	-	-	-	100, 120, 200-208, 220-230 or 240 ± 10% @ 60Hz	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$213,500	4-6	Vendor	Updated model, equipment name and description
200 L Storage Tote - Equilibrate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
500 L Storage Tote - Wash Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
500 L Storage Tote - Regenerate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
500 L Storage Tote - Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
200 L Storage Tote - Storage Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Added Details to equipment name
200 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Added Details to equipment name
200 L Storage Tote - Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$8,000	18-22	HISTORY - Consultant Estimate	Added
Peristaltic Pump (200 L)	-	-	-	-	-	TBD	TBD	-	-	-	-	BACK-UP POWER	-	-	-	-	$10,500	-	HISTORY - Consultant Estimate	
Nano Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	TBD	TBD	TBD	
DSP - 2 mAbs																				
200 L Storage Tote - Filtrate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated Model, equipment name and description
AKTA Readyflux	-	-	-	-	-	100-240 @60Hz	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$238,000	14-18	Vendor	Updated Utility Requirements, Cost Cost is base. Including Commissioning, etc. Total is $361,000. Included Optional Items are included in quote.
500 L Storage Tote - Wash Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
200 L Storage Tote - Condition Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
500 L Storage Tote - Diafilter Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
200 L Storage Tote - Storage Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
500 L Storage Tote - Caustic	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
500 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
200 L Jacketed Single-Use Mixer	-	-	-	-	-	120 @ 60 Hz	1	4.5A (Max)	-	-	-	BACK-UP POWER	-	-	-	-	$145,400	14-16	Vendor	Updated volume, model, dimensions, utility requirements, etc. Total Cost including Kits, SAT, Commissioning, IQOQ, etc. is $216,700.
200 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
0.2 Micron Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	HISTORY - Consultant Estimate	
Peristaltic Pump (200 L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$10,500	-	HISTORY - Consultant Estimate	

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EQUIPMENT INFORMATION

REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	Area	ROOM	NEW / EXISTING	MFG.	MODEL NUMBER	SPECIFICATION NO.	BID PACKAGE NO.	DIMENSIONS	MAX Weight	FURNISHED BY	INSTALLED BY	FIXED OR PORTABLE
VV																	
B	-	PFD-201 PFD-202	BFD-201	-80°C Freezer - 2	-80°C Ultra-Low Freezer	Viral Vector	2108	EXISTING	Fisher Scientific	TSX60086A	-	-	1006 mm W x 955 mm D x 1981 mm H	358 kg	-	-	-
B	-	PFD-201 PFD-202	BFD-201	Biosafety Cabinet	Class II, Type A2 6 ft Biological Safety Cabinet	Viral Vector	2108	EXISTING	Fisher Scientific	Model - 1377 Catalog - 13261223	-	-	1900 mm W x 800 mm D x 1568 mm H	280 kg (Cabinet) 30.0 kg (Stand)	-	-	-
B	-	PFD-201 PFD-202	BFD-201	Cryogenic Tank	Cryogenic Tank - Cryoplus 3 340 L Load	Viral Vector	2108	NEW	Fisher Scientific	7404	-	-	876 mm W x 1054 mm D x 1041 mm H	249 kg (550 lbs)	-	-	-
B	-	PFD-201 PFD-202	BFD-201	Shaker Incubator	ISF1-Z-Shaker Incubator	Viral Vector	2108	NEW	Kuhner Shaker	SMZ1500	-	-	1288 mm W x 854 mm D x 771 mm H	200 kg	-	-	-
B	-	PFD-203	BFD-201	50 L Bioreactor	XDR50 GRAV Bioreactor RePurpos, TCU Included - Single Use	Viral Vector	2108	NEW	Cytiva	Model - XDR50L Catalog - 29649820	-	-	1466 mm W x 1070 mm D x 2210 mm H Weight X-Station: 601 mm W x 797 mm D x 1466 mm H TCU: 483 mm W x 661 mm D x 775 mm H	468 kg (empty) X-Station: 146 kg TCU: 146 kg	-	-	-
B	-	PFD-203	BFD-201	100 L Storage Tote	100 L Storage Tote - Flex Station PN	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-203	BFD-201	100 L Storage Tote - Media 1	100 L Storage Tote - Flex Station PN (Media 1)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-203	BFD-201	100 L Storage Tote - Media 2	100 L Storage Tote - Flex Station PN (Media 2)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-203	BFD-201	100 L Storage Tote - Base	100 L Storage Tote - Flex Station PN (Base)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-203	BFD-101	Depth Filtration Skid	Depth Filtration Skid - SartoClear Depth Filters	Viral Vector	2108	NEW	Sartorius	2ZGL--0006	-	-	2300 mm W x 930 mm D x 910 mm H	50 kg	-	-	-
B	-	PFD-203	BFD-201	50 L Jacketed Single-Use Mixer - Clarified Broth	50 L Xcellerx XDM Single-Use Mixer - Clarified Broth	Viral Vector	2108	NEW	Cytiva	29054862	-	-	740 mm W x 530 mm D x 1090 mm H	85 kg	-	-	-
B	-	PFD-203	BFD-201	Peristaltic Pump (50 L)	Peristaltic Pump	Viral Vector	2108	NEW	Watson Marlow	TBD	-	-	TBD	TBD	-	-	-
B	-	PFD-203	BFD-201	Peristaltic Pump (200 L)	Peristaltic Pump	Viral Vector	2108	NEW	Watson Marlow	TBD	-	-	TBD	TBD	-	-	-
B	-	PFD-204	BFD-202	Single-Use Chromatography- AEX	AKTA Ready Gradient Chromatography System - Single Use (including Column Trolley) - AEX	Viral Vector	2108	NEW	Cytiva	29032038	-	-	1160 mm W x 1650 mm D x 800 mm H	250 kg	-	-	-
B	-	PFD-204	BFD-202	100 L Storage Tote - Equilibrate Buffer	100 L Storage Tote - Flex Station PN (Equilbrate Buffer)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-204	BFD-202	100 L Storage Tote - Wash Buffer	100 L Storage Tote - Flex Station PN (Wash Buffer)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-204	BFD-202	100 L Storage Tote - Regenerate Buffer	100 L Storage Tote - Flex Station PN (Regenerate Buffer)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-204	BFD-202	100 L Storage Tote - Eluate Buffer	100 L Storage Tote - Flex Station PN (Eluate Buffer)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-204	BFD-202	100 L Storage Tote - Storage Buffer	100 L Storage Tote - Flex Station PN (Storage Buffer)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-204	BFD-202	100 L Storage Tote - AWFI	100 L Storage Tote - Flex Station PN (AWFI)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-204	BFD-202	100 L Storage Tote	100 L Storage Tote - Flex Station PN	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-204	BFD-202	Single-Use Chromatography- MMC	AKTA Ready Gradient Chromatography System - Single Use (including Column Trolley) - MMC	Viral Vector	2108	NEW	Cytiva	29032038	-	-	1160 mm W x 1650 mm D x 800 mm H	250 kg	-	-	-
B	-	PFD-204	BFD-202	100 L Storage Tote - Equilibrate Buffer	100 L Storage Tote - Flex Station PN (Equilbrate Buffer)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-204	BFD-202	100 L Storage Tote - Wash Buffer	100 L Storage Tote - Flex Station PN (Wash Buffer)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-204	BFD-202	100 L Storage Tote - Regenerate Buffer	100 L Storage Tote - Flex Station PN (Regenerate Buffer)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-204	BFD-202	100 L Storage Tote - Eluate Buffer	100 L Storage Tote - Flex Station PN (Eluate Buffer)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-204	BFD-202	100 L Storage Tote - Storage Buffer	100 L Storage Tote - Flex Station PN (Storage Buffer)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-204	BFD-202	100 L Storage Tote - AWFI	100 L Storage Tote - Flex Station PN (AWFI)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-205	BFD-202	Peristaltic Pump (200 L)	Peristaltic Pump	Up Stream	2116	NEW	Watson Marlow	TBD	-	-	TBD	TBD	-	-	-
B	-	PFD-205	BFD-202	Nano Filter	Nano Filter	Down Stream 1	2135	NEW	Millipore	TBD	-	-	TBD	TBD	-	-	-
B	-	PFD-205	BFD-202	100 L Storage Tote - Filtrate	100 L Storage Tote - Flex Station PN (Filtrate)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-205	BFD-202	AKTA Flux 6 (TFF System)	Flux Tangential Flow Filtration System - Single Use	Viral Vector	2108	EXISTING	Cytiva	29-0384-38	-	-	640 mm W x 470 mm L x 720 mm H	53 kg	-	-	-
B	-	PFD-205	BFD-202	100 L Storage Tote - Wash Buffer	100 L Storage Tote - Flex Station PN (Wash Buffer)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-205	BFD-202	100 L Storage Tote - Condition Buffer	100 L Storage Tote - Flex Station PN (Condition Buffer)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-205	BFD-202	100 L Storage Tote - Diafilter Buffer	100 L Storage Tote - Flex Station PN (Diafilter Buffer)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-205	BFD-202	100 L Storage Tote - Storage Buffer	100 L Storage Tote - Flex Station PN (Storage Buffer)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-205	BFD-202	100 L Storage Tote - Caustic	100 L Storage Tote - Flex Station PN (Caustic)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-205	BFD-202	100 L Storage Tote - AWFI	100 L Storage Tote - Flex Station PN (AWFI)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-205	BFD-202	50 L Jacketed Single-Use Mixer	50 L Xcellerx XDM Single-Use Mixer - Concentration Adjustment	Viral Vector	2108	NEW	Cytiva	29054862	-	-	740 mm W x 530 mm D x 1090 mm H	85 kg	-	-	-
B	-	PFD-205	BFD-202	100 L Storage Tote - AWFI	100 L Storage Tote - Flex Station PN (AWFI)	Viral Vector	2108	NEW	Meissner Filtration	FSB0100FB	-	-	609 mm W x 809 mm D x 833 mm H	30 kg	-	-	-
B	-	PFD-206	BFD-202	0.2 Micron Filter	0.2 Micron Filter	Viral Vector	2108	NEW	Pall	TBD	-	-	TBD	TBD	-	-	-
B	-	PFD-206	BFD-202	Peristaltic Pump (50 L)	Peristaltic Pump	Viral Vector	2108	NEW	Watson Marlow	TBD	-	-	TBD	TBD	-	-	-
MWS																	
B	-	-	-	Parts Washer	Reliance®280 PG Pharmaceutical Grade Washer	Component Prep	2102	NEW	Steris	Reliance 280PG	-	-	1353 mm W x 813 mm L x 231 mm H	894 kg (shipping0 880 kg (operating)	-	-	-
B	-	-	-	Sterilization Autoclave	Finn-Aqua GMP Bio Pharma Sterilizer (BPS)	Sterile Prep	2103	NEW	Steris	BPS6912	-	-	2320 mm W x 1742 mm D x 1950 mm H	1044 kg (installation) 1315 kg (Full Chamber)	-	-	-
B	-	-	-	Decon Autoclave	Finn-Aqua GMP Bio Pharma Sterilizer (BPS)	Mech.	2107	NEW	Steris	BPS6912	-	-	2320 mm W x 1742 mm D x 1950 mm H	1044 kg (installation) 1315 kg (Full Chamber)	-	-	-
B	-	-	-	Floor Scale	Floor Scale	-	-	EXISTING	Rice Lake	Model - BSP Catalog - SPX48501 (Custom Made)	-	-	TBD	TBD	-	-	-
B	-	-	-	500 L Jacketed Single-Use Mixer	500 L Xcellerx XDM Single-Use Mixer	Media Buffer Prep	2119	NEW	Cytiva	29054862	-	-	1350 mm W x 1200 mm D x 1480 mm H (with I/O Panel)	315 kg (690 lb)	-	-	-
B	-	-	-	500 L Jacketed Single-Use Mixer	500 L Xcellerx XDM Single-Use Mixer	Media Buffer Prep	2119	NEW	Cytiva	29054862	-	-	1350 mm W x 1200 mm D x 1480 mm H (with I/O Panel)	315 kg (690 lb)	-	-	-
B	-	-	-	500 L Jacketed Single-Use Mixer	500 L Xcellerx XDM Single-Use Mixer	Media Buffer Prep	2119	NEW	Cytiva	29054862	-	-	1350 mm W x 1200 mm D x 1480 mm H (with I/O Panel)	315 kg (690 lb)	-	-	-
B	-	-	-	50 L Jacketed Single-Use Mixer	50 L Xcellerx XDM Single-Use Mixer	Media Buffer Prep	2119	NEW	Cytiva	29054862	-	-	740 mm W x 530 mm D x 1090 mm H	85 kg	-	-	-
B	-	-	-	50 L Jacketed Single-Use Mixer	50 L Xcellerx XDM Single-Use Mixer	Media Buffer Prep	2119	NEW	Cytiva	29054862	-	-	740 mm W x 530 mm D x 1090 mm H	85 kg	-	-	-
B	-	-	-	Fume Hood - Extraction Booth	FumeGard Conventional Fume Hood	-	-	NEW	Fisher Scientific	F-100-48G7 60000580	-	-	1219 mm W x 911 mm D x 1451 mm H	TBD	-	-	-
Utilities																	
B	-	-	-	CS Generation Skid	CS Generation Skid (300 kg/hr @ ~45 psig)	Clean Utilities	1134	TBD	Stilmas	Pre-Treatment: 4400C Generation: PSG 300 DTS	-	-	Pre-Treatment: 966 mm L x 737 mm W x 2045 mm H Generation: 1130 m L x 11500 mm W x 2900 mm H	Pre-Treatment: 200 kg (full) Generation: 480 kg (empty) 775 kg (full)	-	-	-
B	-	-	-	CS Distribution Skid	CS Distribution Skid	Clean Utilities	1134	TBD	TBD	TBD	-	-	TBD	TBD	-	-	-
B	-	-	-	Water Softener System	Water Softener + 2 Carbon Filters	Clean Utilities	1134	TBD	Stilmas	Water Softner: TAFS-150P Carbon Filter: TAFC-1465	-	-	Water Softner: 18" Dia x 65" H Carbon Filter: 14" Dia x 65" H	-	-	-	-
B	-	-	-	WFI Generation Skid	WFI Generation Skid (1000 Lbs/hr capacity)	Clean Utilities	1134	TBD	Stilmas	BD 1000	-	-	3200 mm L x 1500 mm W x 2400 mm H	2640 kg (empty) 4300 kg (full)	-	-	-
B	-	-	-	WFI Distribution Skid	WFI Distribution Skid (Including 2,000 L Storage Tank + Heat Sanitization Capacity)	Clean Utilities	1134	TBD	Stilmas	TBD	-	-	Storage Tank: 50" Dia x 60" H 4013 mm L x 2185 mm W x 2616 mm H	4630 kg (full)	-	-	-
B	-	-	-	N2 Distribution System	N2 Distribution System	Clean Utilities	1134	TBD	TBD	TBD	-	-	TBD	TBD	-	-	-
B	-	-	-	O2 Distribution System	O2 Distribution System	Clean Utilities	1134	TBD	TBD	TBD	-	-	TBD	TBD	-	-	-
B	-	-	-	CO2 Distribution System	CO2 Distribution System	Clean Utilities	1134	TBD	TBD	TBD	-	-	TBD	TBD	-	-	-
B	-	-	-	Bio Kill System	Single-Pass Thermo Bio Kill System	Bio-Kill	1135	NEW	PRI	Afc-9000LPH	-	-	103" W x 246" L x 85"	TBD	-	-	-
B	-	-	-	Neutralization System	Neutralization System - labTREAT LT50 - 50 GPM +2000 GAL Equalization Hold Tank	Waste Neutralization	1137	NEW	Dignital Analysis	LT50	-	-	60" W x 144" L x 84" H Tank: 64" D x 151" H	1900 lbs (dry)	-	-	-
B	-	-	-	CS Sample Cooler	CS Sample Cooler	-	-	NEW	Spirax Sarco	SSC20	-	-	102 mm W x 102 mm D x 458 mm H	3.1 kg	-	-	-

PROCESS UTILITIES / PLANT UTILITIES

EQUIPMENT NAME	HOT WFI HWFI LPM	HOT WFI HWFI PSIG	PURIFIED WATER PW LPM	PURIFIED WATER PW PSIG	CIP LPM	CIP PSIG	CLEAN STEAM CS kg/h	CLEAN STEAM CS PSIG	CLEAN STEAM CONDENSATE CSC kg/h	CLEAN STEAM CONDENSATE CSC PSIG	NITROGEN N_2 SCFM	NITROGEN N_2 CFM	NITROGEN N_2 PSIG	OXYGEN O_2 SCFM	OXYGEN O_2 CFM	OXYGEN O_2 PSIG	CABRON DIOXIDE CO_2 SCFM	CABRON DIOXIDE CO_2 CFM	CABRON DIOXIDE CO_2 PSIG	PROCESS AIR CCA SCFM	PROCESS AIR CCA CFM	PROCESS AIR CCA PSIG	INSTRUMENT AIR IA SCFM	INSTRUMENT AIR IA CFM	INSTRUMENT AIR IA PSIG	HEAT XFER FLUID (S/R) GPM	HEAT XFER FLUID (S/R) PSIG	PLANT STEAM PS kg/h	PLANT STEAM PS PSIG	PLANT STEAM CONDENSATE kg/h	PLANT STEAM CONDENSATE PSIG	DOMESTIC COLD WATER (T=60°F) CW LPM	DOMESTIC COLD WATER (T=60°F) CW PSIG	PROCESS CHILLED WATER PCHWS/R LPM	PROCESS CHILLED WATER PCHWS/R PSIG	RELIEF VENT PV SCFM	RELIEF VENT PV CFM	RELIEF VENT PV PSIG	INTAKE AIR SCFM	EXHAUST SCFM	EXHAUST CFM	EXHAUST PSIG	SANITARY SEWER SAN LPM	SANITARY SEWER SAN PSIG	PROCESS WASTE PW LPM	PROCESS WASTE PW PSIG	BIOWASTE BIOD LPM	BIOWASTE BIOD PSIG	HEAT LOAD kW
VV																																																	
-80°C Freezer - 2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Biosafety Cabinet	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Cryogenic Tank	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Shaker Incubator	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	8.9	-	29 max	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
50 L Bioreactor	-	-	-	-	-	-	-	-	-	-	-	-	-	11.96	-	44	11.96	-	44	11.96	-	44	11.96	-	44	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Media 1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Media 2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Base	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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50 L Jacketed Single-Use Mixer - Clarified Broth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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Single-Use Chromatography- AEX	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	[illegible]	[illegible]	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Equilibrate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Wash Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Regenerate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Storage Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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Single-Use Chromatography- MMC	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	[illegible]	[illegible]	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Equilibrate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Wash Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Regenerate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Storage Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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100 L Storage Tote - Filtrate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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100 L Storage Tote - Wash Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Condition Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Diafilter Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Storage Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - Caustic	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
50 L Jacketed Single-Use Mixer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
100 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
0.2 Micron Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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Sterilization Autoclave	-	-	-	-	-	-	238	40-44	-	-	-	-	-	-	-	-	-	-	-	57	-	77-120	-	-	-	-	-	-	-	-	-	13	15-44	-	-	1135 kg/h 450 kg/h	-	45 max	-	96.7	-	15-44	-	-	-	-	-	-	3.0
Decon Autoclave	-	-	-	-	-	-	238	40-44	-	-	-	-	-	-	-	-	-	-	-	57	-	77-120	-	-	-	-	-	-	-	-	-	13	15-44	-	-	1135 kg/h 450 kg/h	-	45 max	-	96.7	-	15-44	-	-	-	-	-	-	3.0
Floor Scale	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
500 L Jacketed Single-Use Mixer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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500 L Jacketed Single-Use Mixer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
50 L Jacketed Single-Use Mixer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
50 L Jacketed Single-Use Mixer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Fume Hood - Extraction Booth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Utilities																																																	
CS Generation Skid	5.5	29	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0.03	116	-	-	-	-	-	-	-	390	87	-	-	0.67	43.5	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CS Distribution Skid	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Water Softener System	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
WFI Generation Skid	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0.03	116	-	-	-	-	-	130	50.8	-	-	18.3	50.8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
WFI Distribution Skid	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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Bio Kill System	-	-	-	-	-	-	TBD	TBD	-	-	-	-	-	-	-	-	-	-	-	TBD	TBD	90	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Neutralization System	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	80	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CS Sample Cooler	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

AUTOMATION / ELECTRICAL / COST / NOTES

EQUIPMENT NAME	CONTROL (OEM, PCS, BAS, N/A)	QUANTITY	BMS or SCADA	ELECTRICAL DESCRIPTION	HP	VOLTAGE	PHASE	AMPS	KVA	FIELD CONNECTION	CLASS OF POWER	BACK-UP POWER / UPS	DATA INTEGRATION (PCS, MES, BAS, EMS, N/A)	UNIT COST	QUANTITY	INSTALLATION FACTOR	ESTIMATED TOTAL COST	LEAD TIME (WEEKS ARO)	ESTIMATION SOURCE	NOTES
VV																				
-80°C Freezer - 2	-	-	-	-	-	115 @ 60 Hz	-	9.5	-	-	-	BACK-UP POWER	-	-	-	-	$23,190	4	Vendor	
Biosafety Cabinet	-	-	-	-	-	120 @ 60 Hz	-	-	-	-	-	UPS	-	-	-	-	$17,500	18-24	Vendor	
Cryogenic Tank	-	-	-	-	-	115 @ 60 Hz	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$20,000	25-29	Vendor	Added
Shaker Incubator	-	-	-	-	-	120 @ 60 Hz	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$29,700	13-17	Vendor	New Generation model
50 L Bioreactor	-	-	-	-	-	110 ± 10% @ 60Hz TCU: 460 V @ 60 Hz	1 3	14 18	-	-	-	Back-Up + UPS: X-Station: 110 ± 10% @ 60Hz 1 Ph, 2.9A	-	-	-	-	$270,000	20-24	Vendor	Updated Utility requirements, dimensions and weight. These do NOT include TCY requirements. Price is base unit price. Total with TCU, SAT, Commissioning, IQOQ, etc. is 368,000. No results when looking for this specific catalog number.
100 L Storage Tote	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Added
100 L Storage Tote - Media 1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
100 L Storage Tote - Media 2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
100 L Storage Tote - Base	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
Depth Filtration Skid	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$42,000	14-16	Vendor	
50 L Jacketed Single-Use Mixer - Clarified Broth	-	-	-	-	-	120 @ 60 Hz	1	4.5 (max)	-	-	-	BACK-UP POWER	-	-	-	-	$74,000	14-16	Vendor	Updated volume, model, dimensions, utility requirements, etc.
Peristaltic Pump (50 L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$10,500	-	HISTORY - Consultant Estimate	
Peristaltic Pump (200 L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$10,500	-	HISTORY - Consultant Estimate	Added
Single-Use Chromatography- AEX	-	-	-	-	-	100, 120, 200-208, 220-230 or 240 ± 10% @ 60Hz	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$213,500	4-6	Vendor	Updated model, equipment name and description
100 L Storage Tote - Equilibrate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
100 L Storage Tote - Wash Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
100 L Storage Tote - Regenerate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
100 L Storage Tote - Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
100 L Storage Tote - Storage Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
100 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
100 L Storage Tote	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Added
Single-Use Chromatography- MMC	-	-	-	-	-	100, 120, 200-208, 220-230 or 240 ± 10% @ 60Hz	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$213,500	4-6	Vendor	Updated model, equipment name and description
100 L Storage Tote - Equilibrate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
100 L Storage Tote - Wash Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
100 L Storage Tote - Regenerate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
100 L Storage Tote - Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
100 L Storage Tote - Storage Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
100 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
Peristaltic Pump (200 L)	-	-	-	-	-	TBD	TBD	-	-	-	-	BACK-UP POWER	-	-	-	-	$10,500	-	HISTORY - Consultant Estimate	
Nano Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	TBD	TBD	TBD	
100 L Storage Tote - Filtrate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
AKTA Flux 6 (TFF System)	-	-	-	-	-	100-120 / 220-240 ± 10% @ 50-60 Hz	1	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$34,850	14-18	Vendor	Updated Utility Requirements, Cost Cost is base. Including Commissioning, etc. Total is $59,600. Included Optional Items are included in quote.
100 L Storage Tote - Wash Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
100 L Storage Tote - Condition Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
100 L Storage Tote - Diafilter Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
100 L Storage Tote - Storage Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
100 L Storage Tote - Caustic	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
100 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
50 L Jacketed Single-Use Mixer	-	-	-	-	-	120 @ 60 Hz	1	4.5 (max)	-	-	-	BACK-UP POWER	-	-	-	-	$74,000	14-16	Vendor	Updated volume, model, dimensions, utility requirements, etc.
100 L Storage Tote - AWFI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
0.2 Micron Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	HISTORY - Consultant Estimate	
Peristaltic Pump (50 L)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$10,500	-	HISTORY - Consultant Estimate	Added
MWS																				
Parts Washer	-	-	-	-	-	480 @ 60 Hz	3	-	-	-	-	Back-up: 120 V @ 60 Hz (Option)	-	-	-	-	$308,411	28-30	Vendor	Added - Pricing includes FAT, SAT IQ/OQ, etc.
Sterilization Autoclave	-	-	-	-	-	480 @ 60 Hz	3	3.2 kW	-	-	-	Back-up: 120 V @ 0.5kW	-	-	-	-	$402,500	38-42	Vendor	Moved from UPS mAbs - Smaller Unit - Price includes FAT, SAT, IQ/OQ, ETC. (Not Base Unit Price)
Decon Autoclave	-	-	-	-	-	480 @ 60 Hz	3	3.2 kW	-	-	-	Back-up: 120 V @ 0.5kW	-	-	-	-	$402,500	38-42	Vendor	Moved from UPS mAbs - Smaller Unit - Price includes FAT, SAT, IQ/OQ, ETC. (Not Base Unit Price)
Floor Scale	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	-	-	-	No results when looking for this specific catalog number. Moved from UPS mAbs
500 L Jacketed Single-Use Mixer	-	-	-	-	-	120 @ 60 Hz	3	4.5A (Max)	-	-	-	BACK-UP POWER	-	-	-	-	$155,000	14-16	Vendor	Added - Updated volume, model, dimensions, utility requirements, etc. Total Cost including Kits, SAT, Commissioning, IQOQ, etc. is $245,000.
500 L Jacketed Single-Use Mixer	-	-	-	-	-	120 @ 60 Hz	3	4.5A (Max)	-	-	-	BACK-UP POWER	-	-	-	-	$155,000	14-16	Vendor	Added - Updated volume, model, dimensions, utility requirements, etc. Total Cost including Kits, SAT, Commissioning, IQOQ, etc. is $245,000.
500 L Jacketed Single-Use Mixer	-	-	-	-	-	120 @ 60 Hz	3	4.5A (Max)	-	-	-	BACK-UP POWER	-	-	-	-	$155,000	14-16	Vendor	Added - Updated volume, model, dimensions, utility requirements, etc. Total Cost including Kits, SAT, Commissioning, IQOQ, etc. is $245,000.
50 L Jacketed Single-Use Mixer	-	-	-	-	-	120 @ 60 Hz	1	4.5 (max)	-	-	-	BACK-UP POWER	-	-	-	-	$74,000	14-16	Vendor	Added
50 L Jacketed Single-Use Mixer	-	-	-	-	-	120 @ 60 Hz	1	4.5 (max)	-	-	-	BACK-UP POWER	-	-	-	-	$74,000	14-16	Vendor	Added
Fume Hood - Extraction Booth	-	-	-	-	-	120		20	-	-	-	BACK-UP POWER	-	-	-	-	$10,450	4-8	Vendor	Added
Utilities																				
CS Generation Skid	-	-	-	-	-	TBD	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$238,769	30-35	Vendor	Total Cost does not include Documentation, Activities and Validation Package (Approx. $145,770.00). This is packaged with the MES documentation, activities and validation.
CS Distribution Skid	-	-	-	-	-	TBD	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	TBD	TBD	TBD	
Water Softener System	-	-	-	-	-	TBD	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$10,510	30-35	Vendor	
WFI Generation Skid	-	-	-	-	-	TBD	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$501,236	30-35	Vendor	Total Cost does not include Documentation, Activities and Validation Package (Approx. $145,770.00). This is packaged with the PSG documentation, activities and validation.
WFI Distribution Skid	-	-	-	-	-	TBD	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$571,495	30-35	Vendor	Cost breakdown: WFI Storage is approx. $156,115.00 CAD. Distribution is approx. $415,380.00 CAD. Total Cost does not include Documentation, Activities and Validation Package (Approx. $86,480.00).
N2 Distribution System	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	TBD	TBD	TBD	
O2 Distribution System	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	TBD	TBD	TBD	
CO2 Distribution System	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	TBD	TBD	TBD	
Bio Kill System	-	-	-	-	-	480 V @ 60 Hz	3	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$600,000	24-28	Vendor	
Neutralization System	-	-	-	-	-	480 V @ 60 Hz	3.0	20.0	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$181,500	24-28	Vendor	Neutralization Skid Cost:$144,000. Hold Tank: $12,500. Cooler: $25,000
CS Sample Cooler	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	$7,300	-	HISTORY - Consultant Estimate	

EQUIPMENT INFORMATION																		
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	Area	ROOM	NEW / EXISTING	MFG.	MODEL NUMBER	SPECIFICATION NO.	BID PACKAGE NO.	DIMENSIONS	MAX Weight	FURNISHED BY	INSTALLED BY	FIXED OR PORTABLE
Accessories																	
A	-	-	-	Quantum Pump	Quantum Bioprocessing Pump	TBD	TBD	EXISTING	Watson Marlow	Model - Quantum 600 universal Catalog - 0D0.6040.00A	-	-	297 mm W x 736 mm D x 231 mm H	38 kg	-	-	-
A	-	-	-	Pump Drive - 1	Drive MFLEX Digital 115/30 Pump	TBD	TBD	EXISTING	Cole-Parmer	77420-10	-	-	282 mm W x 424 mm L x 328 mm H	Not Specified	-	-	-
A	-	-	-	Pump Head - 1	PUMPHD MFLEX EASY-LOAD PPS/SS	TBD	TBD	EXISTING	Cole-Parmer	77602-10	-	-	187 mm W x 89 mm L x 201 mm H	Not Specified	-	-	-
A	-	-	-	Pump Drive - 2	Drive MFLEX Digital 115/30 Pump	TBD	TBD	EXISTING	Cole-Parmer	77420-10	-	-	282 mm W x 424 mm L x 328 mm H	Not Specified	-	-	-
A	-	-	-	Pump Head - 2	PUMPHD MFLEX EASY-LOAD PPS/SS	TBD	TBD	EXISTING	Cole-Parmer	77602-10	-	-	187 mm W x 89 mm L x 201 mm H	Not Specified	-	-	-
A	-	-	-	Pump Drive - 3	Drive MFLEX L/S 600rpm 115/230	TBD	TBD	EXISTING	Cole-Parmer	07522-20	-	-	216 mm W x 254 mm L x 216 mm H	Not Specified	-	-	-
A	-	-	-	Pump Head - 3	Pump Head L/S EAS-LOAD 3 SS	TBD	TBD	EXISTING	Cole-Parmer	77800-60	-	-	88 mm W 78 mm L x 121 mm H	Not Specified	-	-	-
A	-	-	-	Bag Integrity Tester -1	inSITE Integrity Testing System - US multichannel	TBD	TBD	NEW	Sartorius	Sartocheck 4 Plus Bag Tester	-	-	460 mm W 390 mm D x 245m H	15 kg	-	-	-
A	-	-	-	Bag Integrity Tester -2	inSITE Integrity Testing System - US multichannel	TBD	TBD	NEW	Sartorius	Sartocheck 4 Plus Bag Tester	-	-	460 mm W 390 mm D x 245m H	15 kg	-	-	-
A	-	-	-	Filter Integrity Tester -1	Sartocheck 5 Plus Filter Tester	TBD	TBD	NEW	Sartorius	Sartocheck 5 Plus	-	-	348 mm W x 379 mm D x 286 mm H	16.8 kg	-	-	-
A	-	-	-	Filter Integrity Tester -2	Sartocheck 5 Plus Filter Tester	TBD	TBD	NEW	Sartorius	Sartocheck 5 Plus	-	-	348 mm W x 379 mm D x 286 mm H	16.8 kg	-	-	-
A	-	-	-	Tuber Welder -1	BioWelder TC - SterileTube Welder	TBD	TBD	NEW	Sartorius	BioWelder 16370	-	-	300 mm W x 300 mm D x 220 mm H	0.5 kg	-	-	-
A	-	-	-	Tuber Welder -2	BioWelder TC - SterileTube Welder	TBD	TBD	NEW	Sartorius	BioWelder 16370	-	-	300 mm W x 300 mm D x 220 mm H	0.5 kg	-	-	-
	-	-	-	Tuber Welder -3	BioWelder TC - SterileTube Welder	TBD	TBD	NEW	Sartorius	BioWelder 16370	-	-	300 mm W x 300 mm D x 220 mm H	0.5 kg	-	-	-
A	-	-	-	Tube Sealer -1	BioSealer TC - Sterile Tube Sealer	TBD	TBD	EXISTING	Sartorius	Model - DE-37079 Catalog - 16391-000	-	-	115 mm W x 391 mm L x 147 mm H	Approx. 3.0 kg	-	-	-
A	-	-	-	Tube Sealer -2	BioSealer TC - Sterile Tube Sealer	TBD	TBD	NEW	Sartorius	BioSealer 16360-P	-	-	220 mm W x 150 mm D x 210 mm H	3.0 kg	-	-	-
	-	-	-	Tube Sealer -3	BioSealer TC - Sterile Tube Sealer	TBD	TBD	NEW	Sartorius	BioSealer 16360-P	-	-	220 mm W x 150 mm D x 210 mm H	3.0 kg	-	-	-

	PROCESS UTILITIES																										
	HOT WFI HWFI		PURIFIED WATER PW		CIP		CLEAN STEAM CS		CLEAN STEAM CONDENSATE CSC		NITROGEN N_2			OXYGEN O_2			CABRON DIOXIDE CO_2			PROCESS AIR CCA			INSTRUMENT AIR IA			HEAT XFER FLUID (S/R)	
EQUIPMENT NAME	LPM	PSIG	LPM	PSIG	LPM	PSIG	kg/h	PSIG	kg/h	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	GPM	PSIG
Quantum Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pump Drive - 1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pump Head - 1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pump Drive - 2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pump Head - 2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pump Drive - 3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pump Head - 3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Bag Integrity Tester -1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Bag Integrity Tester -2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Filter Integrity Tester -1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Filter Integrity Tester -2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tuber Welder -1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tuber Welder -2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tuber Welder -3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tube Sealer -1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tube Sealer -2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tube Sealer -3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

	PLANT UTILITES																					
	PLANT STEAM PS		PLANT STEAM CONDENSATE		DOMESTIC COLD WATER (T=60°F) CW		PROCESS CHILLED WATER PCHWS/R		RELIEF VENT PV			INTAKE AIR	EXHAUST			SANITARY SEWER SAN		PROCESS WASTE PW		BIOWASTE BIOD		HEAT LOAD
EQUIPMENT NAME	kg/h	PSIG	kg/h	PSIG	LPM	PSIG	LPM	PSIG	SCFM	CFM	PSIG	SCFM	SCFM	CFM	PSIG	LPM	PSIG	LPM	PSIG	LPM	PSIG	kW
Quantum Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pump Drive - 1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pump Head - 1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pump Drive - 2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pump Head - 2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pump Drive - 3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pump Head - 3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Bag Integrity Tester -1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Bag Integrity Tester -2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Filter Integrity Tester -1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Filter Integrity Tester -2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tuber Welder -1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tuber Welder -2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tuber Welder -3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tube Sealer -1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tube Sealer -2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tube Sealer -3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

	AUTOMATION			ELECTRICAL																
EQUIPMENT NAME	CONTROL (OEM, PCS, BAS, N/A)	QUANTITY	BMS or SCADA	ELECTRICAL DESCRIPTION	HP	VOLTAGE	PHASE	AMPS	KVA	FIELD CONNECTION	CLASS OF POWER	BACK-UP POWER / UPS	DATA INTEGRATION (PCS, MES, BAS, EMS, N/A)	UNIT COST	QUANTITY	INSTALLATION FACTOR	ESTIMATED TOTAL COST	LEAD TIME (WEEKS ARO)	ESTIMATION SOURCE	NOTES
Quantum Pump	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
Pump Drive - 1	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
Pump Head - 1	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	This is one unit with equipment above.
Pump Drive - 2	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
Pump Head - 2	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	This is one unit with equipment above.
Pump Drive - 3	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
Pump Head - 3	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	This is one unit with equipment above.
Bag Integrity Tester -1	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$47,000	8-10	**Vendor**	Estimate is for system only. Estimate increases to $91,000 for system with trolley for 2D Bags.
Bag Integrity Tester -2	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$47,000	8-10	**Vendor**	Estimate is for system only. Estimate increases to $91,000 for system with trolley for 2D Bags.
Filter Integrity Tester -1	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$41,000	8-10	**Vendor**	
Filter Integrity Tester -2	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$41,000	8-10	**Vendor**	
Tuber Welder -1	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$55,000	4-6	**Vendor**	
Tuber Welder -2	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$55,000	6-8	**Vendor**	
Tuber Welder -3	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$55,000	6-8	**Vendor**	
Tube Sealer -1	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$28,000	6-8	**Vendor**	
Tube Sealer -2	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$28,000	6-8	**Vendor**	
Tube Sealer -3	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$28,000	6-8	**Vendor**	

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EQUIPMENT INFORMATION																	
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	Area	ROOM	NEW / EXISTING	MFG.	MODEL NUMBER	SPECIFICATION NO.	BID PACKAGE NO.	DIMENSIONS	MAX Weight	FURNISHED BY	INSTALLED BY	FIXED OR PORTABLE
Cell Innoculation mAbs																	
B	-	PFD-102	BFD-101	-20^{0}C Freezer	-20^{0}C Manual Defrost Freezer	Freezer Room	2128	EXISTING	Fisher Scientific	TSX2320FA	-	-	711 mm W x 990 mm D x 1994 mm H	208 kg	-	-	-
B	-	PFD-102	BFD-101	-80^{0}C Freezer - 1	-80^{0}C Ultra-Low Freezer	Freezer Room	2128	EXISTING	Fisher Scientific	TSX60086A	-	-	1006 mm W x 955 mm D x 1981 mm H	358 kg	-	-	-
B	-	PFD-101 PFD-102	BFD-101	Regrigerator +2^{0}C to +8^{0}C	+2^{0}C to +8^{0}C High Perf. Lab Refrigerators	Freezer Room	2128	EXISTING	Fisher Scientific	TSX5005SA	-	-	1435 mm W x 962 mm D x 1994 mm H	282 kg	-	-	-
B	-	PFD-101 PFD-102	BFD-101	Biosafety Cabinet - 1	Class II, Type A2 6 ft Biological Safety Cabinet	Cell Innoculation	2115	EXISTING	Fisher Scientific	Model - 1377 Catalog - 13261223	-	-	1900 mm W x 800 mm D x 1568 mm H	280 kg (Cabinet) 30.0 kg (Stand)	-	-	-
B	-	PFD-101 PFD-102	BFD-101	Shaker Incubator	**ISF1-Z**-Shaker Incubator	Cell Innoculation	2115	NEW	Kuhner Shaker	**SMZ1500**	-	-	**1288 mm W x 854 mm D x** 771 mm H	**200 kg**	-	-	-
B	-	PFD-101 PFD-102	BFD-101	**Cryogenic Tank**	**Cryogenic Tank - Cryoplus 3 340 L Load**	Cell Innoculation	2115	NEW	**Fisher Scientific**	**7404**	-	-	**876 mm W x 1054 mm D x 1041 mm H**	**249 kg (550 lbs)**	-	-	-
USP mAbs																	
B	-	PFD-103	BFD-101	50 L Bioreactor	XDR50 GRAV Bioreactor RePurpos, TCU Included - Single Use	Up Stream	2116	EXISTING	Cytiva	Model - XDR50L Catalog - 29649820	-	-	**1466 mm W x 1070 mm D** x 2210 mm H **Weight X-Station: 601 mm W x 797 mm D x 1466 mm H** **TCU: 483 mm W x 661 mm D x 775 mm H**	**468 kg (empty)** **X-Station: 146 kg** **TCU: 146 kg**	-	-	-
B	-	PFD-103	BFD-101	**100 L Storage Tote**	**100 L Storage Tote - Flex Station PN**	Up Stream	2116	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-103	BFD-101	500 L Bioreactor	XDR500 Bioreator DP RePurpos, TCU Included - Single Use	Up Stream	2116	EXISTING	Cytiva	Model - XDR500L Catalog - 29653172	-	-	**1466 mm W x 1070 mm D** x 2210 mm H **Weight X-Station: 601 mm W x 797 mm D x 1466 mm H** **TCU: 483 mm W x 661 mm D x 775 mm H**	**669 kg (empty)** **X-Station: 146 kg** **TCU: 146 kg**	-	-	-
B	-	PFD-103	BFD-101	**200 L** Storage Tote **- Base**	**200 L** Storage Tote - **Flex Station PN** (Base)	Up Stream	2116	NEW	**Meissner Filtration**	**FSB0200TD**	-	-	**609 mm W x 809 mm D x 833 mm H**	**20 kg (empty)**	-	-	-
B	-	PFD-103	BFD-101	**200 L** Storage Tote **- Media 1**	**200 L** Storage Tote - **Flex Station PN** (Media 1)	Up Stream	2116	NEW	**Meissner Filtration**	**FSB0200TD**	-	-	**609 mm W x 809 mm D x 833 mm H**	**20 kg (empty)**	-	-	-
B	-	PFD-103	BFD-101	**200 L** Storage Tote **- Media 2**	**200 L** Storage Tote - **Flex Station PN** (Media 2)	Up Stream	2116	NEW	**Meissner Filtration**	**FSB0200TD**	-	-	**609 mm W x 809 mm D x 833 mm H**	**20 kg (empty)**	-	-	-
B	-	PFD-103	BFD-101	Depth Filtration Skid	Depth Filtration Skid - SartoClear Depth Filters	Up Stream	2116	NEW	Sartorius	2ZGL–0006	-	-	2300 mm W x 930 mm D x 910 mm H	50 kg	-	-	-
B	-	PFD-103	BFD-101	**500 L** Jacketed **Single-Use Mixer - Clarified Broth**	**500 L Xcellerx XDM Single-Use Mixer - Clarified Broth**	Up Stream	2116	NEW	**Cytiva**	**29054862**	-	-	**1350 mm W x 1200 mm D x 1480 mm H** **(with I/O Panel)**	**315 kg (690 lbs)**	-	-	-
B	-	PFD-103	BFD-101	Peristaltic Pump (50 L)	Peristaltic Pump	Up Stream	2116	NEW	Watson Marlow	TBD	-	-	TBD	TBD	-	-	-
B	-	PFD-103	BFD-101	Peristaltic Pump (200 L)	Peristaltic Pump	Up Stream	2116	NEW	Watson Marlow	TBD	-	-	TBD	TBD	-	-	-
DSP - 1 mAbs																	
B	-	PFD-104	BFD-102	**Single-Use Chromatogrraphy - Affinity**	**AKTA Ready Gradient** Chromatography System - Single Use (including Column Trolley) - Affinity	Down Stream 1	2135	EXISTING	Cytiva	29032038	-	-	1160 mm W x **800 mm D x 1650 mm H**	250 kg	-	-	-
B	-	PFD-104	BFD-102	200 L Storage Tote **- Equilibrate Buffer**	**200 L** Storage Tote - **Flex Station PN** (Equilbrate Buffer)	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0200TD**	-	-	**609 mm W x 809 mm D x 833 mm H**	**20 kg (empty)**	-	-	-
B	-	PFD-104	BFD-102	500 L Storage Tote **- Wash Buffer**	500 L Storage Tote **- Flex Station PN** (Wash Buffer)	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0500TD**	-	-	**915 mm W x 1200 mm D x 1260 mm H**	**70 kg (empty)**	-	-	-
B	-	PFD-104	BFD-102	500 L Storage Tote **- Regenerate Buffer**	500 L Storage Tote **- Flex Station PN** (Regenerate Buffer)	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0500TD**	-	-	**915 mm W x 1200 mm D x 1260 mm H**	**70 kg (empty)**	-	-	-
B	-	PFD-104	BFD-102	500 L Storage Tote **- Eluate Buffer**	500 L Storage Tote **- Flex Station PN** (Eluate Buffer)	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0500TD**	-	-	**915 mm W x 1200 mm D x 1260 mm H**	**70 kg (empty)**	-	-	-
B	-	PFD-104	BFD-102	200 L Storage Tote **- Storage Buffer**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0200TD**	-	-	**609 mm W x 809 mm D x 833 mm H**	**20 kg (empty)**	-	-	-
B	-	PFD-104	BFD-102	**1000 L Storage Tote - WFI**	**1000 L Storage Tote -** Flex Station PN **(WFI)**	Down Stream 1	2135	EXISTING	Meissner Filtration	Model - Flex Station 'IND331' **FSB1000TD**	-	-	1000 mm W x 1200 mm L x 1260 mm H	125 kg (empty)	-	-	-
B	-	PFD-104	BFD-102	**1000 L Storage** Mobile Cart with load cells.	**1000 L Storage Tote -** Flex Station Mobile Cart	Down Stream 1	2135	EXISTING	Meissner Filtration	FSC11A-LC	-	-	1031 mm W x 1229 mm L x 185 mm H	34 kg	-	-	-
B	-	PFD-104	BFD-102	**200** L Jacketed Single-Use Mixer	**200 L Xcellerx XDM** Single-Use Mixer	Down Stream 1	2135	NEW	**Cytiva**	**29054862**	-	-	**1140 mm W x 1000 mm D x 1120 mm H** **(with I/O Panel)**	**200 kg (440 lbs)**	-	-	-
B	-	PFD-104	BFD-102	**100 L** Storage Tote **- Acid**	**100 L** Storage Tote - **Flex Station PN** (Acid)	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-104	BFD-102	Depth Filtration Skid	Depth Filtration Skid - SartoClear Depth Filters	Down Stream 1	2135	NEW	Sartorius	2ZGL–0006	-	-	2300 mm W x 930 mm D x 910 mm H	50 kg	-	-	-
B	-	PFD-104	BFD-102	**Peristaltic Pump (200 L)**	**Peristaltic Pump**	Down Stream 1	2135	NEW	**Watson Marlow**	**TBD**	-	-	**TBD**	**TBD**	-	-	-
B	-	PFD-104	BFD-102	200 L Jacketed Single-Use Mixer	**200 L Xcellerx XDM** Single-Use Mixer	Down Stream 1	2135	NEW	**Cytiva**	**29054862**	-	-	**1140 mm W x 1000 mm D x 1120 mm H** **(with I/O Panel)**	**200 kg (440 lbs)**	-	-	-
B	-	PFD-104	BFD-102	**100 L** Storage Tote **- Base**	**100 L** Storage Tote - **Flex Station PN** (Base)	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-105	BFD-102	**Single Use - Storage**	**Flex Station PN - 1000 L**	Down Stream 1	2135	NEW	**Meissner Filtration**	**Model - Flex Station 'IND331'** **FSB1000TD**	-	-	**1000 mm W x 1200 mm L x 1260 mm H**	**125 kg (empty)**	-	-	-
B	-	PFD-105	BFD-102	**Mobile Cart with load cells.**	**Flex Station Mobile Cart - 1000 L**	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSC11A-LC**	-	-	**1031 mm W x 1229 mm L x 185 mm H**	**34 kg**	-	-	-
B	-	PFD-105	BFD-102	**Single-Use Chromatogrraphy - AEX**	**AKTA Ready Gradient** Chromatography System - Single Use (including Column Trolley) **- AEX**	Down Stream 1	2135	EXISTING	Cytiva	29032038	-	-	1160 mm W x 1650 mm D x 800 mm H	250 kg	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote **- Equilibrate Buffer**	**200 L** Storage Tote - **Flex Station PN** (Equilbrate Buffer)	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0200TD**	-	-	**609 mm W x 809 mm D x 833 mm H**	**20 kg (empty)**	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote **- Wash Buffer**	500 L Storage Tote **- Flex Station PN** (Wash Buffer)	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0500TD**	-	-	**915 mm W x 1200 mm D x 1260 mm H**	**70 kg (empty)**	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote **- Regenerate Buffer**	500 L Storage Tote **- Flex Station PN** (Regenerate Buffer)	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0500TD**	-	-	**915 mm W x 1200 mm D x 1260 mm H**	**70 kg (empty)**	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote **- Eluate Buffer**	500 L Storage Tote **- Flex Station PN** (Eluate Buffer)	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0500TD**	-	-	**915 mm W x 1200 mm D x 1260 mm H**	**70 kg (empty)**	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote **- Storage Buffer**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0200TD**	-	-	**609 mm W x 809 mm D x 833 mm H**	**20 kg (empty)**	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote **- AWFI**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0200TD**	-	-	**609 mm W x 809 mm D x 833 mm H**	**20 kg (empty)**	-	-	-
B	-	PFD-105	BFD-102	**200 L Storage Tote**	**200 L Storage Tote - Flex Station PN**	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0200TD**	-	-	**609 mm W x 809 mm D x 833 mm H**	**20 kg (empty)**	-	-	-

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						PROCESS UTILITIES																											
						HOT WFI HWFI		PURIFIED WATER PW		CIP		CLEAN STEAM CS		CLEAN STEAM CONDENSATE CSC		NITROGEN N_2			OXYGEN O_2			CABRON DIOXIDE CO_2			PROCESS AIR CCA			INSTRUMENT AIR IA			HEAT XFER FLUID (S/R)	
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	LPM	PSIG	LPM	PSIG	LPM	PSIG	kg/h	PSIG	kg/h	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	GPM	PSIG
Cell Innoculation mAbs																																	
B	-	PFD-102	BFD-101	-20^{0}C Freezer	-20^{0}C Manual Defrost Freezer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-102	BFD-101	-80^{0}C Freezer - 1	-80^{0}C Ultra-Low Freezer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-101 PFD-102	BFD-101	Regrigerator +2^{0}C to +8^{0}C	+2^{0}C to +8^{0}C High Perf. Lab Refrigerators	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-101 PFD-102	BFD-101	Biosafety Cabinet - 1	Class II, Type A2 6 ft Biological Safety Cabinet	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-101 PFD-102	BFD-101	Shaker Incubator	**ISF1-Z**-Shaker Incubator	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**8.9**	-	**29 max**	-	-	-	-	-	-	-	-	-
B	-	PFD-101 PFD-102	BFD-101	**Cryogenic Tank**	**Cryogenic Tank - Cryoplus 3 340 L Load**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
USP mAbs																																	
B	-	PFD-103	BFD-101	50 L Bioreactor	XDR50 GRAV Bioreactor RePurpos, TCU Included - Single Use	-	-	-	-	-	-	-	-	-	-	-	-	-	**11.96**	-	**44**	**11.96**	-	**44**	**11.96**	-	**44**	**11.96**	-	**44**	-	-
B	-	PFD-103	BFD-101	**100 L Storage Tote**	**100 L Storage Tote - Flex Station PN**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-103	BFD-101	500 L Bioreactor	XDR500 Bioreator DP RePurpos, TCU Included - Single Use	-	-	-	-	-	-	-	-	-	-	-	-	-	**11.96**	-	**44**	**11.96**	-	**44**	**11.96**	-	**44**	**11.96**	-	**44**	-	-
B	-	PFD-103	BFD-101	**200 L** Storage Tote - **Base**	**200 L** Storage Tote - **Flex Station PN** (Base)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-103	BFD-101	**200 L** Storage Tote - **Media 1**	**200 L** Storage Tote - **Flex Station PN** (Media 1)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-103	BFD-101	**200 L** Storage Tote - **Media 2**	**200 L** Storage Tote - **Flex Station PN** (Media 2)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-103	BFD-101	Depth Filtration Skid	Depth Filtration Skid - SartoClear Depth Filters	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-103	BFD-101	**500 L** Jacketed **Single-Use Mixer - Clarified Broth**	**500 L Xcellerx XDM Single-Use Mixer - Clarified Broth**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-103	BFD-101	Peristaltic Pump (50 L)	Peristaltic Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-103	BFD-101	Peristaltic Pump (200 L)	Peristaltic Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DSP - 1 mAbs																																	
B	-	PFD-104	BFD-102	**Single-Use Chromatogrraphy - Affinity**	**AKTA Ready Gradient** Chromatography System - Single Use (including Column Trolley) - Affinity	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**1.77**	**79.8 - 101.5**	-	-
B	-	PFD-104	BFD-102	200 L Storage Tote - **Equilibrate Buffer**	**200 L** Storage Tote - **Flex Station PN** (Equilbrate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	500 L Storage Tote - **Wash Buffer**	500 L Storage Tote - **Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	500 L Storage Tote - **Regenerate Buffer**	500 L Storage Tote - **Flex Station PN** (Regenerate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	500 L Storage Tote - **Eluate Buffer**	500 L Storage Tote - **Flex Station PN** (Eluate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	200 L Storage Tote - **Storage Buffer**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	**1000 L Storage Tote - WFI**	**1000 L Storage Tote -** Flex Station PN **(WFI)**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	**1000 L Storage** Mobile Cart with load cells.	**1000 L Storage Tote -** Flex Station Mobile Cart	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	**200** L Jacketed Single-Use Mixer	**200 L Xcellerx XDM** Single-Use Mixer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	**100 L** Storage Tote - **Acid**	**100 L** Storage Tote - **Flex Station PN** (Acid)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	Depth Filtration Skid	Depth Filtration Skid - SartoClear Depth Filters	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	**Peristaltic Pump (200 L)**	**Peristaltic Pump**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	200 L Jacketed Single-Use Mixer	**200 L Xcellerx XDM** Single-Use Mixer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	**100 L** Storage Tote - **Base**	**100 L** Storage Tote - **Flex Station PN** (Base)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	**Single Use - Storage**	**Flex Station PN - 1000 L**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	**Mobile Cart with load cells.**	**Flex Station Mobile Cart - 1000 L**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	**Single-Use Chromatogrraphy - AEX**	**AKTA Ready Gradient** Chromatography System - Single Use (including Column Trolley) - **AEX**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**1.77**	**79.8 - 101.5**	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote - **Equilibrate Buffer**	**200 L** Storage Tote - **Flex Station PN** (Equilbrate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote - **Wash Buffer**	500 L Storage Tote - **Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote - **Regenerate Buffer**	500 L Storage Tote - **Flex Station PN** (Regenerate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote - **Eluate Buffer**	500 L Storage Tote - **Flex Station PN** (Eluate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote - **Storage Buffer**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote - **AWFI**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	**200 L Storage Tote**	**200 L Storage Tote - Flex Station PN**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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						PLANT UTILITES																					AUTOMATION		
						PLANT STEAM PS		PLANT STEAM CONDENSATE		DOMESTIC COLD WATER (T=60°F) CW		PROCESS CHILLED WATER PCHWS/R		RELIEF VENT PV			INTAKE AIR	EXHAUST			SANITARY SEWER SAN		PROCESS WASTE PW		BIOWASTE BIOD		HEAT LOAD			
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	kg/h	PSIG	kg/h	PSIG	LPM	PSIG	LPM	PSIG	SCFM	CFM	PSIG	SCFM	SCFM	CFM	PSIG	LPM	PSIG	LPM	PSIG	LPM	PSIG	kW	CONTROL (OEM, PCS, BAS, N/A)	QUANTITY	BMS or SCADA
Cell Innoculation mAbs																														
B	-	PFD-102	BFD-101	-20^{0}C Freezer	-20^{0}C Manual Defrost Freezer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-102	BFD-101	-80^{0}C Freezer - 1	-80^{0}C Ultra-Low Freezer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-101 PFD-102	BFD-101	Regrigerator +2^{0}C to +8^{0}C	+2^{0}C to +8^{0}C High Perf. Lab Refrigerators	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-101 PFD-102	BFD-101	Biosafety Cabinet - 1	Class II, Type A2 6 ft Biological Safety Cabinet	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-101 PFD-102	BFD-101	Shaker Incubator	**ISF1-Z-**Shaker Incubator	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-101 PFD-102	BFD-101	**Cryogenic Tank**	**Cryogenic Tank - Cryoplus 3 340 L Load**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
USP mAbs																														
B	-	PFD-103	BFD-101	50 L Bioreactor	XDR50 GRAV Bioreactor RePurpos, TCU Included - Single Use	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-103	BFD-101	**100 L Storage Tote**	**100 L Storage Tote - Flex Station PN**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-103	BFD-101	500 L Bioreactor	XDR500 Bioreator DP RePurpos, TCU Included - Single Use	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-103	BFD-101	**200 L** Storage Tote **- Base**	**200 L** Storage Tote **- Flex Station PN** (Base)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-103	BFD-101	**200 L** Storage Tote **- Media 1**	**200 L** Storage Tote - **Flex Station PN** (Media 1)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-103	BFD-101	**200 L** Storage Tote **- Media 2**	**200 L** Storage Tote - **Flex Station PN** (Media 2)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-103	BFD-101	Depth Filtration Skid	Depth Filtration Skid - SartoClear Depth Filters	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-103	BFD-101	**500 L** Jacketed **Single-Use Mixer - Clarified Broth**	**500 L Xcellerx XDM Single-Use Mixer - Clarified Broth**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-103	BFD-101	Peristaltic Pump (50 L)	Peristaltic Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-103	BFD-101	Peristaltic Pump (200 L)	Peristaltic Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DSP - 1 mAbs																														
B	-	PFD-104	BFD-102	**Single-Use Chromatogrraphy - Affinity**	**AKTA Ready Gradient** Chromatography System - Single Use (including Column Trolley) - Affinity	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	200 L Storage Tote **- Equilibrate Buffer**	**200 L** Storage Tote - **Flex Station PN** (Equilbrate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	500 L Storage Tote **- Wash Buffer**	500 L Storage Tote **- Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	500 L Storage Tote **- Regenerate Buffer**	500 L Storage Tote - **Flex Station PN** (Regenerate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	500 L Storage Tote **- Eluate Buffer**	500 L Storage Tote - **Flex Station PN** (Eluate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	200 L Storage Tote **- Storage Buffer**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	**1000 L Storage Tote - WFI**	**1000 L Storage Tote -** Flex Station PN **(WFI)**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	**1000 L Storage** Mobile Cart with load cells.	**1000 L Storage Tote -** Flex Station Mobile Cart	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	**200** L Jacketed Single-Use Mixer	**200 L Xcellerx XDM** Single-Use Mixer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	**100 L** Storage Tote **- Acid**	**100 L** Storage Tote - **Flex Station PN** (Acid)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	Depth Filtration Skid	Depth Filtration Skid - SartoClear Depth Filters	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	**Peristaltic Pump (200 L)**	**Peristaltic Pump**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	200 L Jacketed Single-Use Mixer	**200 L Xcellerx XDM** Single-Use Mixer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-104	BFD-102	**100 L** Storage Tote **- Base**	**100 L** Storage Tote - **Flex Station PN** (Base)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	**Single Use - Storage**	**Flex Station PN - 1000 L**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	**Mobile Cart with load cells.**	**Flex Station Mobile Cart - 1000 L**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	**Single-Use Chromatogrraphy - AEX**	**AKTA Ready Gradient** Chromatography System - Single Use (including Column Trolley) **- AEX**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote **- Equilibrate Buffer**	**200 L** Storage Tote - **Flex Station PN** (Equilbrate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote **- Wash Buffer**	500 L Storage Tote **- Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote **- Regenerate Buffer**	500 L Storage Tote - **Flex Station PN** (Regenerate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote **- Eluate Buffer**	500 L Storage Tote - **Flex Station PN** (Eluate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote **- Storage Buffer**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote **- AWFI**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	**200 L Storage Tote**	**200 L Storage Tote - Flex Station PN**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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						ELECTRICAL																
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	ELECTRICAL DESCRIPTION	HP	VOLTAGE	PHASE	AMPS	KVA	FIELD CONNECTION	CLASS OF POWER	BACK-UP POWER / UPS	DATA INTEGRATION (PCS, MES, BAS, EMS, N/A)	UNIT COST	QUANTITY	INSTALLATION FACTOR	ESTIMATED TOTAL COST	LEAD TIME (WEEKS ARO)	ESTIMATION SOURCE	NOTES
Cell Innoculation mAbs																						
B	-	PFD-102	BFD-101	-20^{0}C Freezer	-20^{0}C Manual Defrost Freezer	-	-	**115 @ 60 Hz**	-	-	-	-	-	BACK-UP POWER	-	-	-	-	**$8,069**	**4-6**	**Vendor**	
B	-	PFD-102	BFD-101	-80^{0}C Freezer - 1	-80^{0}C Ultra-Low Freezer	-	-	**115 @ 60 Hz**	-	**9.5**	-	-	-	BACK-UP POWER	-	-	-	-	**$23,190**	**4-6**	**Vendor**	
B	-	PFD-101 PFD-102	BFD-101	Regrigerator +2^{0}C to +8^{0}C	+2^{0}C to +8^{0}C High Perf. Lab Refrigerators	-	-	**115 @ 60 Hz**	-	-	-	-	-	BACK-UP POWER	-	-	-	-	**$10,293**	**4-6**	**Vendor**	
B	-	PFD-101 PFD-102	BFD-101	Biosafety Cabinet - 1	Class II, Type A2 6 ft Biological Safety Cabinet	-	-	**120 @ 60 Hz**	-	-	-	-	-	UPS	-	-	-	-	**$17,500**	**18-24**	**Vendor**	Updated Utility Requirements
B	-	PFD-101 PFD-102	BFD-101	Shaker Incubator	**ISF1-Z**-Shaker Incubator	-	-	**120 @ 60 Hz**	-	-	-	-	-	BACK-UP POWER	-	-	-	-	**$29,700**	**13-17**	**Vendor**	Updated Model and Utility Requirements
B	-	PFD-101 PFD-102	BFD-101	**Cryogenic Tank**	**Cryogenic Tank - Cryoplus 3 340 L Load**	-	-	**115 @ 60 Hz**	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$20,000	25-29	**Vendor**	Added
USP mAbs																						
B	-	PFD-103	BFD-101	50 L Bioreactor	XDR50 GRAV Bioreactor RePurpos, TCU Included - Single Use		-	**110 ± 10% @ 60Hz TCU: 460 V @ 60 Hz**	**1 3**	**14 18**	-	-	-	**Back-Up + UPS: X-Station: 110 ± 10% @ 60Hz 1 Ph, 2.9A**	-	-	-	-	**$270,000**	20-24	**Vendor**	Updated Utility requirements, dimensions and weight. These do NOT include TCY requirements. Price is base unit price. Total with TCU, SAT, Commissioning, IQOQ, etc. is 368,000. No results when looking for this specific catalog number.
B	-	PFD-103	BFD-101	**100 L Storage Tote**	**100 L Storage Tote - Flex Station PN**	-	-	-	-	-	-	-	-	-	-	-	-	-	$8,000	18-22	HISTORY - Consultant Estimate	Added
B	-	PFD-103	BFD-101	500 L Bioreactor	XDR500 Bioreator DP RePurpos, TCU Included - Single Use	-	-	**110 ± 10% @ 60Hz TCU: 460 V @ 60 Hz**	**1 3**	**14 18**	-	-	-	**Back-Up + UPS: X-Station: 110 ± 10% @ 60Hz 1 Ph, 2.9A**	-	-	-	-	**$460,000**	20-24	**Vendor**	Updated Utility requirements, dimensions and weight. These do NOT include TCY requirements. Price is base unit price. Total with TCU, SAT, Commissioning, IQOQ, etc. is 565,000. No results when looking for this specific catalog number.
B	-	PFD-103	BFD-101	**200 L** Storage Tote **- Base**	**200 L** Storage Tote **- Flex Station PN** (Base)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-103	BFD-101	**200 L** Storage Tote **- Media 1**	**200 L** Storage Tote - **Flex Station PN** (Media 1)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-103	BFD-101	**200 L** Storage Tote **- Media 2**	**200 L** Storage Tote - **Flex Station PN** (Media 2)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-103	BFD-101	Depth Filtration Skid	Depth Filtration Skid - SartoClear Depth Filters	-	-	-	-	-	-	-	-	-	-	-	-	-	$42,000	14-16	**Vendor**	
B	-	PFD-103	BFD-101	**500 L** Jacketed **Single-Use Mixer - Clarified Broth**	**500 L Xcellerx XDM Single-Use Mixer - Clarified Broth**	-	-	**120 @ 60 Hz**	**3**	**4.5A (Max)**	-	-	-	BACK-UP POWER	-	-	-	-	**$155,000**	14-16	**Vendor**	Updated volume, model, dimensions, utility requirements, etc. Total Cost including Kits, SAT, Commissioning, IQOQ, etc. is $245,000.
B	-	PFD-103	BFD-101	Peristaltic Pump (50 L)	Peristaltic Pump	-	-	**TBD**	**TBD**	-	-	-	-	BACK-UP POWER	-	-	-	-	$10,500	-	HISTORY - Consultant Estimate	
B	-	PFD-103	BFD-101	Peristaltic Pump (200 L)	Peristaltic Pump	-	-	**TBD**	**TBD**	-	-	-	-	BACK-UP POWER	-	-	-	-	$10,500	-	HISTORY - Consultant Estimate	
DSP - 1 mAbs																						
B	-	PFD-104	BFD-102	**Single-Use Chromatogrraphy - Affinity**	**AKTA Ready Gradient** Chromatography System - Single Use (including Column Trolley) - Affinity	-	-	**100, 120, 200-208, 220-230 or 240 ± 10% @ 60Hz**	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$213,500	4-6	**Vendor**	Added - Details to equipment name and description Updated utility requirements
B	-	PFD-104	BFD-102	200 L Storage Tote **- Equilibrate Buffer**	**200 L** Storage Tote - **Flex Station PN** (Equilbrate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-104	BFD-102	500 L Storage Tote **- Wash Buffer**	500 L Storage Tote **- Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
B	-	PFD-104	BFD-102	500 L Storage Tote **- Regenerate Buffer**	500 L Storage Tote **- Flex Station PN** (Regenerate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
B	-	PFD-104	BFD-102	500 L Storage Tote **- Eluate Buffer**	500 L Storage Tote **- Flex Station PN** (Eluate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
B	-	PFD-104	BFD-102	200 L Storage Tote **- Storage Buffer**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Added Details to equipment name
B	-	PFD-104	BFD-102	**1000 L Storage Tote - WFI**	**1000 L Storage Tote -** Flex Station PN **(WFI)**	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	No results when looking for this specific catalog number. Used the model number 'FSB1000TD' as basis. Moved from UPS mAbs and updated name and description
B	-	PFD-104	BFD-102	**1000 L Storage** Mobile Cart with load cells.	**1000 L Storage Tote -** Flex Station Mobile Cart	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Accessory to the above unit Moved from UPS mAbs and updated name and description.
B	-	PFD-104	BFD-102	**200** L Jacketed Single-Use Mixer	**200 L Xcellerx XDM** Single-Use Mixer	-	-	**120 @ 60 Hz**	**3**	**4.5A (Max)**	-	-	-	BACK-UP POWER	-	-	-	-	**$145,400**	14-16	**Vendor**	Updated volume, model, dimensions, utility requirements, etc. Total Cost including Kits, SAT, Commissioning, IQOQ, etc. is $245,000.
B	-	PFD-104	BFD-102	**100 L** Storage Tote **- Acid**	**100 L** Storage Tote - **Flex Station PN** (Acid)	-	-	-	-	-	-	-	-	-	-	-	-	-	$8,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-104	BFD-102	Depth Filtration Skid	Depth Filtration Skid - SartoClear Depth Filters	-	-	-	-	-	-	-	-	-	-	-	-	-	$42,000	14-16	**Vendor**	
B	-	PFD-104	BFD-102	**Peristaltic Pump (200 L)**	**Peristaltic Pump**	-	-	-	-	-	-	-	-	-	-	-	-	-	$10,500	-	HISTORY - Consultant Estimate	Added
B	-	PFD-104	BFD-102	200 L Jacketed Single-Use Mixer	**200 L Xcellerx XDM** Single-Use Mixer	-	-	**120 @ 60 Hz**	**3**	**4.5A (Max)**	-	-	-	BACK-UP POWER	-	-	-	-	**$145,400**	14-16	**Vendor**	Updated volume, model, dimensions, utility requirements, etc. Total Cost including Kits, SAT, Commissioning, IQOQ, etc. is $245,000.
B	-	PFD-104	BFD-102	**100 L** Storage Tote **- Base**	**100 L** Storage Tote - **Flex Station PN** (Base)	-	-	-	-	-	-	-	-	-	-	-	-	-	$8,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-105	BFD-102	**Single Use - Storage**	**Flex Station PN - 1000 L**	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	No results when looking for this specific catalog number. Used the model number 'FSB1000TD' as basis. Added
B	-	PFD-105	BFD-102	**Mobile Cart with load cells.**	**Flex Station Mobile Cart - 1000 L**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		Accessory to the above unit. Added
B	-	PFD-105	BFD-102	**Single-Use Chromatogrraphy - AEX**	**AKTA Ready Gradient** Chromatography System - Single Use (including Column Trolley) **- AEX**	-		**100, 120, 200-208, 220-230 or 240 ± 10% @ 60Hz**	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$213,500	4-6	**Vendor**	Added Details to equipment name and description
B	-	PFD-105	BFD-102	200 L Storage Tote **- Equilibrate Buffer**	**200 L** Storage Tote - **Flex Station PN** (Equilbrate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-105	BFD-102	500 L Storage Tote **- Wash Buffer**	500 L Storage Tote **- Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
B	-	PFD-105	BFD-102	500 L Storage Tote **- Regenerate Buffer**	500 L Storage Tote **- Flex Station PN** (Regenerate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
B	-	PFD-105	BFD-102	500 L Storage Tote **- Eluate Buffer**	500 L Storage Tote **- Flex Station PN** (Eluate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
B	-	PFD-105	BFD-102	200 L Storage Tote **- Storage Buffer**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Added Details to equipment name
B	-	PFD-105	BFD-102	200 L Storage Tote **- AWFI**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Added Details to equipment name
B	-	PFD-105	BFD-102	**200 L Storage Tote**	**200 L Storage Tote - Flex Station PN**	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Added

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EQUIPMENT INFORMATION

REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	Area	ROOM	NEW / EXISTING	MFG.	MODEL NUMBER	SPECIFICATION NO.	BID PACKAGE NO.	DIMENSIONS	MAX Weight	FURNISHED BY	INSTALLED BY	FIXED OR PORTABLE
B	-	PFD-105	BFD-102	**Single-Use** Chromatography- **MMC / CEX**	**AKTA Ready Gradient Chromatography System - Single Use (including Column Trolley) - MMC / CEX**	Down Stream 1	2135	NEW	**Cytiva**	**29032038**	-	-	**1160 mm W x 1650 mm D x 800 mm H**	**250 kg**	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote **- Equilibrate Buffer**	**200 L** Storage Tote - **Flex Station PN** (Equilbrate Buffer)	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0200TD**	-	-	**609 mm W x 809 mm D x 833 mm H**	**20 kg (empty)**	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote **- Wash Buffer**	500 L Storage Tote **- Flex Station PN** (Wash Buffer)	Down Stream 1	2135	NEW	**Meissner Filtration**		-	-	**915 mm W x 1200 mm D x 1260 mm H**	**70 kg (empty)**	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote **- Regenerate Buffer**	500 L Storage Tote **- Flex Station PN** (Regenerate Buffer)	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0500TD**	-	-	**915 mm W x 1200 mm D x 1260 mm H**	**70 kg (empty)**	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote **- Eluate Buffer**	500 L Storage Tote **- Flex Station PN** (Eluate Buffer)	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0500TD**	-	-	**915 mm W x 1200 mm D x 1260 mm H**	**70 kg (empty)**	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote **- Storage Buffer**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0200TD**	-	-	**609 mm W x 809 mm D x 833 mm H**	**20 kg (empty)**	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote **- AWFI**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0200TD**	-	-	**609 mm W x 809 mm D x 833 mm H**	**20 kg (empty)**	-	-	-
B	-	PFD-105	BFD-102	**200 L Storage Tote - Eluate Buffer**	**200 L Storage Tote - Flex Station PN** Eluate Buffer	Down Stream 1	2135	NEW	**Meissner Filtration**	**FSB0200TD**	-	-	**609 mm W x 809 mm D x 833 mm H**	**20 kg (empty)**	-	-	-
B	-	PFD-105	BFD-102	Peristaltic Pump (200 L)	Peristaltic Pump	Up Stream	2116	NEW	Watson Marlow	TBD	-	-	TBD	TBD	-	-	-
B	-	PFD-105	BFD-102	Nano Filter	Nano Filter	Down Stream 1	2135	NEW	**Millipore**	**TBD**	-		**TBD**	**TBD**	-	-	-
DSP - 2 mAbs																	
B	-	PFD-106	BFD-103	200 L Storage Tote **- Filtrate**	200 L Storage Tote **- Flex Station PN (Filtrate)**	Down Stream 2 & Bulk Fill	2139	NEW	**Meissner Filtration**	**FSB0200TD**	-	-	**609 mm W x 809 mm D x 833 mm H**	**20 kg (empty)**	-	-	-
B	-	PFD-106	BFD-103	AKTA Readyflux	Tangential Flow Filtration System - Single Use	Down Stream 2 & Bulk Fill	2139	EXISTING	Cytiva	29151000	-	-	1100 mm W x **880 mm D x 1520 mm H**	280 kg	-	-	-
B	-	PFD-106	BFD-103	500 L Storage Tote **- Wash Buffer**	500 L Storage Tote **- Flex Station PN** (Wash Buffer)	Down Stream 2 & Bulk Fill	2139	NEW	**Meissner Filtration**	**FSB0500TD**	-	-	**915 mm W x 1200 mm D x 1260 mm H**	**70 kg (empty)**	-	-	-
B	-	PFD-106	BFD-103	**200** L Storage Tote **- Condition Buffer**	**200 L** Storage Tote **- Flex Station PN** (Condition Buffer)	Down Stream 2 & Bulk Fill	2139	NEW	**Meissner Filtration**	**FSB0200TD**	-	-	**609 mm W x 809 mm D x 833 mm H**	**20 kg (empty)**	-	-	-
B	-	PFD-106	BFD-103	500 L Storage Tote **- Diafilter Buffer**	500 L Storage Tote **- Flex Station PN** (Diafilter Buffer)	Down Stream 2 & Bulk Fill	2139	NEW	**Meissner Filtration**	**FSB0500TD**	-	-	**915 mm W x 1200 mm D x 1260 mm H**	**70 kg (empty)**	-	-	-
B	-	PFD-106	BFD-103	**200 L** Storage Tote **- Storage Buffer**	**200 L** Storage Tote **- Flex Station PN** (Storage Buffer)	Down Stream 2 & Bulk Fill	2139	NEW	**Meissner Filtration**	**FSB0200TD**	-	-	**609 mm W x 809 mm D x 833 mm H**	**20 kg (empty)**	-	-	-
B	-	PFD-106	BFD-103	500 L Storage Tote **- Caustic**	500 L Storage Tote **- Flex Station PN** (Caustic)	Down Stream 2 & Bulk Fill	2139	NEW	**Meissner Filtration**	**FSB0500TD**	-	-	**915 mm W x 1200 mm D x 1260 mm H**	**70 kg (empty)**	-	-	-
B	-	PFD-106	BFD-103	**500 L** Storage Tote **- AWFI**	**500 L** Storage Tote **- Flex Station PN** (AWFI)	Down Stream 2 & Bulk Fill	2139	NEW	**Meissner Filtration**	**FSB0500TD**	-	-	**915 mm W x 1200 mm D x 1260 mm H**	**70 kg (empty)**	-	-	-
B	-	PFD-106	BFD-103	**200 L** Jacketed Single-Use Mixer	**200 L Xcellerx XDM** Single-Use Mixer **- Concentration Adjustment**	Down Stream 2 & Bulk Fill	2139	NEW	**Cytiva**	**29054862**	-	-	**1140 mm W x 1000 mm D x 1120 mm H (with I/O Panel)**	**200 kg (440 lbs)**	-	-	-
B	-	PFD-106	BFD-103	200 L Storage Tote **- AWFI**	200 L Storage Tote **- Flex Station PN** (AWFI)	Down Stream 2 & Bulk Fill	2139	NEW	**Meissner Filtration**	**FSB0500TD**	-	-	**915 mm W x 1200 mm D x 1260 mm H**	**70 kg (empty)**	-	-	-
B	-	PFD-107	BFD-103	0.2 Micron Filter	0.2 Micron Filter	Down Stream 2 & Bulk Fill	2139	NEW	Pall	TBD	-	-	TBD	TBD	-	-	-
B	-	PFD-107	BFD-103	Peristaltic Pump (200 L)	Peristaltic Pump	Down Stream 2 & Bulk Fill	2139	NEW	Watson Marlow	TBD	-	-	TBD	TBD	-	-	-
VV																	
B	-	PFD-201 PFD-202	BFD-201	-80°C Freezer - 2	-80°C Ultra-Low Freezer	Viral Vector	2108	EXISTING	Fisher Scientific	TSX60086A	-	-	1006 mm W x 955 mm D x 1981 mm H	358 kg	-	-	-
B	-	PFD-201 PFD-202	BFD-201	Biosafety Cabinet	Class II, Type A2 6 ft Biological Safety Cabinet	Viral Vector	2108	EXISTING	Fisher Scientific	Model - 1377 Catalog - 13261223	-	-	1900 mm W x 800 mm D x 1568 mm H	280 kg (Cabinet) 30.0 kg (Stand)	-	-	-
B	-	PFD-201 PFD-202	BFD-201	**Cryogenic Tank**	**Cryogenic Tank - Cryoplus 3 340 L Load**	Viral Vector	2108	NEW	**Fisher Scientific**	**7404**	-	-	**876 mm W x 1054 mm D x 1041 mm H**	**249 kg (550 lbs)**	-	-	-
B	-	PFD-201 PFD-202	BFD-201	Shaker Incubator	**ISF1-Z**-Shaker Incubator	Viral Vector	2108	NEW	Kuhner Shaker	**SMZ1500**	-	-	**1288 mm W x 854 mm D x** 771 mm H	**200 kg**	-	-	-
B	-	PFD-203	BFD-201	50 L Bioreactor	XDR50 GRAV Bioreactor RePurpos, TCU Included - Single Use	Viral Vector	2108	NEW	Cytiva	Model - XDR50L Catalog - 29649820	-	-	**1466 mm W x 1070 mm D** x 2210 mm H **Weight X-Station: 601 mm W x 797 mm D x 1466 mm H TCU: 483 mm W x 661 mm D x 775 mm H**	**468 kg (empty) X-Station: 146 kg TCU: 146 kg**	-	-	-
B	-	PFD-203	BFD-201	**100 L Storage Tote**	**100 L Storage Tote - Flex Station PN**	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-203	BFD-201	**100 L** Storage Tote **- Media** 1	**100 L** Storage Tote - **Flex Station PN** (Media 1)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-203	BFD-201	**100 L** Storage Tote **- Media** 2	**100 L** Storage Tote - **Flex Station PN** (Media 2)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-203	BFD-201	**100 L** Storage Tote **- Base**	**100 L** Storage Tote **- Flex Station PN** (Base)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-203	BFD-101	Depth Filtration Skid	Depth Filtration Skid - SartoClear Depth Filters	Viral Vector	2108	NEW	Sartorius	2ZGL--0006	-	-	2300 mm W x 930 mm D x 910 mm H	50 kg	-	-	-
B	-	PFD-203	BFD-201	**50 L** Jacketed **Single-Use Mixer - Clarified Broth**	**50 L Xcellerx XDM Single-Use Mixer - Clarified Broth**	Viral Vector	2108	NEW	**Cytiva**	**29054862**	-	-	**740 mm W x 530 mm D x 1090 mm H**	**85 kg**	-	-	-
B	-	PFD-203	BFD-201	Peristaltic Pump (50 L)	Peristaltic Pump	Viral Vector	2108	NEW	Watson Marlow	TBD	-	-	TBD	TBD	-	-	-
B	-	PFD-203	BFD-201	**Peristaltic Pump (200 L)**	**Peristaltic Pump**	Viral Vector	2108	NEW	**Watson Marlow**	**TBD**	-	-	**TBD**	**TBD**	-	-	-

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						PROCESS UTILITIES																											
						HOT WFI HWFI		PURIFIED WATER PW		CIP		CLEAN STEAM CS		CLEAN STEAM CONDENSATE CSC		NITROGEN N_2			OXYGEN O_2			CABRON DIOXIDE CO_2			PROCESS AIR CCA			INSTRUMENT AIR IA			HEAT XFER FLUID (S/R)	
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	LPM	PSIG	LPM	PSIG	LPM	PSIG	kg/h	PSIG	kg/h	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	GPM	PSIG
B	-	PFD-105	BFD-102	**Single-Use** Chromatography- **MMC / CEX**	**AKTA Ready Gradient Chromatography System - Single Use (including Column Trolley) - MMC / CEX**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**1.77**	**79.8 - 101.5**	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote **- Equilibrate Buffer**	**200 L** Storage Tote - **Flex Station PN** (Equilbrate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote **- Wash Buffer**	500 L Storage Tote **- Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote **- Regenerate Buffer**	500 L Storage Tote **- Flex Station PN** (Regenerate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote **- Eluate Buffer**	500 L Storage Tote **- Flex Station PN** (Eluate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote **- Storage Buffer**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote **- AWFI**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	**200 L Storage Tote - Eluate Buffer**	**200 L Storage Tote - Flex Station PN** Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	Peristaltic Pump (200 L)	Peristaltic Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	Nano Filter	Nano Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DSP - 2 mAbs																																	
B	-	PFD-106	BFD-103	200 L Storage Tote **- Filtrate**	200 L Storage Tote **- Flex Station PN (Filtrate)**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-106	BFD-103	AKTA Readyflux	Tangential Flow Filtration System - Single Use	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**1.77**	**79.8 - 101.5**	-	-
B	-	PFD-106	BFD-103	500 L Storage Tote **- Wash Buffer**	500 L Storage Tote **- Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-106	BFD-103	**200** L Storage Tote **- Condition Buffer**	**200 L** Storage Tote **- Flex Station PN** (Condition Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-106	BFD-103	500 L Storage Tote **- Diafilter Buffer**	500 L Storage Tote **- Flex Station PN** (Diafilter Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-106	BFD-103	**200 L** Storage Tote **- Storage Buffer**	**200 L** Storage Tote **- Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-106	BFD-103	500 L Storage Tote **- Caustic**	500 L Storage Tote **- Flex Station PN** (Caustic)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-106	BFD-103	**500 L** Storage Tote **- AWFI**	**500 L** Storage Tote **- Flex Station PN** (AWFI)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-106	BFD-103	**200 L** Jacketed Single-Use Mixer	**200 L Xcellerx XDM** Single-Use Mixer **- Concentration Adjustment**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-106	BFD-103	200 L Storage Tote **- AWFI**	200 L Storage Tote **- Flex Station PN** (AWFI)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-107	BFD-103	0.2 Micron Filter	0.2 Micron Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-107	BFD-103	Peristaltic Pump (200 L)	Peristaltic Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
VV																																	
B	-	PFD-201 PFD-202	BFD-201	-80^{0}C Freezer - 2	-80^{0}C Ultra-Low Freezer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-201 PFD-202	BFD-201	Biosafety Cabinet	Class II, Type A2 6 ft Biological Safety Cabinet	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-201 PFD-202	BFD-201	**Cryogenic Tank**	**Cryogenic Tank - Cryoplus 3 340 L Load**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-201 PFD-202	BFD-201	Shaker Incubator	**ISF1-Z**-Shaker Incubator	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**8.9**	-	**29 max**	-	-	-	-	-	-	-	-
B	-	PFD-203	BFD-201	50 L Bioreactor	XDR50 GRAV Bioreactor RePurpos, TCU Included - Single Use	-	-	-	-	-	-	-	-	-	-	-	-	-	**11.96**	-	**44**	**11.96**	-	**44**	**11.96**	-	**44**	**11.96**	-	**44**	-	-
B	-	PFD-203	BFD-201	**100 L Storage Tote**	**100 L Storage Tote - Flex Station PN**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-203	BFD-201	**100 L** Storage Tote **- Media** 1	**100 L** Storage Tote - **Flex Station PN** (Media 1)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-203	BFD-201	**100 L** Storage Tote **- Media** 2	**100 L** Storage Tote - **Flex Station PN** (Media 2)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-203	BFD-201	**100 L** Storage Tote **- Base**	**100 L** Storage Tote **- Flex Station PN** (Base)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-203	BFD-101	Depth Filtration Skid	Depth Filtration Skid - SartoClear Depth Filters	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-203	BFD-201	**50 L** Jacketed **Single-Use Mixer - Clarified Broth**	**50 L Xcellerx XDM Single-Use Mixer - Clarified Broth**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-203	BFD-201	Peristaltic Pump (50 L)	Peristaltic Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-203	BFD-201	**Peristaltic Pump (200 L)**	**Peristaltic Pump**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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						PLANT UTILITES																					AUTOMATION		
						PLANT STEAM PS		PLANT STEAM CONDENSATE		DOMESTIC COLD WATER (T=60°F) CW		PROCESS CHILLED WATER PCHWS/R		RELIEF VENT PV			INTAKE AIR	EXHAUST			SANITARY SEWER SAN		PROCESS WASTE PW		BIOWASTE BIOD		HEAT LOAD			
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	kg/h	PSIG	kg/h	PSIG	LPM	PSIG	LPM	PSIG	SCFM	CFM	PSIG	SCFM	SCFM	CFM	PSIG	LPM	PSIG	LPM	PSIG	LPM	PSIG	kW	CONTROL (OEM, PCS, BAS, N/A)	QUANTITY	BMS or SCADA
B	-	PFD-105	BFD-102	**Single-Use** Chromatography- **MMC / CEX**	**AKTA Ready Gradient Chromatography System - Single Use (including Column Trolley) - MMC / CEX**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote - **Equilibrate Buffer**	**200 L** Storage Tote - **Flex Station PN** (Equilibrate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote - **Wash Buffer**	500 L Storage Tote - **Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote - **Regenerate Buffer**	500 L Storage Tote - **Flex Station PN** (Regenerate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	500 L Storage Tote - **Eluate Buffer**	500 L Storage Tote - **Flex Station PN** (Eluate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote - **Storage Buffer**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	200 L Storage Tote - **AWFI**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	**200 L Storage Tote - Eluate Buffer**	**200 L Storage Tote - Flex Station PN** Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	Peristaltic Pump (200 L)	Peristaltic Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-105	BFD-102	Nano Filter	Nano Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DSP - 2 mAbs																														
B	-	PFD-106	BFD-103	200 L Storage Tote - **Filtrate**	200 L Storage Tote - **Flex Station PN (Filtrate)**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-106	BFD-103	AKTA Readyflux	Tangential Flow Filtration System - Single Use	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-106	BFD-103	500 L Storage Tote - **Wash Buffer**	500 L Storage Tote - **Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-106	BFD-103	**200** L Storage Tote - **Condition Buffer**	**200 L** Storage Tote - **Flex Station PN** (Condition Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-106	BFD-103	500 L Storage Tote - **Diafilter Buffer**	500 L Storage Tote - **Flex Station PN** (Diafilter Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-106	BFD-103	**200 L** Storage Tote - **Storage Buffer**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-106	BFD-103	500 L Storage Tote - **Caustic**	500 L Storage Tote - **Flex Station PN** (Caustic)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-106	BFD-103	**500 L** Storage Tote - **AWFI**	**500 L** Storage Tote - **Flex Station PN** (AWFI)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-106	BFD-103	**200 L** Jacketed Single-Use Mixer	**200 L Xcellerx XDM** Single-Use Mixer **- Concentration Adjustment**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-106	BFD-103	200 L Storage Tote - **AWFI**	200 L Storage Tote - **Flex Station PN** (AWFI)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-107	BFD-103	0.2 Micron Filter	0.2 Micron Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-107	BFD-103	Peristaltic Pump (200 L)	Peristaltic Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
VV																														
B	-	PFD-201 PFD-202	BFD-201	-80^{0}C Freezer - 2	-80^{0}C Ultra-Low Freezer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-201 PFD-202	BFD-201	Biosafety Cabinet	Class II, Type A2 6 ft Biological Safety Cabinet	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-201 PFD-202	BFD-201	**Cryogenic Tank**	**Cryogenic Tank - Cryoplus 3 340 L Load**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-201 PFD-202	BFD-201	Shaker Incubator	**ISF1-Z**-Shaker Incubator	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-203	BFD-201	50 L Bioreactor	XDR50 GRAV Bioreactor RePurpos, TCU Included - Single Use	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-203	BFD-201	**100 L Storage Tote**	**100 L Storage Tote - Flex Station PN**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-203	BFD-201	**100 L** Storage Tote - **Media** 1	**100 L** Storage Tote - **Flex Station PN** (Media 1)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-203	BFD-201	**100 L** Storage Tote - **Media** 2	**100 L** Storage Tote - **Flex Station PN** (Media 2)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-203	BFD-201	**100 L** Storage Tote - **Base**	**100 L** Storage Tote - **Flex Station PN** (Base)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-203	BFD-101	Depth Filtration Skid	Depth Filtration Skid - SartoClear Depth Filters	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-203	BFD-201	**50 L** Jacketed **Single-Use Mixer - Clarified Broth**	**50 L Xcellerx XDM Single-Use Mixer - Clarified Broth**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-203	BFD-201	Peristaltic Pump (50 L)	Peristaltic Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-203	BFD-201	**Peristaltic Pump (200 L)**	**Peristaltic Pump**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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						ELECTRICAL																
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	ELECTRICAL DESCRIPTION	HP	VOLTAGE	PHASE	AMPS	KVA	FIELD CONNECTION	CLASS OF POWER	BACK-UP POWER / UPS	DATA INTEGRATION (PCS, MES, BAS, EMS, N/A)	UNIT COST	QUANTITY	INSTALLATION FACTOR	ESTIMATED TOTAL COST	LEAD TIME (WEEKS ARO)	ESTIMATION SOURCE	NOTES
B	-	PFD-105	BFD-102	**Single-Use** Chromatography- **MMC / CEX**	**AKTA Ready Gradient Chromatography System - Single Use (including Column Trolley) - MMC / CEX**	-		**100, 120, 200-208, 220-230 or 240 ± 10% @ 60Hz**	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$213,500	4-6	**Vendor**	Updated model, equipment name and description
B	-	PFD-105	BFD-102	200 L Storage Tote **- Equilibrate Buffer**	**200 L** Storage Tote - **Flex Station PN** (Equilbrate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-105	BFD-102	500 L Storage Tote **- Wash Buffer**	500 L Storage Tote **- Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
B	-	PFD-105	BFD-102	500 L Storage Tote **- Regenerate Buffer**	500 L Storage Tote **- Flex Station PN** (Regenerate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
B	-	PFD-105	BFD-102	500 L Storage Tote **- Eluate Buffer**	500 L Storage Tote **- Flex Station PN** (Eluate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
B	-	PFD-105	BFD-102	200 L Storage Tote **- Storage Buffer**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Added Details to equipment name
B	-	PFD-105	BFD-102	200 L Storage Tote **- AWFI**	**200 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Added Details to equipment name
B	-	PFD-105	BFD-102	**200 L Storage Tote - Eluate Buffer**	**200 L Storage Tote - Flex Station PN** Eluate Buffer	-	-	-	-	-	-	-	-	-	-	-	-	-	**$8,000**	**18-22**	HISTORY - Consultant Estimate	Added
B	-	PFD-105	BFD-102	Peristaltic Pump (200 L)	Peristaltic Pump	-	-	**TBD**	**TBD**	-	-	-	-	BACK-UP POWER	-	-	-	-	$10,500	-	HISTORY - Consultant Estimate	
B	-	PFD-105	BFD-102	Nano Filter	Nano Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	TBD	TBD	TBD	
DSP - 2 mAbs																						
B	-	PFD-106	BFD-103	200 L Storage Tote **- Filtrate**	200 L Storage Tote **- Flex Station PN (Filtrate)**	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated Model, equipment name and description
B	-	PFD-106	BFD-103	AKTA Readyflux	Tangential Flow Filtration System - Single Use	-	-	**100-240 @60Hz**	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	**$238,000**	14-18	**Vendor**	Updated Utility Requirements, Cost Cost is base. Including Commissioning, etc. Total is $361,000. Included Optional Items are included in quote.
B	-	PFD-106	BFD-103	500 L Storage Tote **- Wash Buffer**	500 L Storage Tote **- Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
B	-	PFD-106	BFD-103	**200 L** Storage Tote **- Condition Buffer**	**200 L** Storage Tote **- Flex Station PN** (Condition Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-106	BFD-103	500 L Storage Tote **- Diafilter Buffer**	500 L Storage Tote **- Flex Station PN** (Diafilter Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
B	-	PFD-106	BFD-103	**200 L** Storage Tote **- Storage Buffer**	**200 L** Storage Tote **- Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-106	BFD-103	500 L Storage Tote **- Caustic**	500 L Storage Tote **- Flex Station PN** (Caustic)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
B	-	PFD-106	BFD-103	**500 L** Storage Tote **- AWFI**	**500 L** Storage Tote **- Flex Station PN** (AWFI)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
B	-	PFD-106	BFD-103	**200 L** Jacketed Single-Use Mixer	**200 L Xcellerx XDM** Single-Use Mixer **- Concentration Adjustment**	-	-	**120 @ 60 Hz**	1	**4.5A (Max)**	-	-	-	BACK-UP POWER	-	-	-	-	**$145,400**	14-16	**Vendor**	Updated volume, model, dimensions, utility requirements, etc. Total Cost including Kits, SAT, Commissioning, IQOQ, etc. is $216,700.
B	-	PFD-106	BFD-103	200 L Storage Tote **- AWFI**	200 L Storage Tote **- Flex Station PN** (AWFI)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Update Model. Added Details to equipment name
B	-	PFD-107	BFD-103	0.2 Micron Filter	0.2 Micron Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	HISTORY - Consultant Estimate	
B	-	PFD-107	BFD-103	Peristaltic Pump (200 L)	Peristaltic Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	$10,500	-	HISTORY - Consultant Estimate	
VV																						
B	-	PFD-201 PFD-202	BFD-201	-80°C Freezer - 2	-80°C Ultra-Low Freezer	-	-	**115 @ 60 Hz**	-	**9.5**	-	-	-	BACK-UP POWER	-	-	-	-	**$23,190**	**4**	**Vendor**	
B	-	PFD-201 PFD-202	BFD-201	Biosafety Cabinet	Class II, Type A2 6 ft Biological Safety Cabinet	-	-	**120 @ 60 Hz**	-	-	-	-	-	UPS	-	-	-	-	**$17,500**	**18-24**	**Vendor**	
B	-	PFD-201 PFD-202	BFD-201	**Cryogenic Tank**	**Cryogenic Tank - Cryoplus 3 340 L Load**	-	-	**115 @ 60 Hz**	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$20,000	25-29	**Vendor**	Added
B	-	PFD-201 PFD-202	BFD-201	Shaker Incubator	**ISF1-Z**-Shaker Incubator	-	-	**120 @ 60 Hz**	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$29,700	13-17	**Vendor**	New Generation model
B	-	PFD-203	BFD-201	50 L Bioreactor	XDR50 GRAV Bioreactor RePurpos, TCU Included - Single Use	-	-	**110 ± 10% @ 60Hz TCU: 460 V @ 60 Hz**	**1 3**	**14 18**	-	-	-	**Back-Up + UPS: X-Station: 110 ± 10% @ 60Hz 1 Ph, 2.9A**	-	-	-	-	**$270,000**	20-24	**Vendor**	Updated Utility requirements, dimensions and weight. These do NOT include TCY requirements. Price is base unit price. Total with TCU, SAT, Commissioning, IQOQ, etc. is 368,000. No results when looking for this specific catalog number.
B	-	PFD-203	BFD-201	**100 L Storage Tote**	**100 L Storage Tote - Flex Station PN**	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Added
B	-	PFD-203	BFD-201	**100 L** Storage Tote **- Media** 1	**100 L** Storage Tote - **Flex Station PN** (Media 1)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-203	BFD-201	**100 L** Storage Tote **- Media** 2	**100 L** Storage Tote - **Flex Station PN** (Media 2)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-203	BFD-201	**100 L** Storage Tote **- Base**	**100 L** Storage Tote **- Flex Station PN** (Base)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-203	BFD-101	Depth Filtration Skid	Depth Filtration Skid - SartoClear Depth Filters	-	-	-	-	-	-	-	-	-	-	-	-	-	$42,000	14-16	**Vendor**	
B	-	PFD-203	BFD-201	**50 L** Jacketed **Single-Use Mixer - Clarified Broth**	**50 L Xcellerx XDM Single-Use Mixer - Clarified Broth**	-	-	**120 @ 60 Hz**	**1**	**4.5 (max)**	-	-	-	BACK-UP POWER	-	-	-	-	$74,000	14-16	**Vendor**	Updated volume, model, dimensions, utility requirements, etc.
B	-	PFD-203	BFD-201	Peristaltic Pump (50 L)	Peristaltic Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	$10,500	-	HISTORY - Consultant Estimate	
B	-	PFD-203	BFD-201	**Peristaltic Pump (200 L)**	**Peristaltic Pump**	-	-	-	-	-	-	-	-	-	-	-	-	-	$10,500	-	HISTORY - Consultant Estimate	Added

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EQUIPMENT INFORMATION																	
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	Area	ROOM	NEW / EXISTING	MFG.	MODEL NUMBER	SPECIFICATION NO.	BID PACKAGE NO.	DIMENSIONS	MAX Weight	FURNISHED BY	INSTALLED BY	FIXED OR PORTABLE
B	-	PFD-204	BFD-202	**Single-Use** Chromatography- **AEX**	**AKTA Ready Gradient Chromatography System - Single Use (including Column Trolley) - AEX**	Viral Vector	2108	NEW	**Cytiva**	**29032038**	-	-	**1160 mm W x 1650 mm D x 800 mm H**	**250 kg**	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Equilibrate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Equilbrate Buffer)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Wash Buffer**	**100 L** Storage Tote - **Flex Station PN** (Wash Buffer)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Regenerate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Regenerate Buffer)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Eluate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Eluate Buffer)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Storage Buffer**	**100 L** Storage Tote - **Flex Station PN** (Storage Buffer)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- AWFI**	**100 L** Storage Tote - **Flex Station PN** (AWFI)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-204	BFD-202	**100 L Storage Tote**	**100 L Storage Tote - Flex Station PN**	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-204	BFD-202	**Single-Use** Chromatography- **MMC**	**AKTA Ready Gradient Chromatography System - Single Use (including Column Trolley) - MMC**	Viral Vector	2108	NEW	**Cytiva**	**29032038**	-	-	**1160 mm W x 1650 mm D x 800 mm H**	**250 kg**	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Equilibrate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Equilbrate Buffer)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Wash Buffer**	**100 L** Storage Tote - **Flex Station PN** (Wash Buffer)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Regenerate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Regenerate Buffer)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Eluate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Eluate Buffer)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Storage Buffer**	**100 L** Storage Tote - **Flex Station PN** (Storage Buffer)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- AWFI**	**100 L** Storage Tote - **Flex Station PN** (AWFI)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-205	BFD-202	Peristaltic Pump (200 L)	Peristaltic Pump	Up Stream	2116	NEW	Watson Marlow	TBD	-	-	TBD	TBD	-	-	-
B	-	PFD-205	BFD-202	Nano Filter	Nano Filter	Down Stream 1	2135	NEW	**Millipore**	**TBD**	-		**TBD**	**TBD**	-	-	-
B	-	PFD-205	BFD-202	**100 L Storage Tote - Filtrate**	**100 L** Storage Tote - **Flex Station PN (Filtrate)**	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-205	BFD-202	AKTA Flux 6 (TFF System)	Flux Tangential Flow Filtration System - Single Use	Viral Vector	2108	EXISTING	Cytiva	29-0384-38	-	-	640 mm W x 470 mm L x 720 mm H	53 kg	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote **- Wash Buffer**	**100 L** Storage Tote - **Flex Station PN** (Wash Buffer)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote **- Condition Buffer**	**100 L** Storage Tote - **Flex Station PN** (Condition Buffer)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote **- Diafilter Buffer**	**100 L** Storage Tote - **Flex Station PN** (Diafilter Buffer)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote **- Storage Buffer**	**100 L** Storage Tote - **Flex Station PN** (Storage Buffer)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote **- Caustic**	**100 L** Storage Tote - **Flex Station PN** (Caustic)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote **- AWFI**	**100 L** Storage Tote - **Flex Station PN** (AWFI)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-205	BFD-202	50 L Jacketed Single-Use Mixer	50 L **Xcellerx XDM** Single-Use Mixer - Concentration Adjustment	Viral Vector	2108	NEW	**Cytiva**	**29054862**	-	-	**740 mm W x 530 mm D x 1090 mm H**	**85 kg**	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote **- AWFI**	**100 L** Storage Tote - **Flex Station PN** (AWFI)	Viral Vector	2108	NEW	**Meissner Filtration**	**FSB0100FB**	-	-	**609 mm W x 809 mm D x 833 mm H**	**30 kg**	-	-	-
B	-	PFD-206	BFD-202	0.2 Micron Filter	0.2 Micron Filter	Viral Vector	2108	NEW	Pall	TBD	-	-	TBD	TBD	-	-	-
B	-	PFD-206	BFD-202	**Peristaltic Pump (50 L)**	**Peristaltic Pump**	Viral Vector	2108	NEW	**Watson Marlow**	**TBD**	-	-	**TBD**	**TBD**	-	-	-
MWS																	
B	-	-	-	Parts Washer	**Reliance®280 PG Pharmaceutical Grade Washer**	Component Prep	2102	NEW	**Steris**	**Reliance 280PG**	-	-	**1353 mm W x 813 mm L x 231 mm H**	**894 kg (shipping0 880 kg (operating)**	-	-	-
B	-	-	-	Sterilization Autoclave	**Finn-Aqua GMP Bio Pharma Sterilizer (BPS)**	Sterile Prep	2103	NEW	Steris	**BPS6912**	-	-	**2320 mm W x 1742 mm D x 1950 mm H**	**1044 kg (installation) 1315 kg (Full Chamber)**	-	-	-
B	-	-	-	Decon Autoclave	**Finn-Aqua GMP Bio Pharma Sterilizer (BPS)**	Mech.	2107	NEW	Steris	**BPS6912**	-	-	**2320 mm W x 1742 mm D x 1950 mm H**	**1044 kg (installation) 1315 kg (Full Chamber)**	-	-	-
B	-	-	-	Floor Scale	Floor Scale	-	-	EXISTING	Rice Lake	Model - BSP Catalog - SPX48501 (Custom Made)	-	-	TBD	TBD	-	-	-
B	-	-	-	**500 L** Jacketed **Single-Use Mixer**	**500 L Xcellerx XDM Single-Use Mixer**	Media Buffer Prep	2119	NEW	**Cytiva**	**29054862**	-	-	**1350 mm W x 1200 mm D x 1480 mm H (with I/O Panel)**	**315 kg (690 lb)**	-	-	-
B	-	-	-	**500 L** Jacketed **Single-Use Mixer**	**500 L Xcellerx XDM Single-Use Mixer**	Media Buffer Prep	2119	NEW	**Cytiva**	**29054862**	-	-	**1350 mm W x 1200 mm D x 1480 mm H (with I/O Panel)**	**315 kg (690 lb)**	-	-	-
B	-	-	-	**500 L** Jacketed **Single-Use Mixer**	**500 L Xcellerx XDM Single-Use Mixer**	Media Buffer Prep	2119	NEW	**Cytiva**	**29054862**	-	-	**1350 mm W x 1200 mm D x 1480 mm H (with I/O Panel)**	**315 kg (690 lb)**	-	-	-
B	-	-	-	**50 L** Jacketed **Single-Use Mixer**	**50 L Xcellerx XDM Single-Use Mixer**	Media Buffer Prep	2119	NEW	**Cytiva**	**29054862**	-	-	**740 mm W x 530 mm D x 1090 mm H**	**85 kg**	-	-	-
B	-	-	-	**50 L** Jacketed **Single-Use Mixer**	**50 L Xcellerx XDM Single-Use Mixer**	Media Buffer Prep	2119	NEW	**Cytiva**	**29054862**	-	-	**740 mm W x 530 mm D x 1090 mm H**	**85 kg**	-	-	-
B	-	-	-	**Fume Hood - Extraction Booth**	**FumeGard Conventional Fume Hood**	-	-	NEW	**Fisher Scientific**	**F-100-48G7 60000580**	-	-	**1219 mm W x 911 mm D x 1451 mm H**	**TBD**	-	-	-
Utilities																	
B	-	-	-	CS Generation Skid	CS Generation Skid **(300 kg/hr @ ~45 psig)**	Clean Utilities	1134	TBD	**Stilmas**	**Pre-Treatment: 4400C Generation: PSG 300 DTS**	-	-	**Pre-Treatment: 966 mm L x 737 mm W x 2045 mm H Generation: 1130 m L x 11500 mm W x 2900 mm H**	**Pre-Treatment: 200 kg (full) Generation: 480 kg (empty) 775 kg (full)**	-	-	-
B	-	-	-	CS Distribution Skid	CS Distribution Skid	Clean Utilities	1134	TBD	TBD	TBD	-	-	TBD	TBD	-	-	-
B	-	-	-	Water Softener System	Water Softener + 2 Carbon Filters	Clean Utilities	1134	TBD	**Stilmas**	**Water Softner: TAFS-150P Carbon Filter: TAFC-1465**	-	-	**Water Softner: 18" Dia x 65" H Carbon Filter: 14" Dia x 65" H**	-	-	-	-
B	-	-	-	WFI Generation Skid	WFI Generation Skid **(1000 Lbs/hr capacity)**	Clean Utilities	1134	TBD	**Stilmas**	**BD 1000**	-	-	**3200 mm L x 1500 mm W x 2400 mm H**	**2640 kg (empty) 4300 kg (full)**	-	-	-

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						PROCESS UTILITIES																									
						HOT WFI HWFI		PURIFIED WATER PW		CIP		CLEAN STEAM CS		CLEAN STEAM CONDENSATE CSC		NITROGEN N_2			OXYGEN O_2			CABRON DIOXIDE CO_2			PROCESS AIR CCA			INSTRUMENT AIR IA			HEAT XFER FLUID (S/R)	
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	LPM	PSIG	LPM	PSIG	LPM	PSIG	kg/h	PSIG	kg/h	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	GPM	PSIG
B	-	PFD-204	BFD-202	**Single-Use** Chromatography- **AEX**	**AKTA Ready Gradient Chromatography System - Single Use (including Column Trolley) - AEX**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**1.77**	**79.8 - 101.5**	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Equilibrate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Equilbrate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Wash Buffer**	**100 L** Storage Tote - **Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Regenerate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Regenerate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Eluate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Eluate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Storage Buffer**	**100 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **AWFI**	**100 L** Storage Tote - **Flex Station PN** (AWFI)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L Storage Tote**	**100 L Storage Tote - Flex Station PN**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**Single-Use** Chromatography- **MMC**	**AKTA Ready Gradient Chromatography System - Single Use (including Column Trolley) - MMC**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**1.77**	**79.8 - 101.5**	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Equilibrate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Equilbrate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Wash Buffer**	**100 L** Storage Tote - **Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Regenerate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Regenerate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Eluate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Eluate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Storage Buffer**	**100 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **AWFI**	**100 L** Storage Tote - **Flex Station PN** (AWFI)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	Peristaltic Pump (200 L)	Peristaltic Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	Nano Filter	Nano Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	**100 L Storage Tote - Filtrate**	**100 L** Storage Tote - **Flex Station PN (Filtrate)**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	AKTA Flux 6 (TFF System)	Flux Tangential Flow Filtration System - Single Use	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote - **Wash Buffer**	**100 L** Storage Tote - **Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote - **Condition Buffer**	**100 L** Storage Tote - **Flex Station PN** (Condition Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote - **Diafilter Buffer**	**100 L** Storage Tote - **Flex Station PN** (Diafilter Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote - **Storage Buffer**	**100 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote - **Caustic**	**100 L** Storage Tote - **Flex Station PN** (Caustic)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote - **AWFI**	**100 L** Storage Tote - **Flex Station PN** (AWFI)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	50 L Jacketed Single-Use Mixer	50 L **Xcellerx XDM** Single-Use Mixer - Concentration Adjustment	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote - **AWFI**	**100 L** Storage Tote - **Flex Station PN** (AWFI)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-206	BFD-202	0.2 Micron Filter	0.2 Micron Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-206	BFD-202	**Peristaltic Pump (50 L)**	**Peristaltic Pump**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
MWS																																
B	-	-	-	Parts Washer	**Reliance®280 PG Pharmaceutical Grade Washer**	-	-	-	-	-	-	47	-	-	-	-	-	-	-	-	-	-	-	-	32	-	90	-	-	-	-	-
B	-	-	-	Sterilization Autoclave	**Finn-Aqua GMP Bio Pharma Sterilizer (BPS)**	-	-	-	-	-	-	238	40-44	-	-	-	-	-	-	-	-	-	-	-	57	-	77-120	-	-	-	-	-
B	-	-	-	Decon Autoclave	**Finn-Aqua GMP Bio Pharma Sterilizer (BPS)**	-	-	-	-	-	-	238	40-44	-	-	-	-	-	-	-	-	-	-	-	57	-	77-120	-	-	-	-	-
B	-	-	-	Floor Scale	Floor Scale	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	**500 L** Jacketed **Single-Use Mixer**	**500 L Xcellerx XDM Single-Use Mixer**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	**500 L** Jacketed **Single-Use Mixer**	**500 L Xcellerx XDM Single-Use Mixer**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	**500 L** Jacketed **Single-Use Mixer**	**500 L Xcellerx XDM Single-Use Mixer**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	**50 L** Jacketed **Single-Use Mixer**	**50 L Xcellerx XDM Single-Use Mixer**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	**50 L** Jacketed **Single-Use Mixer**	**50 L Xcellerx XDM Single-Use Mixer**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	**Fume Hood - Extraction Booth**	**FumeGard Conventional Fume Hood**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Utilities																																
B	-	-	-	CS Generation Skid	CS Generation Skid **(300 kg/hr @ ~45 psig)**	5.5	29	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0.03	116	-	-	-	-	-
B	-	-	-	CS Distribution Skid	CS Distribution Skid	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Water Softener System	Water Softener + 2 Carbon Filters	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	WFI Generation Skid	WFI Generation Skid **(1000 Lbs/hr capacity)**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**0.03**	**116**	-	-	-	-	-

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						PLANT UTILITES																					AUTOMATION		
						PLANT STEAM PS		PLANT STEAM CONDENSATE		DOMESTIC COLD WATER (T=60°F) CW		PROCESS CHILLED WATER PCHWS/R		RELIEF VENT PV			INTAKE AIR	EXHAUST			SANITARY SEWER SAN		PROCESS WASTE PW		BIOWASTE BIOD		HEAT LOAD			
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	kg/h	PSIG	kg/h	PSIG	LPM	PSIG	LPM	PSIG	SCFM	CFM	PSIG	SCFM	SCFM	CFM	PSIG	LPM	PSIG	LPM	PSIG	LPM	PSIG	kW	CONTROL (OEM, PCS, BAS, N/A)	QUANTITY	BMS or SCADA
B	-	PFD-204	BFD-202	**Single-Use** Chromatography- **AEX**	**AKTA Ready Gradient Chromatography System - Single Use (including Column Trolley) - AEX**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Equilibrate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Equilbrate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Wash Buffer**	**100 L** Storage Tote - **Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Regenerate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Regenerate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Eluate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Eluate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Storage Buffer**	**100 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **AWFI**	**100 L** Storage Tote - **Flex Station PN** (AWFI)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L Storage Tote**	**100 L Storage Tote - Flex Station PN**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**Single-Use** Chromatography- **MMC**	**AKTA Ready Gradient Chromatography System - Single Use (including Column Trolley) - MMC**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Equilibrate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Equilbrate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Wash Buffer**	**100 L** Storage Tote - **Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Regenerate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Regenerate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Eluate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Eluate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **Storage Buffer**	**100 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-204	BFD-202	**100 L** Storage Tote - **AWFI**	**100 L** Storage Tote - **Flex Station PN** (AWFI)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	Peristaltic Pump (200 L)	Peristaltic Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	Nano Filter	Nano Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	**100 L Storage Tote - Filtrate**	**100 L** Storage Tote - **Flex Station PN (Filtrate)**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	AKTA Flux 6 (TFF System)	Flux Tangential Flow Filtration System - Single Use	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote - **Wash Buffer**	**100 L** Storage Tote - **Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote - **Condition Buffer**	**100 L** Storage Tote - **Flex Station PN** (Condition Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote - **Diafilter Buffer**	**100 L** Storage Tote - **Flex Station PN** (Diafilter Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote - **Storage Buffer**	**100 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote - **Caustic**	**100 L** Storage Tote - **Flex Station PN** (Caustic)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote - **AWFI**	**100 L** Storage Tote - **Flex Station PN** (AWFI)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	50 L Jacketed Single-Use Mixer	50 L **Xcellerx XDM** Single-Use Mixer - Concentration Adjustment	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-205	BFD-202	**100 L** Storage Tote - **AWFI**	**100 L** Storage Tote - **Flex Station PN** (AWFI)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-206	BFD-202	0.2 Micron Filter	0.2 Micron Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	PFD-206	BFD-202	**Peristaltic Pump (50 L)**	**Peristaltic Pump**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
MWS																														
B	-	-	-	Parts Washer	**Reliance®280 PG Pharmaceutical Grade Washer**	-	-	-	-	19	-	19	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Sterilization Autoclave	**Finn-Aqua GMP Bio Pharma Sterilizer (BPS)**	-	-	-	-	13	15-44	-	-	1135 kg/h 450 kg/h	-	45 max	-	96.7	-	15-44	-	-	-	-	-	-	3.0	-	-	-
B	-	-	-	Decon Autoclave	**Finn-Aqua GMP Bio Pharma Sterilizer (BPS)**	-	-	-	-	13	15-44	-	-	1135 kg/h 450 kg/h	-	45 max	-	96.7	-	15-44	-	-	-	-	-	-	3.0	-	-	-
B	-	-	-	Floor Scale	Floor Scale	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	**500 L** Jacketed **Single-Use Mixer**	**500 L Xcellerx XDM Single-Use Mixer**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	**500 L** Jacketed **Single-Use Mixer**	**500 L Xcellerx XDM Single-Use Mixer**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	**500 L** Jacketed **Single-Use Mixer**	**500 L Xcellerx XDM Single-Use Mixer**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	**50 L** Jacketed **Single-Use Mixer**	**50 L Xcellerx XDM Single-Use Mixer**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	**50 L** Jacketed **Single-Use Mixer**	**50 L Xcellerx XDM Single-Use Mixer**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	**Fume Hood - Extraction Booth**	**FumeGard Conventional Fume Hood**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Utilities																														
B	-	-	-	CS Generation Skid	CS Generation Skid **(300 kg/hr @ ~45 psig)**	-	-	390	87	-	-	0.67	43.5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	CS Distribution Skid	CS Distribution Skid	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Water Softener System	Water Softener + 2 Carbon Filters	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	WFI Generation Skid	WFI Generation Skid **(1000 Lbs/hr capacity)**	**130**	**50.8**	-	-	**18.3**	**50.8**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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						ELECTRICAL																NOTES
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	ELECTRICAL DESCRIPTION	HP	VOLTAGE	PHASE	AMPS	KVA	FIELD CONNECTION	CLASS OF POWER	BACK-UP POWER / UPS	DATA INTEGRATION (PCS, MES, BAS, EMS, N/A)	UNIT COST	QUANTITY	INSTALLATION FACTOR	ESTIMATED TOTAL COST	LEAD TIME (WEEKS ARO)	ESTIMATION SOURCE	
B	-	PFD-204	BFD-202	**Single-Use** Chromatography- **AEX**	**AKTA Ready Gradient Chromatography System - Single Use (including Column Trolley) - AEX**	-	-	**100, 120, 200-208, 220-230 or 240 ± 10% @ 60Hz**	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$213,500	4-6	**Vendor**	Updated model, equipment name and description
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Equilibrate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Equilibrate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Wash Buffer**	**100 L** Storage Tote - **Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Regenerate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Regenerate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Eluate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Eluate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Storage Buffer**	**100 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- AWFI**	**100 L** Storage Tote - **Flex Station PN** (AWFI)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-204	BFD-202	**100 L Storage Tote**	**100 L Storage Tote - Flex Station PN**	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Added
B	-	PFD-204	BFD-202	**Single-Use** Chromatography- **MMC**	**AKTA Ready Gradient Chromatography System - Single Use (including Column Trolley) - MMC**	-	-	**100, 120, 200-208, 220-230 or 240 ± 10% @ 60Hz**	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$213,500	4-6	**Vendor**	Updated model, equipment name and description
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Equilibrate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Equilibrate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Wash Buffer**	**100 L** Storage Tote - **Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Regenerate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Regenerate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Eluate Buffer**	**100 L** Storage Tote - **Flex Station PN** (Eluate Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- Storage Buffer**	**100 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-204	BFD-202	**100 L** Storage Tote **- AWFI**	**100 L** Storage Tote - **Flex Station PN** (AWFI)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-205	BFD-202	Peristaltic Pump (200 L)	Peristaltic Pump	-	-	**TBD**	**TBD**	-	-	-	-	BACK-UP POWER	-	-	-	-	$10,500	-	HISTORY - Consultant Estimate	
B	-	PFD-205	BFD-202	Nano Filter	Nano Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	TBD	TBD	TBD	
B	-	PFD-205	BFD-202	**100 L Storage Tote - Filtrate**	**100 L** Storage Tote - **Flex Station PN (Filtrate)**	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-205	BFD-202	AKTA Flux 6 (TFF System)	Flux Tangential Flow Filtration System - Single Use	-	-	**100-120 / 220-240 ± 10% @ 50-60 Hz**	**1**	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	**$34,850**	14-18	**Vendor**	Updated Utility Requirements, Cost Cost is base. Including Commissioning, etc. Total is $59,600. Included Optional Items are included in quote.
B	-	PFD-205	BFD-202	**100 L** Storage Tote **- Wash Buffer**	**100 L** Storage Tote - **Flex Station PN** (Wash Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-205	BFD-202	**100 L** Storage Tote **- Condition Buffer**	**100 L** Storage Tote - **Flex Station PN** (Condition Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-205	BFD-202	**100 L** Storage Tote **- Diafilter Buffer**	**100 L** Storage Tote - **Flex Station PN** (Diafilter Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-205	BFD-202	**100 L** Storage Tote **- Storage Buffer**	**100 L** Storage Tote - **Flex Station PN** (Storage Buffer)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-205	BFD-202	**100 L** Storage Tote **- Caustic**	**100 L** Storage Tote - **Flex Station PN** (Caustic)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-205	BFD-202	**100 L** Storage Tote **- AWFI**	**100 L** Storage Tote - **Flex Station PN** (AWFI)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-205	BFD-202	50 L Jacketed Single-Use Mixer	50 L **Xcellerx XDM** Single-Use Mixer - Concentration Adjustment	-	-	**120 @ 60 Hz**	**1**	**4.5 (max)**	-	-	-	BACK-UP POWER	-	-	-	-	$74,000	14-16	**Vendor**	Updated volume, model, dimensions, utility requirements, etc.
B	-	PFD-205	BFD-202	**100 L** Storage Tote **- AWFI**	**100 L** Storage Tote - **Flex Station PN** (AWFI)	-	-	-	-	-	-	-	-	-	-	-	-	-	$9,000	18-22	HISTORY - Consultant Estimate	Updated volume, model, dimensions, etc.
B	-	PFD-206	BFD-202	0.2 Micron Filter	0.2 Micron Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	HISTORY - Consultant Estimate	
B	-	PFD-206	BFD-202	**Peristaltic Pump (50 L)**	**Peristaltic Pump**	-	-	-	-	-	-	-	-	-	-	-	-	-	$10,500	-	HISTORY - Consultant Estimate	Added
MWS																						
B	-	-	-	Parts Washer	**Reliance®280 PG Pharmaceutical Grade Washer**	-	-	**480 @ 60 Hz**	**3**	-	-	-	-	**Back-up: 120 V @ 60 Hz (Option)**	-	-	-	-	**$308,411**	**28-30**	**Vendor**	Added - Pricing includes FAT, SAT IQ/OQ, etc.
B	-	-	-	Sterilization Autoclave	**Finn-Aqua GMP Bio Pharma Sterilizer (BPS)**	-	-	**480 @ 60 Hz**	**3**	**3.2 kW**	-	-	-	**Back-up: 120 V @ 0.5kW**	-	-	-	-	**$402,500**	**38-42**	**Vendor**	Moved from UPS mAbs - Smaller Unit - Price includes FAT, SAT, IQ/OQ, ETC. (Not Base Unit Price)
B	-	-	-	Decon Autoclave	**Finn-Aqua GMP Bio Pharma Sterilizer (BPS)**	-	-	**480 @ 60 Hz**	**3**	**3.2 kW**	-	-	-	**Back-up: 120 V @ 0.5kW**	-	-	-	-	**$402,500**	**38-42**	**Vendor**	Moved from UPS mAbs - Smaller Unit - Price includes FAT, SAT, IQ/OQ, ETC. (Not Base Unit Price)
B	-	-	-	Floor Scale	Floor Scale	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	-	-	-	No results when looking for this specific catalog number. Moved from UPS mAbs
B	-	-	-	**500 L** Jacketed **Single-Use Mixer**	**500 L Xcellerx XDM Single-Use Mixer**	-	-	**120 @ 60 Hz**	**3**	**4.5A (Max)**	-	-	-	BACK-UP POWER	-	-	-	-	**$155,000**	14-16	**Vendor**	Added - Updated volume, model, dimensions, utility requirements, etc. Total Cost including Kits, SAT, Commissioning, IQOQ, etc. is $245,000.
B	-	-	-	**500 L** Jacketed **Single-Use Mixer**	**500 L Xcellerx XDM Single-Use Mixer**	-	-	**120 @ 60 Hz**	**3**	**4.5A (Max)**	-	-	-	BACK-UP POWER	-	-	-	-	**$155,000**	14-16	**Vendor**	Added - Updated volume, model, dimensions, utility requirements, etc. Total Cost including Kits, SAT, Commissioning, IQOQ, etc. is $245,000.
B	-	-	-	**500 L** Jacketed **Single-Use Mixer**	**500 L Xcellerx XDM Single-Use Mixer**	-	-	**120 @ 60 Hz**	**3**	**4.5A (Max)**	-	-	-	BACK-UP POWER	-	-	-	-	**$155,000**	14-16	**Vendor**	Added - Updated volume, model, dimensions, utility requirements, etc. Total Cost including Kits, SAT, Commissioning, IQOQ, etc. is $245,000.
B	-	-	-	**50 L** Jacketed **Single-Use Mixer**	**50 L Xcellerx XDM Single-Use Mixer**	-	-	**120 @ 60 Hz**	**1**	**4.5 (max)**	-	-	-	BACK-UP POWER	-	-	-	-	$74,000	14-16	**Vendor**	Added
B	-	-	-	**50 L** Jacketed **Single-Use Mixer**	**50 L Xcellerx XDM Single-Use Mixer**	-	-	**120 @ 60 Hz**	**1**	**4.5 (max)**	-	-	-	BACK-UP POWER	-	-	-	-	$74,000	14-16	**Vendor**	Added
B	-	-	-	**Fume Hood - Extraction Booth**	**FumeGard Conventional Fume Hood**	-	-	**120**		**20**	-	-	-	BACK-UP POWER	-	-	-	-	**$10,450**	**4-8**	**Vendor**	Added
Utilities																						
B	-	-	-	CS Generation Skid	CS Generation Skid **(300 kg/hr @ ~45 psig)**	-	-	**TBD**	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$238,769	30-35	**Vendor**	Total Cost does not include Documentation, Activities and Validation Package (Approx. $145,770.00). This is packaged with the MES documentation, activities and validation.
B	-	-	-	CS Distribution Skid	CS Distribution Skid	-	-	**TBD**	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	TBD	TBD	TBD	
B	-	-	-	Water Softener System	Water Softener + 2 Carbon Filters	-	-	**TBD**	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$10,510	30-35	**Vendor**	
B	-	-	-	WFI Generation Skid	WFI Generation Skid **(1000 Lbs/hr capacity)**	-	-	**TBD**	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$501,236	30-35	**Vendor**	Total Cost does not include Documentation, Activities and Validation Package (Approx. $145,770.00). This is packaged with the PSG documentation, activities and validation.

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EQUIPMENT INFORMATION

REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	Area	ROOM	NEW / EXISTING	MFG.	MODEL NUMBER	SPECIFICATION NO.	BID PACKAGE NO.	DIMENSIONS	MAX Weight	FURNISHED BY	INSTALLED BY	FIXED OR PORTABLE
B	-	-	-	WFI Distribution Skid	WFI Distribution Skid **(Including 2,000 L Storage Tank + Heat Sanitization Capacity)**	Clean Utilities	1134	TBD	**Stilmas**	TBD	-	-	**Storage Tank: 50" Dia x 60" H 4013 mm L x 2185 mm W x 2616 mm H**	**4630 kg (full)**	-	-	-
B	-	-	-	N2 Distribution System	N2 Distribution System	Clean Utilities	1134	TBD	TBD	TBD	-	-	TBD	TBD	-	-	-
B	-	-	-	O2 Distribution System	O2 Distribution System	Clean Utilities	1134	TBD	TBD	TBD	-	-	TBD	TBD	-	-	-
B	-	-	-	CO2 Distribution System	CO2 Distribution System	Clean Utilities	1134	TBD	TBD	TBD	-	-	TBD	TBD	-	-	-
B	-	-	-	Bio Kill System	Single-Pass Thermo Bio Kill System	Bio-Kill	1135	NEW	PRI	Afc-9000LPH	-	-	103" W x 246" L x 85"	TBD	-	-	-
B	-	-	-	Neutralization System	Neutralization System - labTREAT LT50 - 50 GPM +2000 GAL Equalization Hold Tank	Waste Neutralization	1137	NEW	Dignital Analysis	LT50	-	-	60" W x 144" L x 84" H Tank: 64" D x 151" H	1900 lbs (dry)	-	-	-
B	-	-	-	CS Sample Cooler	CS Sample Cooler	-	-	NEW	Spirax Sarco	SSC20	-	-	102 mm W x 102 mm D x 458 mm H	3.1 kg	-	-	-
Accessories																	
A	-	-	-	Quantum Pump	Quantum Bioprocessing Pump	TBD	TBD	EXISTING	Watson Marlow	Model - Quantum 600 universal Catalog - 000.6040.00A	-	-	297 mm W x 736 mm D x 231 mm H	38 kg	-	-	-
A	-	-	-	Pump Drive - 1	Drive MFLEX Digital 115/30 Pump	TBD	TBD	EXISTING	Cole-Parmer	77420-10	-	-	282 mm W x 424 mm L x 328 mm H	Not Specified	-	-	-
A	-	-	-	Pump Head - 1	PUMPHD MFLEX EASY-LOAD PPS/SS	TBD	TBD	EXISTING	Cole-Parmer	77602-10	-	-	187 mm W x 89 mm L x 201 mm H	Not Specified	-	-	-
A	-	-	-	Pump Drive - 2	Drive MFLEX Digital 115/30 Pump	TBD	TBD	EXISTING	Cole-Parmer	77420-10	-	-	282 mm W x 424 mm L x 328 mm H	Not Specified	-	-	-
A	-	-	-	Pump Head - 2	PUMPHD MFLEX EASY-LOAD PPS/SS	TBD	TBD	EXISTING	Cole-Parmer	77602-10	-	-	187 mm W x 89 mm L x 201 mm H	Not Specified	-	-	-
A	-	-	-	Pump Drive - 3	Drive MFLEX L/S 600rpm 115/230	TBD	TBD	EXISTING	Cole-Parmer	07522-20	-	-	216 mm W x 254 mm L x 216 mm H	Not Specified	-	-	-
A	-	-	-	Pump Head - 3	Pump Head L/S EAS-LOAD 3 SS	TBD	TBD	EXISTING	Cole-Parmer	77800-60	-	-	88 mm W 78 mm L x 121 mm H	Not Specified	-	-	-
A	-	-	-	Bag Integrity Tester -1	inSITE Integrity Testing System - US multichannel	TBD	TBD	NEW	Sartorius	Sartocheck 4 Plus Bag Tester	-	-	460 mm W 390 mm D x 245m H	15 kg	-	-	-
A	-	-	-	Bag Integrity Tester -2	inSITE Integrity Testing System - US multichannel	TBD	TBD	NEW	Sartorius	Sartocheck 4 Plus Bag Tester	-	-	460 mm W 390 mm D x 245m H	15 kg	-	-	-
A	-	-	-	Filter Integrity Tester -1	Sartocheck 5 Plus Filter Tester	TBD	TBD	NEW	Sartorius	Sartocheck 5 Plus	-	-	348 mm W x 379 mm D x 286 mm H	16.8 kg	-	-	-
A	-	-	-	Filter Integrity Tester -2	Sartocheck 5 Plus Filter Tester	TBD	TBD	NEW	Sartorius	Sartocheck 5 Plus	-	-	348 mm W x 379 mm D x 286 mm H	16.8 kg	-	-	-
A	-	-	-	Tuber Welder -1	BioWelder TC - SterileTube Welder	TBD	TBD	NEW	Sartorius	BioWelder 16370	-	-	300 mm W x 300 mm D x 220 mm H	0.5 kg	-	-	-
A	-	-	-	Tuber Welder -2	BioWelder TC - SterileTube Welder	TBD	TBD	NEW	Sartorius	BioWelder 16370	-	-	300 mm W x 300 mm D x 220 mm H	0.5 kg	-	-	-
	-	-	-	Tuber Welder -3	BioWelder TC - SterileTube Welder	TBD	TBD	NEW	Sartorius	BioWelder 16370	-	-	300 mm W x 300 mm D x 220 mm H	0.5 kg	-	-	-
A	-	-	-	Tube Sealer -1	BioSealer TC - Sterile Tube Sealer	TBD	TBD	EXISTING	Sartorius	Model - DE-37079 Catalog - 16391-000	-	-	115 mm W x 391 mm L x 147 mm H	Approx. 3.0 kg	-	-	-
A	-	-	-	Tube Sealer -2	BioSealer TC - Sterile Tube Sealer	TBD	TBD	NEW	Sartorius	BioSealer 16360-P	-	-	220 mm W x 150 mm D x 210 mm H	3.0 kg	-	-	-
	-	-	-	Tube Sealer -3	BioSealer TC - Sterile Tube Sealer	TBD	TBD	NEW	Sartorius	BioSealer 16360-P	-	-	220 mm W x 150 mm D x 210 mm H	3.0 kg	-	-	-

Sheet Notes:
1. If equipment has both back-up power and UPS, it is assumed that the main skid will be connected via back-up power and the controls will be connected via UPS.

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						PROCESS UTILITIES																											
						HOT WFI HWFI		PURIFIED WATER PW		CIP		CLEAN STEAM CS		CLEAN STEAM CONDENSATE CSC		NITROGEN N_2			OXYGEN O_2			CABRON DIOXIDE CO_2			PROCESS AIR CCA			INSTRUMENT AIR IA			HEAT XFER FLUID (S/R)	
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	LPM	PSIG	LPM	PSIG	LPM	PSIG	kg/h	PSIG	kg/h	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	GPM	PSIG
B	-	-	-	WFI Distribution Skid	WFI Distribution Skid **(Including 2,000 L Storage Tank + Heat Sanitization Capacity)**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	N2 Distribution System	N2 Distribution System	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	O2 Distribution System	O2 Distribution System	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	CO2 Distribution System	CO2 Distribution System	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Bio Kill System	Single-Pass Thermo Bio Kill System	-	-	-	-	-	-	TBD	TBD	-	-	-	-	-	-	-	-	-	-	-	TBD	TBD	90	-	-	-	-	-
B	-	-	-	Neutralization System	Neutralization System - labTREAT LT50 - 50 GPM +2000 GAL Equalization Hold Tank	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	80	-	-
B	-	-	-	CS Sample Cooler	CS Sample Cooler	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Accessories																																	
A	-	-	-	Quantum Pump	Quantum Bioprocessing Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Pump Drive - 1	Drive MFLEX Digital 115/30 Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Pump Head - 1	PUMPHD MFLEX EASY-LOAD PPS/SS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Pump Drive - 2	Drive MFLEX Digital 115/30 Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Pump Head - 2	PUMPHD MFLEX EASY-LOAD PPS/SS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Pump Drive - 3	Drive MFLEX L/S 600rpm 115/230	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Pump Head - 3	Pump Head L/S EAS-LOAD 3 SS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Bag Integrity Tester -1	inSITE Integrity Testing System - US multichannel	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Bag Integrity Tester -2	inSITE Integrity Testing System - US multichannel	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Filter Integrity Tester -1	Sartocheck 5 Plus Filter Tester	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Filter Integrity Tester -2	Sartocheck 5 Plus Filter Tester	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Tuber Welder -1	BioWelder TC - SterileTube Welder	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Tuber Welder -2	BioWelder TC - SterileTube Welder	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-	-	-	Tuber Welder -3	BioWelder TC - SterileTube Welder	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Tube Sealer -1	BioSealer TC - Sterile Tube Sealer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Tube Sealer -2	BioSealer TC - Sterile Tube Sealer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-	-	-	Tube Sealer -3	BioSealer TC - Sterile Tube Sealer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Sheet Notes:
1. If equipment has both back-up power and UPS, it is assumed that the main skid will be connected via back-up power and the controls will be connected via UPS.

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						PLANT UTILITES																					AUTOMATION		
						PLANT STEAM PS		PLANT STEAM CONDENSATE		DOMESTIC COLD WATER (T=60°F) CW		PROCESS CHILLED WATER PCHWS/R		RELIEF VENT PV			INTAKE AIR	EXHAUST			SANITARY SEWER SAN		PROCESS WASTE PW		BIOWASTE BIOD		HEAT LOAD			
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	kg/h	PSIG	kg/h	PSIG	LPM	PSIG	LPM	PSIG	SCFM	CFM	PSIG	SCFM	SCFM	CFM	PSIG	LPM	PSIG	LPM	PSIG	LPM	PSIG	kW	CONTROL (OEM, PCS, BAS, N/A)	QUANTITY	BMS or SCADA
B	-	-	-	WFI Distribution Skid	WFI Distribution Skid **(Including 2,000 L Storage Tank + Heat Sanitization Capacity)**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	N2 Distribution System	N2 Distribution System	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	O2 Distribution System	O2 Distribution System	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	CO2 Distribution System	CO2 Distribution System	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Bio Kill System	Single-Pass Thermo Bio Kill System	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Neutralization System	Neutralization System - labTREAT LT50 - 50 GPM +2000 GAL Equalization Hold Tank	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	CS Sample Cooler	CS Sample Cooler	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Accessories																														
A	-	-	-	Quantum Pump	Quantum Bioprocessing Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Pump Drive - 1	Drive MFLEX Digital 115/30 Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Pump Head - 1	PUMPHD MFLEX EASY-LOAD PPS/SS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Pump Drive - 2	Drive MFLEX Digital 115/30 Pump	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Pump Head - 2	PUMPHD MFLEX EASY-LOAD PPS/SS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Pump Drive - 3	Drive MFLEX L/S 600rpm 115/230	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Pump Head - 3	Pump Head L/S EAS-LOAD 3 SS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Bag Integrity Tester -1	inSITE Integrity Testing System - US multichannel	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Bag Integrity Tester -2	inSITE Integrity Testing System - US multichannel	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Filter Integrity Tester -1	Sartocheck 5 Plus Filter Tester	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Filter Integrity Tester -2	Sartocheck 5 Plus Filter Tester	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Tuber Welder -1	BioWelder TC - SterileTube Welder	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Tuber Welder -2	BioWelder TC - SterileTube Welder	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-	-	-	Tuber Welder -3	BioWelder TC - SterileTube Welder	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Tube Sealer -1	BioSealer TC - Sterile Tube Sealer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Tube Sealer -2	BioSealer TC - Sterile Tube Sealer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-	-	-	Tube Sealer -3	BioSealer TC - Sterile Tube Sealer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Sheet Notes:
1. If equipment has both back-up power and UPS, it is assumed that the main skid will be connected via back-up power and the controls will be connected via UPS.

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						ELECTRICAL																
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	ELECTRICAL DESCRIPTION	HP	VOLTAGE	PHASE	AMPS	KVA	FIELD CONNECTION	CLASS OF POWER	BACK-UP POWER / UPS	DATA INTEGRATION (PCS, MES, BAS, EMS, N/A)	UNIT COST	QUANTITY	INSTALLATION FACTOR	ESTIMATED TOTAL COST	LEAD TIME (WEEKS ARO)	ESTIMATION SOURCE	NOTES
B	-	-	-	WFI Distribution Skid	WFI Distribution Skid **(Including 2,000 L Storage Tank + Heat Sanitization Capacity)**	-	-	**TBD**	-	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$571,495	30-35	**Vendor**	Cost breakdown: WFI Storage is approx. $156,115.00 CAD. Distribution is approx. $415,380.00 CAD. Total Cost does not include Documentation, Activities and Validation Package (Approx. $86,480.00).
B	-	-	-	N2 Distribution System	N2 Distribution System	-	-	-	-	-	-	-	-	-	-	-	-	-	TBD	TBD	TBD	
B	-	-	-	O2 Distribution System	O2 Distribution System	-	-	-	-	-	-	-	-	-	-	-	-	-	TBD	TBD	TBD	
B	-	-	-	CO2 Distribution System	CO2 Distribution System	-	-	-	-	-	-	-	-	-	-	-	-	-	TBD	TBD	TBD	
B	-	-	-	Bio Kill System	Single-Pass Thermo Bio Kill System	-	-	480 V @ 60 Hz	3	-	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$600,000	24-28	**Vendor**	
B	-	-	-	Neutralization System	Neutralization System - labTREAT LT50 - 50 GPM +2000 GAL Equalization Hold Tank	-	-	480 V @ 60 Hz	3.0	20.0	-	-	-	BACK-UP POWER + UPS	-	-	-	-	$181,500	24-28	**Vendor**	Neutralization Skid Cost:$144,000. Hold Tank: $12,500. Cooler: $25,000
B	-	-	-	CS Sample Cooler	CS Sample Cooler	-	-	-	-	-	-	-	-	-	-	-	-	-	$7,300	-	HISTORY - Consultant Estimate	
Accessories																						
A	-	-	-	Quantum Pump	Quantum Bioprocessing Pump	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
A	-	-	-	Pump Drive - 1	Drive MFLEX Digital 115/30 Pump	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
A	-	-	-	Pump Head - 1	PUMPHD MFLEX EASY-LOAD PPS/SS	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	This is one unit with equipment above.
A	-	-	-	Pump Drive - 2	Drive MFLEX Digital 115/30 Pump	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
A	-	-	-	Pump Head - 2	PUMPHD MFLEX EASY-LOAD PPS/SS	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	This is one unit with equipment above.
A	-	-	-	Pump Drive - 3	Drive MFLEX L/S 600rpm 115/230	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
A	-	-	-	Pump Head - 3	Pump Head L/S EAS-LOAD 3 SS	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	This is one unit with equipment above.
A	-	-	-	Bag Integrity Tester -1	inSITE Integrity Testing System - US multichannel	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$47,000	8-10	**Vendor**	Estimate is for system only. Estimate increases to $91,000 for system with trolley for 2D Bags.
A	-	-	-	Bag Integrity Tester -2	inSITE Integrity Testing System - US multichannel	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$47,000	8-10	**Vendor**	Estimate is for system only. Estimate increases to $91,000 for system with trolley for 2D Bags.
A	-	-	-	Filter Integrity Tester -1	Sartocheck 5 Plus Filter Tester	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$41,000	8-10	**Vendor**	
A	-	-	-	Filter Integrity Tester -2	Sartocheck 5 Plus Filter Tester	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$41,000	8-10	**Vendor**	
A	-	-	-	Tuber Welder -1	BioWelder TC - SterileTube Welder	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$55,000	4-6	**Vendor**	
A	-	-	-	Tuber Welder -2	BioWelder TC - SterileTube Welder	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$55,000	6-8	**Vendor**	
	-	-	-	Tuber Welder -3	BioWelder TC - SterileTube Welder	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$55,000	6-8	**Vendor**	
A	-	-	-	Tube Sealer -1	BioSealer TC - Sterile Tube Sealer	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$28,000	6-8	**Vendor**	
A	-	-	-	Tube Sealer -2	BioSealer TC - Sterile Tube Sealer	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$28,000	6-8	**Vendor**	
	-	-	-	Tube Sealer -3	BioSealer TC - Sterile Tube Sealer	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$28,000	6-8	**Vendor**	

Sheet Notes:
1. If equipment has both back-up power and UPS, it is assumed that the main skid will be connected via back-up power and the controls will be connected via UPS.

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EQUIPMENT INFORMATION

REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	Area	ROOM	NEW / EXISTING	MFG.	MODEL NUMBER	SPECIFICATION NO.	BID PACKAGE NO.	DIMENSIONS	MAX Weight	FURNISHED BY	INSTALLED BY	FIXED OR PORTABLE
Microbiology Lab																	
B	-	-	-	Automated Cell Counter	Automated Cell Viability Counter	Microbiology Lab	1118	NEW	Beckman Coulter	Vi-CELL BLU Cell Viability Analyzer	-	-	54 cm D x 42 cm W x 45 cm H (21" D x 16.5" W x 18" H)	28 kg (63 lb)	-	-	-
B	-	-	-	Isolator	4 ft PharmaGard ES Total Exhaust Aseptic Containment Isolator	Microbiology Lab	1118	NEW	NuAire	NU-NTE800-400	-	-	1270 mm W x 826 mm D 1550 mm H	211 kg (465 lbs)	-	-	-
B	-	-	-	Benchtop Scale	Precision Balance 610 mg x 1 mg	QC Lab	1117	NEW	Thermo Fisher Scientific	QUINTIX613-1S	-	-	360 mm D x 218 mm W x 320mm H	4.9 kg	-	-	-
B	-	-	-	Water Bath	Water Bath	Microbiology Lab	1118	NEW	Fisher Scientific	TSGP02	-	-	200 mm W x 230 mm L x 233 mm H	3.2 kg	-	-	-
B	-	-	-	Spectrophotometer	Double Beam UV-Vis Spectrophotometer	Microbiology Lab	1118	NEW	Thermo-Fisher Scientific	Genesys 180 UV-Vis Spectrophotometer	-	-	35.5 cm D x 38.5 cm W x 19.5 cm H	7.5 kg (16.5 lb)	-	-	-
QC LAB																	
B	-	-	-	-80°C Freezer - 3	-80°C Ultra-Low Freezer	QC Lab	1117	EXISTING	Thermo Fisher Scientific	TSX8950086A	-	-	955 mm D x 864 mm W x 1981 mm H	327 kg	-	-	-
B	-	-	-	Biosafety Cabinet	4 ft Class II, Type A2 Biological Safety Cabinet	QC Lab	1117	NEW	Thermo Fisher Scientific	Catalogue Number: 13261222	-	-	800 mm D x 1300 mm W x 1568 mm H (31.5" D x 51.2" W x 61.8" H)	430 kg (195 lb)	-	-	-
B	-	-	-	Benchtop Scale	Precision Balance 610 mg x 1 mg	QC Lab	1117	NEW	Thermo Fisher Scientific	QUINTIX613-1S	-	-	360 mm D x 218 mm W x 320mm H	4.9 kg	-	-	-
B	-	-	-	Water Bath	Precision General Purpose Water Bath	QC Lab	1117	NEW	Thermo Fisher Scientific	TSGP20	-	-	230 mm D x 200 mm W x 233 mm H (15.4" D x 21.8" W x 9.2" H) 20 L	3.2 kg	-	-	-
B	-	-	-	Spectrophotometer	Double Beam UV-Vis Spectrophotometer	QC Lab	1117	NEW	Thermo-Fisher Scientific	Genesys 180 UV-Vis Spectrophotometer	-	-	35.5 cm D x 38.5 cm W x 19.5 cm H	7.5 kg (16.5 lb)	-	-	-
B	-	-	-	Western Blot Apparatus	Western Blot Apparatus	QC Lab	1117	NEW	Bio-Rad	Trans-Blot SD Semi-Dry Electrophoretic Transfer Cell	-	-	24 cm D x 37 cm W x 11 cm H	3.6 kg (7.9 lb)			
B	-	-	-	High Performance Liquid Chromatography (HPLC)	High Performance Liquid Chromatography (HPLC)	QC Lab	1117	NEW	Agilent Technologies, Inc.	1220 Infinity II LC System G4294B Configuration	-	-	420 mm D x 370 mm W x 640 mm H (16.5" D x 14.6" W x 25.2" H)	43 kg (94 lb)			
B	-	-	-	High Performance Liquid Chromatography (HPLC) Fluorescence Detector	High Performance Liquid Chromatography (HPLC) Fluorescence Detector	QC Lab	1117	NEW	Agilent Technologies, Inc.	1260 Infinity II Fluorescence Detector	-	-	436 mm D x 396 mm W x 140 mm H (17.2" D x 15.6" W x 5.5" H)	11.9 kg (26.2 lb)			
B	-	-	-	Microscope	Inverted Microscope with manual components, one-deck standard configuration	QC Lab	1117	NEW	Olympus	IX73: One-Deck System	-	-	475 mm D x 323 mm W x 656 mm H	35 kg (77.2 lb)			
B	-	-	-	Osmometer	Single Sample Micro-Osmometer	QC Lab	1117	NEW	Advanced Instruments	OsmoTECH XT Single-Sample Micro-Osmometer	-	-	38 cm D x 36 cm W x 38 cm H (15" D x 14" W x 11.5" H)	11.4 kg (25 lb)			
B	-	-	-	Labelling Equipment	Label Maker	QC Lab	1117	NEW	Brady	BMP51 Lab Starter Kit	-	-	TBD	TBD			
B	-	-	-	ELISA Microplate Reader with Temperature Control	ELISA Microplate Reader with Temperature Control (Wavelength Range: 190 nm - 1000 nm)	QC Lab	1117	NEW	Molecular Devices	SpectraMax ABS Plus Absorbance ELISA Microplate Readers	-	-	41.4 cm D x 30.5 cm W x 20.3 cm H (16.3" D x 12" W x 8" H)	11.3 kg (25 lb)			
B	-	-	-	Oven (100-400 °C) for depyrogenization	Heratherm Advanced Protocol Security Mechanical Convection Oven (temperature range: 5 °C to 330 °C)	QC Lab	1117	NEW	Thermo Fisher Scientific	Catalogue Number: 51028136H	-	-	56.5 cm D x 53 cm W x 72 cm H (22.2" D x 20.9" W x 28.3" H) 61 L	44 kg (97 lb)			
B	-	-	-	Automated Cell Counter	Automated Cell Viability Counter	QC Lab	1117	NEW	Beckman Coulter	Vi-CELL BLU Cell Viability Analyzer	-	-	54 cm D x 42 cm W x 45 cm H (21" D x 16.5" W x 18" H)	28 kg (63 lb)			
B	-	-	-	Shaker Incubator with CO_2 Control	Shaker Incubator	QC Lab	1117	NEW	Kuhner Shaker	ISF1-Z Basic (SMZ1500)	-	-	854 mm D x 1288 mm W x 771 mm H	200 kg			
B	-	-	-	Imaging System	Chemiluminescence and Fluorescence Detection	QC Lab	1117	NEW	Bio-Rad	ChemiDoc MP	-	-	61 cn D x 51 cm W x 53 cm H	35 kg (78 lb)			
B	-	-	-	Capillary Electrophoresis	Capillary Electrophoresis	QC Lab	1117	NEW	Agilent Technologies, Inc.	7100 CE System	-	-	51 cm D x 35 cm W x 59 cm H	35 kg (77.2 lb)			
B	-	-	-	Polymerase Chain Reaction (PCR) System with Thermal Gradient	Reverse Transcription Polymerase Chain Reaction (PCR) with Thermal Gradient	QC Lab	1117	NEW	Bio-Rad	T100 Thermal Cycler, 96-well thermal cycler	-	-	54.6 cm D x 33 cm W x 36 cm H (22" D x 13" W x 14" H)	22 kg (48 lb)			
B	-	-	-	Sterilization Autoclave	Fisherbrand SterilElite Tabletop Autoclave	QC Lab	1117	NEW	Thermo Fisher Scientific	STE4022009	-	-	570 mm D x 766 mm W x 486 mm H (22.4" D x 30.1" W x 19.1" H) 40L	77 kg (169.8 lb)			
B	-	-	-	Manual Pipettes	Single Channel Electronic Pipettes (0.2 -10 µL, 10-20 µL, 20-200 µL, 100-1000 µL), 2 sets of each size	QC Lab	1117	NEW	Mettler Toledo	Rainin E4 Manual Pipette, LTS E4-10XLS+	-	-	TBD	TBD			
B	-	-	-	Manual Pipettes	8 and 12-Channel Electronic Pipettes (25-300 µL, 30-300 µL), 2 sets of each size	QC Lab	1117	NEW	Mettler Toledo	Rainin E4 Multi Pipette L8-10XLS+	-	-	TBD	TBD			
B	-	-	-	Automatic Pipettes	Single Channel Electronic Pipettes (0.2 -10 µL, 10-20 µL, 20-200 µL, 100-1000 µL), 2 sets of each size	QC Lab	1117	NEW	Mettler Toledo	Rainin E4 Electronic Pipette, LTS E4-10XLS+	-	-	TBD	TBD			
B	-	-	-	Automatic Pipettes	8 and 12-Channel Electronic Pipettes (25-300 µL, 30-300 µL), 2 sets of each size	QC Lab	1117	NEW	Mettler Toledo	Rainin E4 Multi Pipette E8-10XLS+	-	-	TBD	TBD			
B				Sterilized Filter Tips for Manual Pipettes or Automatic Pipettes	Sterilized Filter Pipette Tips are required for ELISA and PCR tests	QC Lab	1117	NEW	Mettler Toledo	Rainin RT LTS Pipette Tips			TBD	TBD			
B	-	-	-	Refrigerated Microcentrifuge	Benchtop Refrigerated General-Purpose Centrifuge	QC Lab	1117	NEW	Beckman Coulter	Avanti J-15R	-	-	TBD	TBD			
B	-	-	-	Refrigerated Microcentrifuge	Benchtop Refrigerated Microcentrifuge (1.5 mL - 2.0 mL tubes only)	QC Lab	1117	NEW	Beckman Coulter	Microfuge 20R	-	-	TBD	TBD			
B	-	-	-	Purified Water (PW) System	Milli-Q IQ 7005 Water Purification System	QC Lab	1117	NEW	Millipore Sigma	ZIQ7005T0	-	-	Purification Unit: 38 cm D x 31.5 cm W x 49.8 cm H (15" D x 12.4" W x 19.6" H), Storage Tank: 50.3 cm D x 40 cm W x 41.5 cm H (19.8" D x 15.7" W x 16.3" H)	Purification Unit: 26.0 kg (57 lb) Max. Operating, Storage Tank: 25 L			
B	-	-	-	Static Incubator 35 °C (temperature control between 32 °C - 38 °C)	Heratherm Advanced Protocol Microbiological Incubator (temperature range: 5 °C to 75 °C)	QC Lab	1117	NEW	Thermo Fisher Scientific	Catalogue Number: 51028064H	-	-	56.5 cm D x 64 cm W x 82 cm H (22.2" D x 25.2" W x 32.3" H) 117 L	51 kg (112 lb)			
B	-	-	-	Laminar Air Flow Hood (part of the in vitro testing in the QC lab)	Vertical Laminar Flow Hood	QC Lab	1117	NEW	NuAire	NU-140-430	-	-	813 mm D x 965 mm W x 1473 mm H (32" D x 38" W x 58" H)	136 kg (300 lb)			
B	-	-	-	Liquid N_2 Cell Storage Tank 200L + Additional Volume for Back-Up for the viral vectors line of production	Liquid Nitrogen Cryogenic Cell Storage, 6 racks	QC Lab	1117	NEW	Thermo Fisher Scientific	CryoPlus 1 Model Number: 7400	-	-	26 cm D x 21.5 cm W x 41 cm H (66" D x 54.6" W x 104.1" H) 90 L	117.9 kg (260 lb)			
B	-	-	-	Liquid N_2 Cell Storage Tank 200L + Additional Volume for Back-Up for the viral vectors line of production	Liquid Nitrogen Cryogenic Cell Storage, 6 racks	QC Lab	1117	NEW	Thermo Fisher Scientific	CryoPlus 1 Model Number: 7400	-	-	26 cm D x 21.5 cm W x 41 cm H (66" D x 54.6" W x 104.1" H) 90 L	117.9 kg (260 lb)			
Accessories																	
A	-	-	-	Total Organic Carbon (TOC) Analyzer	Shimadzu TOC-LCSH Analyzer	TBD	TBD	EXISTING	Mandel	Model - TOC-LCSH Catalog - SZ-638-91105-22	-	-	340 mm W x 660 mm D x 480 mm H	Approx. 35 kg	-	-	-
A	-	-	-	Benchtop Balance	High Capacity Benchtop Balance	TBD	TBD	EXISTING	Sartorius	MCE36200IS-2SOO-0	-	-	400 mm W x 412 mm L x 126-159 mm H	15.8 - 17.1 kg	-	-	-
A	-	-	-	Viable Monitoring Device - 1	Compliant Air Sampler Air Filter	TBD	TBD	EXISTING	EMD Millipore	MAS-100 NT 1.17274.0001 with Filter	-	-	290 mm W x 160 mm L x 230 mm H	7.5 kg (without sampling head)	-	-	-
A	-	-	-	Viable Monitoring Device - 2	Compliant Air Sampler Air Filter	TBD	TBD	EXISTING	EMD Millipore	MAS-100 NT 1.17274.0001 with Filter	-	-	290 mm W x 160 mm L x 230 mm H	7.5 kg (without sampling head)	-	-	-
A	-	-	-	Viable Monitoring Device - 3	PMS minicapt Mobile Microbial Air Sampler100lpm	TBD	TBD	EXISTING	Alpha Controls	790045-0100	-	-	145 mm W x 150 mm D x 260 mm H	2.1 kg	-	-	-
A	-	-	-	Benchtop Stirrer - 1	Benchtop 7" x 7" Stirrer	TBD	TBD	EXISTING	VWR Intl. LLC	Model - VWR 7 x 7 Cer stirrer 120v pro Catalog - 97042-706	-	-	250 mm W x 376 mm D x 109 mm H	5.4 kg	-	-	-
A	-	-	-	Benchtop Stirrer - 2	Benchtop 7" x 7" Stirrer	TBD	TBD	EXISTING	VWR Intl. LLC	Model - VWR 7 x 7 Cer stirrer 120v pro Catalog - 97042-706	-	-	250 mm W x 376 mm D x 109 mm H	5.4 kg	-	-	-
A	-	-	-	pH-Meter - 1	Benchtop pH/Conductivity Multiparameter Benchtop Meter	TBD	TBD	EXISTING	Fisher Scientific	Model - Orion Versa Star Pro Meter Catalog - VSTAR-50	-	-	240 mm W x 282 mm D x 95 mm H	1.15 kg	-	-	-
A	-	-	-	pH-Meter - 2	Benchtop pH/Conductivity Multiparameter Benchtop Meter	TBD	TBD	EXISTING	Fisher Scientific	Model - Orion Versa Star Pro Meter Catalog - VSTAR-50	-	-	240 mm W x 282 mm D x 95 mm H	1.15 kg	-	-	-
A	-	-	-	Pressure MAT	Pressure MAT Sensor Monior	TBD	TBD	EXISTING	pendoTECH	PMAT3P	-	-	199.6 mm W 57.2 mm D x 113.5 mm H	0.65 kg	-	-	-
A	-	-	-	MiniCapt Compressed Gas Kit	PMS minicapt Compressed Gas Kit 1001lpm - Microbial Monitoring Accesory	TBD	TBD	EXISTING	Alpha Controls	Model - R05232.RNLA Catalog - 90790051	-	-	152 mm W x 102 mm D x 216 mm H	1.86 kg	-	-	-
A	-	-	-	Water Bath	Thermo Scientific Precision Circulating (TSPC) Water Bath	TBD	TBD	EXISTING	Fisher Scientific	TSCIR89	-	-	1160 mm W x 546 mm L x 300 mm H	Not Specified	-	-	-
A	-	-	-	EM Particulate Monitor -1	Met-One or similar	TBD	TBD	NEW	Met One	Aerocet 531S	-	-	102mm W x 54 mm D x 159 mm H	0.9 kg (2.0 lbs)	-	-	-
A	-	-	-	EM Particulate Monitor -2	Met-One or similar	TBD	TBD	NEW	Met One	Aerocet 531S	-	-	102mm W x 54 mm D x 159 mm H	0.9 kg (2.0 lbs)	-	-	-
A	-	-	-	EM Particulate Monitor -3	Met-One or similar	TBD	TBD	NEW	Met One	Aerocet 531S	-	-	102mm W x 54 mm D x 159 mm H	0.9 kg (2.0 lbs)	-	-	-

PROCESS UTILITIES / PLANT UTILITIES

EQUIPMENT NAME	HOT WFI HWFI LPM	HOT WFI HWFI PSIG	PURIFIED WATER PW LPM	PURIFIED WATER PW PSIG	CIP LPM	CIP PSIG	CLEAN STEAM CS kg/h	CLEAN STEAM CS PSIG	CLEAN STEAM CONDENSATE CSC kg/h	CLEAN STEAM CONDENSATE CSC PSIG	NITROGEN N_2 SCFM	NITROGEN N_2 CFM	NITROGEN N_2 PSIG	OXYGEN O_2 SCFM	OXYGEN O_2 CFM	OXYGEN O_2 PSIG	CABRON DIOXIDE CO_2 SCFM	CABRON DIOXIDE CO_2 CFM	CABRON DIOXIDE CO_2 PSIG	PROCESS AIR CCA SCFM	PROCESS AIR CCA CFM	PROCESS AIR CCA PSIG	INSTRUMENT AIR IA SCFM	INSTRUMENT AIR IA CFM	INSTRUMENT AIR IA PSIG	HEAT XFER FLUID (S/R) GPM	HEAT XFER FLUID (S/R) PSIG	PLANT STEAM PS kg/h	PLANT STEAM PS PSIG	PLANT STEAM CONDENSATE kg/h	PLANT STEAM CONDENSATE PSIG	DOMESTIC COLD WATER (T=60°F) CW LPM	DOMESTIC COLD WATER (T=60°F) CW PSIG	PROCESS CHILLED WATER LPM	PROCESS CHILLED WATER PSIG	RELIEF VENT PV SCFM	RELIEF VENT PV CFM	RELIEF VENT PV PSIG	INTAKE AIR SCFM	EXHAUST SCFM	EXHAUST CFM	EXHAUST PSIG	SANITARY SEWER SAN LPM	SANITARY SEWER SAN PSIG	PROCESS WASTE PW LPM	PROCESS WASTE PW PSIG	BIOWASTE BIOD LPM	BIOWASTE BIOD PSIG	HEAT LOAD kW
Microbiology Lab																																																
Automated Cell Counter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Isolator	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Benchtop Scale	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Water Bath	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Spectrophotometer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
QC LAB																																																	
-80°C Freezer - 3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Biosafety Cabinet	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Benchtop Scale	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Water Bath	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Spectrophotometer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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Imaging System																																																	
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Polymerase Chain Reaction (PCR) System with Thermal Gradient																																																	
Sterilization Autoclave																																																	
Manual Pipettes																																																	
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Sterilized Filter Tips for Manual Pipettes or Automatic Pipettes																																																	
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Accessories																																																	
Total Organic Carbon (TOC) Analyzer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Benchtop Balance	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Viable Monitoring Device - 1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Viable Monitoring Device - 2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Viable Monitoring Device - 3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Benchtop Stirrer - 1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Benchtop Stirrer - 2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
pH-Meter - 1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
pH-Meter - 2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pressure MAT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
MiniCapt Compressed Gas Kit	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Water Bath	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
EM Particulate Monitor -1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
EM Particulate Monitor -2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
EM Particulate Monitor -3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

AUTOMATION / ELECTRICAL / COST

EQUIPMENT NAME	CONTROL (OEM, PCS, BAS, N/A)	QUANTITY	BMS or SCADA	ELECTRICAL DESCRIPTION	HP	VOLTAGE	PHASE	AMPS	KVA	FIELD CONNECTION	CLASS OF POWER	BACK-UP POWER / UPS	DATA INTEGRATION (PCS, MES, BAS, EMS, N/A)	UNIT COST	QUANTITY	INSTALLATION FACTOR	ESTIMATED TOTAL COST	LEAD TIME (WEEKS ARO)	ESTIMATION SOURCE	NOTES
Microbiology Lab																				
Automated Cell Counter	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$78,525	-	Vendor	Typically 5-12% discount off list price. Price includes reagent pack for start-up, concentration control, focus control, 10 µm polystyrene microsphere package, installation with basic training, and IQ/OQ.
Isolator	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$24,844	-	Vendor	
Benchtop Scale	-	-	-	-	-	100-240 V @ 50-60 Hz	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$2,995	-	Vendor	
Water Bath	-	-	-	-	-	120V @ 60 Hz	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$1,300	-	HISTORY - Consultant Estimate	
Spectrophotometer	-	-	-	-	-	110/220 V @ 50/60 Hz	-	-	-	-	-	UPS	-	-	-	-	$9,597	-	Vendor	
QC LAB																				
-80°C Freezer - 3	-	-	-	-	-	115 V @ 60 Hz	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$23,190	4	Vendor	Given Model Number was possibly incorrect. Used the TSX50086A model.
Biosafety Cabinet	-	-	-	-	-	230 V @ 50 Hz	-	-	-	-	-	UPS	-	-	-	-	$14,560	-	Vendor	
Benchtop Scale	-	-	-	-	-	100-240 V @ 50-60 Hz	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$2,995	-	Vendor	
Water Bath	-	-	-	-	-	120V @ 60 Hz	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$2,013	-	Vendor	
Spectrophotometer	-	-	-	-	-	110/220 V @ 50/60 Hz	-	-	-	-	-	UPS	-	-	-	-	$9,597	-	Vendor	
Western Blot Apparatus												BACK-UP POWER					$2,250		Vendor	Includes 100-120 V/220-240 V semi-dry electrophoretic transfer cell, agarose gel support frame, extra thick blot paper in 4 sheet sizes. Price includes frieght cost.
High Performance Liquid Chromatography (HPLC)												UPS					$70,000		Vendor	
High Performance Liquid Chromatography (HPLC) Fluorescence Detector												UPS					$90,000		Vendor	High-Performance Liquid Chromatography (HPLC) Accessory.
Microscope												BACK-UP POWER					$55,422		Vendor	Price includes a manual stage, nosepiece, well plate holder, slide holder, dish holder, 5 fluorite objectives, 4 phase contrast annuluses, 4 differential interference contrast (DIC) prisms, 1 phase contrast/DIC condenser, C-mount adapter for the addition of a camera if required.
Osmometer												UPS					$48,459		Vendor	Price includes instrument installation with customer training, 4 years service contract, IQ/OQ, dot-matrix printer, and paper roll for dot-matrix printer. Note: Advanced Instruments Model 3300 Micro-Osmometer is no longer sold.
Labelling Equipment																	$485		Vendor	
ELISA Microplate Reader with Temperature Control												UPS					$25,835		Vendor	Molecular Devices partners with VWR for plate reader distribution in Canada.
Oven (100-400 °C) for depyrogenization												BACK-UP POWER					$5,893		Vendor	
Automated Cell Counter												BACK-UP POWER					$78,525		Vendor	Typically 5-12% discount off list price. Price includes reagent pack for start-up, concentration control, focus control, 10 µm polystyrene microsphere package, installation with basic training, and IQ/OQ.
Shaker Incubator with CO_2 Control												BACK-UP POWER					$29,700	13-17	Vendor	
Imaging System												BACK-UP POWER					$53,681		Vendor	Price includes 21 CFR Part 11, IQ/OQ, and 1 year warranty.
Capillary Electrophoresis												UPS					$100,000		Vendor	
Polymerase Chain Reaction (PCR) System with Thermal Gradient												BACK-UP POWER					$9,318		Vendor	Reverse Transcription PCR - need to amplify DNA, in-vitro testing of reverse transcriptase in tubes to detect DNA impurities. Reverse transcription will be done using kits. Price of Thermal Cycler includes IQ/OQ. Total price includes $777 for Sub-Cell GT Horizontal Electrophoresis System to run the PCR products in agarose gel and $2,769 for PowerPac Universal Power Supply for the electrophoresis system.
Sterilization Autoclave												BACK-UP POWER					$12,987		Vendor	
Manual Pipettes																	$625		Vendor	Listed price range are based on unit prices for 1 manual pipette of each size. Multiply price by 2 for 2 sets of each size.
Manual Pipettes																	$1,510 - $1,860		Vendor	Listed price range are based on unit prices for 1 manual pipette of each size. Multiply price by 2 for 2 sets of each size.
Automatic Pipettes																	$1,335 - $1,360		Vendor	Listed price range are based on unit prices for 1 electronic pipette of each size. Multiply price by 2 for 2 sets of each size.
Automatic Pipettes																	$2,390 - $3,405		Vendor	Listed price range are based on unit prices for 1 electronic pipette of each size. Multiply price by 2 for 2 sets of each size.
Sterilized Filter Tips for Manual Pipettes or Automatic Pipettes																	$109.50 - $169.50		Vendor	Listed price range are based on unit prices for 1 box of filtered and sterilized pipette tips of each size. Different boxes contain different quantities of pipette tips.
Refrigerated Microcentrifuge												BACK-UP POWER					$30,628		Vendor	Typically 40% discount off list price. Package includes one swinging bucket, 4 x 750 mL rotor; four 7 x 50 mL conical tube adapters; four 14 x 15 mL conical tube adapters; and two sets of microplate carriers. Price includes two sets of microplate covers, 2 sets of round bucket covers, and IQ/OQ.
Refrigerated Microcentrifuge												BACK-UP POWER					$18,911		Vendor	Typically, 40% discount off list price. Price does not include IQ/OQ because the unit does not offer any traceability so it is usually not required.
Purified Water (PW) System												BACK-UP POWER + UPS					$35,000 - $40,000		Vendor	Milli-Q System includes a storage tank which can store reverse osmosis (RO) water.
Static Incubator 35 °C (temperature control between 32 °C - 38 °C)												BACK-UP POWER					$3,187		Vendor	
Laminar Air Flow Hood (part of the in vitro testing in the QC lab)												UPS					$10,988		Vendor	
Liquid N_2 Cell Storage Tank 200L + Additional Volume for Back-Up for the viral vectors line of production												BACK-UP POWER					$14,983		Vendor	
Liquid N_2 Cell Storage Tank 200L + Additional Volume for Back-Up for the viral vectors line of production												BACK-UP POWER					$14,983		Vendor	
Accessories																				
Total Organic Carbon (TOC) Analyzer	-	-	-	-	-	-	-	-	-	-	-	UPS	-	-	-	-	TBD	TBD	-	
Benchtop Balance	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	No results when looking for this specific catalog number. Used CUBIS II Datasheet with 36201S Model as the Basis.
Viable Monitoring Device - 1	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
Viable Monitoring Device - 2	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
Viable Monitoring Device - 3	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
Benchtop Stirrer - 1	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
Benchtop Stirrer - 2	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
pH-Meter - 1	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
pH-Meter - 2	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
Pressure MAT	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
MiniCapt Compressed Gas Kit	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
Water Bath	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
EM Particulate Monitor -1	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	Alternative Met One Device is "Swift 6.0 Flow Meter"
EM Particulate Monitor -2	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	Alternative Met One Device is "Swift 6.0 Flow Meter"
EM Particulate Monitor -3	-	-	-	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	Alternative Met One Device is "Swift 6.0 Flow Meter"

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EQUIPMENT INFORMATION

REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	Area	ROOM	NEW / EXISTING	MFG.	MODEL NUMBER	SPECIFICATION NO.	BID PACKAGE NO.	DIMENSIONS	MAX Weight	FURNISHED BY	INSTALLED BY	FIXED OR PORTABLE
Microbiology Lab																	
B	-	-	-	Automated Cell Counter	Automated Cell Viability Counter	Microbiology Lab	1118	NEW	Beckman Coulter	Vi-CELL BLU Cell Viability Analyzer	-	-	54 cm D x 42 cm W x 45 cm H (21" D x 16.5" W x 18" H)	28 kg (63 lb)	-	-	-
B	-	-	-	Isolator	4 ft PharmaGard ES Total Exhaust Aseptic Containment Isolator	Microbiology Lab	1118	NEW	NuAire	NU-NTE800-400	-	-	1270 mm W x 826 mm D 1550 mm H	211 kg (465 lbs)	-	-	-
B	-	-	-	Benchtop Scale	Precision Balance 610 mg x 1 mg	QC Lab	1117	NEW	Thermo Fisher Scientific	QUINTIX613-1S	-	-	360 mm D x 218 mm W x 320mm H	4.9 kg	-	-	-
B	-	-	-	Water Bath	Water Bath	Microbiology Lab	1118	NEW	Fisher Scientific	TSGP02	-	-	200 mm W x 230 mm L x 233 mm H	3.2 kg	-	-	-
B	-	-	-	Spectrophotometer	Double Beam UV-Vis Spectrophotometer	Microbiology Lab	1118	NEW	Thermo-Fisher Scientific	Genesys 180 UV-Vis Spectrophotometer	-	-	35.5 cm D x 38.5 cm W x 19.5 cm H	7.5 kg (16.5 lb)	-	-	-
QC LAB																	
B	-	-	-	-80^{0}C Freezer - 3	-80^{0}C Ultra-Low Freezer	QC Lab	1117	EXISTING	Thermo Fisher Scientific	TSX8950086A	-	-	955 mm D x 864 mm W x 1981 mm H	327 kg	-	-	-
B	-	-	-	Biosafety Cabinet	4 ft Class II, Type A2 Biological Safety Cabinet	QC Lab	1117	NEW	Thermo Fisher Scientific	Catalogue Number: 13261222	-	-	800 mm D x 1300 mm W x 1568 mm H (31.5" D x 51.2" W x 61.8" H)	430 kg (195 lb)	-	-	-
B	-	-	-	Benchtop Scale	Precision Balance 610 mg x 1 mg	QC Lab	1117	NEW	Thermo Fisher Scientific	QUINTIX613-1S	-	-	360 mm D x 218 mm W x 320mm H	4.9 kg	-	-	-
B	-	-	-	Water Bath	Precision General Purpose Water Bath	QC Lab	1117	NEW	Thermo Fisher Scientific	TSGP20	-	-	230 mm D x 200 mm W x 233 mm H (15.4" D x 21.8" W x 9.2" H) 20 L	3.2 kg	-	-	-
B	-	-	-	Spectrophotometer	Double Beam UV-Vis Spectrophotometer	QC Lab	1117	NEW	Thermo-Fisher Scientific	Genesys 180 UV-Vis Spectrophotometer	-	-	35.5 cm D x 38.5 cm W x 19.5 cm H	7.5 kg (16.5 lb)	-	-	-
B	-	-	-	Western Blot Apparatus	Western Blot Apparatus	QC Lab	1117	NEW	Bio-Rad	Trans-Blot SD Semi-Dry Electrophoretic Transfer Cell	-	-	24 cm D x 37 cm W x 11 cm H	3.6 kg (7.9 lb)			
B	-	-	-	High Performance Liquid Chromatography (HPLC)	High Performance Liquid Chromatography (HPLC)	QC Lab	1117	NEW	Agilent Technologies, Inc.	1220 Infinity II LC System G4294B Configuration	-	-	420 mm D x 370 mm W x 640 mm H (16.5" D x 14.6" W x 25.2" H)	43 kg (94 lb)			
B	-	-	-	High Performance Liquid Chromatography (HPLC) Fluorescence Detector	High Performance Liquid Chromatography (HPLC) Fluorescence Detector	QC Lab	1117	NEW	Agilent Technologies, Inc.	1260 Infinity II Fluorescence Detector	-	-	436 mm D x 396 mm W x 140 mm H (17.2" D x 15.6" W x 5.5" H)	11.9 kg (26.2 lb)			
B	-	-	-	Microscope	Inverted Microscope with manual components, one-deck standard configuration	QC Lab	1117	NEW	Olympus	IX73: One-Deck System	-	-	475 mm D x 323 mm W x 656 mm H	35 kg (77.2 lb)			
B	-	-	-	Osmometer	Single Sample Micro-Osmometer	QC Lab	1117	NEW	Advanced Instruments	OsmoTECH XT Single-Sample Micro-Osmometer	-	-	38 cm D x 36 cm W x 38 cm H (15" D x 14" W x 11.5" H)	11.4 kg (25 lb)			
B	-	-	-	Labelling Equipment	Label Maker	QC Lab	1117	NEW	Brady	BMP51 Lab Starter Kit	-	-	TBD	TBD			
B	-	-	-	ELISA Microplate Reader with Temperature Control	ELISA Microplate Reader with Temperature Control (Wavelength Range: 190 nm - 1000 nm)	QC Lab	1117	NEW	Molecular Devices	SpectraMax ABS Plus Absorbance ELISA Microplate Readers	-	-	41.4 cm D x 30.5 cm W x 20.3 cm H (16.3" D x 12" W x 8" H)	11.3 kg (25 lb)			
B	-	-	-	Oven (100-400 °C) for depyrogenization	Heratherm Advanced Protocol Security Mechanical Convection Oven (temperature range: 5 °C to 330 °C)	QC Lab	1117	NEW	Thermo Fisher Scientific	Catalogue Number: 51028136H	-	-	56.5 cm D x 53 cm W x 72 cm H (22.2" D x 20.9" W x 28.3" H) 61 L	44 kg (97 lb)			
B	-	-	-	Automated Cell Counter	Automated Cell Viability Counter	QC Lab	1117	NEW	Beckman Coulter	Vi-CELL BLU Cell Viability Analyzer	-	-	54 cm D x 42 cm W x 45 cm H (21" D x 16.5" W x 18" H)	28 kg (63 lb)			
B	-	-	-	Shaker Incubator with CO_2 Control	Shaker Incubator	QC Lab	1117	NEW	Kuhner Shaker	ISF1-Z Basic (SMZ1500)	-	-	854 mm D x 1288 mm W x 771 mm H	200 kg			
B	-	-	-	Imaging System	Chemiluminescence and Fluorescence Detection	QC Lab	1117	NEW	Bio-Rad	ChemiDoc MP	-	-	61 cn D x 51 cm W x 53 cm H	35 kg (78 lb)			
B	-	-	-	Capillary Electrophoresis	Capillary Electrophoresis	QC Lab	1117	NEW	Agilent Technologies, Inc.	7100 CE System	-	-	51 cm D x 35 cm W x 59 cm H	35 kg (77.2 lb)			
B	-	-	-	Polymerase Chain Reaction (PCR) System with Thermal Gradient	Reverse Transcription Polymerase Chain Reaction (PCR) with Thermal Gradient	QC Lab	1117	NEW	Bio-Rad	T100 Thermal Cycler, 96-well thermal cycler	-	-	54.6 cm D x 33 cm W x 36 cm H (22" D x 13" W x 14" H)	22 kg (48 lb)			
B	-	-	-	Sterilization Autoclave	Fisherbrand SterilElite Tabletop Autoclave	QC Lab	1117	NEW	Thermo Fisher Scientific	STE4022009	-	-	570 mm D x 766 mm W x 486 mm H (22.4" D x 30.1" W x 19.1" H) 40L	77 kg (169.8 lb)			
B	-	-	-	Manual Pipettes	Single Channel Electronic Pipettes (0.2 -10 µL, 10-20 µL, 20-200 µL, 100-1000 µL), 2 sets of each size	QC Lab	1117	NEW	Mettler Toledo	Rainin E4 Manual Pipette, LTS E4-10XLS+	-	-	TBD	TBD			
B	-	-	-	Manual Pipettes	8 and 12-Channel Electronic Pipettes (25-300 µL, 30-300 µL), 2 sets of each size	QC Lab	1117	NEW	Mettler Toledo	Rainin E4 Multi Pipette L8-10XLS+	-	-	TBD	TBD			
B	-	-	-	Automatic Pipettes	Single Channel Electronic Pipettes (0.2 -10 µL, 10-20 µL, 20-200 µL, 100-1000 µL), 2 sets of each size	QC Lab	1117	NEW	Mettler Toledo	Rainin E4 Electronic Pipette, LTS E4-10XLS+	-	-	TBD	TBD			
B	-	-	-	Automatic Pipettes	8 and 12-Channel Electronic Pipettes (25-300 µL, 30-300 µL), 2 sets of each size	QC Lab	1117	NEW	Mettler Toledo	Rainin E4 Multi Pipette E8-10XLS+	-	-	TBD	TBD			
B				Sterilized Filter Tips for Manual Pipettes or Automatic Pipettes	Sterilized Filter Pipette Tips are required for ELISA and PCR tests	QC Lab	1117	NEW	Mettler Toledo	Rainin RT LTS Pipette Tips			TBD	TBD			
B	-	-	-	Refrigerated Microcentrifuge	Benchtop Refrigerated General-Purpose Centrifuge	QC Lab	1117	NEW	Beckman Coulter	Avanti J-15R	-	-	TBD	TBD			
B	-	-	-	Refrigerated Microcentrifuge	Benchtop Refrigerated Microcentrifuge (1.5 mL - 2.0 mL tubes only)	QC Lab	1117	NEW	Beckman Coulter	Microfuge 20R	-	-	TBD	TBD			

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						PROCESS UTILITIES																											
						HOT WFI HWFI		PURIFIED WATER PW		CIP		CLEAN STEAM CS		CLEAN STEAM CONDENSATE CSC		NITROGEN N_2			OXYGEN O_2			CABRON DIOXIDE CO_2			PROCESS AIR CCA			INSTRUMENT AIR IA			HEAT XFER FLUID (S/R)	
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	LPM	PSIG	LPM	PSIG	LPM	PSIG	kg/h	PSIG	kg/h	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	GPM	PSIG
Microbiology Lab																																	
B	-	-	-	Automated Cell Counter	Automated Cell Viability Counter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Isolator	4 ft PharmaGard ES Total Exhaust Aseptic Containment Isolator	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Benchtop Scale	Precision Balance 610 mg x 1 mg	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Water Bath	Water Bath	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Spectrophotometer	Double Beam UV-Vis Spectrophotometer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
QC LAB																																	
B	-	-	-	-80ºC Freezer - 3	-80ºC Ultra-Low Freezer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Biosafety Cabinet	4 ft Class II, Type A2 Biological Safety Cabinet	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Benchtop Scale	Precision Balance 610 mg x 1 mg	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Water Bath	Precision General Purpose Water Bath	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Spectrophotometer	Double Beam UV-Vis Spectrophotometer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Western Blot Apparatus	Western Blot Apparatus																												
B	-	-	-	High Performance Liquid Chromatography (HPLC)	High Performance Liquid Chromatography (HPLC)																												
B	-	-	-	High Performance Liquid Chromatography (HPLC) Fluorescence Detector	High Performance Liquid Chromatography (HPLC) Fluorescence Detector																												
B	-	-	-	Microscope	Inverted Microscope with manual components, one-deck standard configuration																												
B	-	-	-	Osmometer	Single Sample Micro-Osmometer																												
B	-	-	-	Labelling Equipment	Label Maker																												
B	-	-	-	ELISA Microplate Reader with Temperature Control	ELISA Microplate Reader with Temperature Control (Wavelength Range: 190 nm - 1000 nm)																												
B	-	-	-	Oven (100-400 °C) for depyrogenization	Heratherm Advanced Protocol Security Mechanical Convection Oven (temperature range: 5 °C to 330 °C)																												
B	-	-	-	Automated Cell Counter	Automated Cell Viability Counter																												
B	-	-	-	Shaker Incubator with CO_2 Control	Shaker Incubator																	8.9		29 max									
B	-	-	-	Imaging System	Chemiluminescence and Fluorescence Detection																												
B	-	-	-	Capillary Electrophoresis	Capillary Electrophoresis																												
B	-	-	-	Polymerase Chain Reaction (PCR) System with Thermal Gradient	Reverse Transcription Polymerase Chain Reaction (PCR) with Thermal Gradient																												
B	-	-	-	Sterilization Autoclave	Fisherbrand SterilElite Tabletop Autoclave																												
B	-	-	-	Manual Pipettes	Single Channel Electronic Pipettes (0.2 -10 µL, 10-20 µL, 20-200 µL, 100-1000 µL), 2 sets of each size																												
B	-	-	-	Manual Pipettes	8 and 12-Channel Electronic Pipettes (25-300 µL, 30-300 µL), 2 sets of each size																												
B	-	-	-	Automatic Pipettes	Single Channel Electronic Pipettes (0.2 -10 µL, 10-20 µL, 20-200 µL, 100-1000 µL), 2 sets of each size																												
B	-	-	-	Automatic Pipettes	8 and 12-Channel Electronic Pipettes (25-300 µL, 30-300 µL), 2 sets of each size																												
B				Sterilized Filter Tips for Manual Pipettes or Automatic Pipettes	Sterilized Filter Pipette Tips are required for ELISA and PCR tests																												
B	-	-	-	Refrigerated Microcentrifuge	Benchtop Refrigerated General-Purpose Centrifuge																												
B	-	-	-	Refrigerated Microcentrifuge	Benchtop Refrigerated Microcentrifuge (1.5 mL - 2.0 mL tubes only)																												

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						PLANT UTILITES																								
						PLANT STEAM PS		PLANT STEAM CONDENSATE		DOMESTIC COLD WATER (T=60°F) CW		PROCESS CHILLED WATER		RELIEF VENT PV			INTAKE AIR	EXHAUST			SANITARY SEWER SAN		PROCESS WASTE PW		BIOWASTE BIOD		HEAT LOAD	AUTOMATION		
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	kg/h	PSIG	kg/h	PSIG	LPM	PSIG	LPM	PSIG	SCFM	CFM	PSIG	SCFM	SCFM	CFM	PSIG	LPM	PSIG	LPM	PSIG	LPM	PSIG	kW	CONTROL (OEM, PCS, BAS, N/A)	QUANTITY	BMS or SCADA
Microbiology Lab																														
B	-	-	-	Automated Cell Counter	Automated Cell Viability Counter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Isolator	4 ft PharmaGard ES Total Exhaust Aseptic Containment Isolator	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Benchtop Scale	Precision Balance 610 mg x 1 mg	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Water Bath	Water Bath	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Spectrophotometer	Double Beam UV-Vis Spectrophotometer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
QC LAB																														
B	-	-	-	-80°C Freezer - 3	-80°C Ultra-Low Freezer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Biosafety Cabinet	4 ft Class II, Type A2 Biological Safety Cabinet	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Benchtop Scale	Precision Balance 610 mg x 1 mg	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Water Bath	Precision General Purpose Water Bath	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Spectrophotometer	Double Beam UV-Vis Spectrophotometer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	Western Blot Apparatus	Western Blot Apparatus																									
B	-	-	-	High Performance Liquid Chromatography (HPLC)	High Performance Liquid Chromatography (HPLC)																									
B	-	-	-	High Performance Liquid Chromatography (HPLC) Fluorescence Detector	High Performance Liquid Chromatography (HPLC) Fluorescence Detector																									
B	-	-	-	Microscope	Inverted Microscope with manual components, one-deck standard configuration																									
B	-	-	-	Osmometer	Single Sample Micro-Osmometer																									
B	-	-	-	Labelling Equipment	Label Maker																									
B	-	-	-	ELISA Microplate Reader with Temperature Control	ELISA Microplate Reader with Temperature Control (Wavelength Range: 190 nm - 1000 nm)																									
B	-	-	-	Oven (100-400 °C) for depyrogenization	Heratherm Advanced Protocol Security Mechanical Convection Oven (temperature range: 5 °C to 330 °C)																									
B	-	-	-	Automated Cell Counter	Automated Cell Viability Counter																									
B	-	-	-	Shaker Incubator with CO_2 Control	Shaker Incubator																									
B	-	-	-	Imaging System	Chemiluminescence and Fluorescence Detection																									
B	-	-	-	Capillary Electrophoresis	Capillary Electrophoresis																									
B	-	-	-	Polymerase Chain Reaction (PCR) System with Thermal Gradient	Reverse Transcription Polymerase Chain Reaction (PCR) with Thermal Gradient																									
B	-	-	-	Sterilization Autoclave	Fisherbrand SterilElite Tabletop Autoclave																									
B	-	-	-	Manual Pipettes	Single Channel Electronic Pipettes (0.2 -10 µL, 10-20 µL, 20-200 µL, 100-1000 µL), 2 sets of each size																									
B	-	-	-	Manual Pipettes	8 and 12-Channel Electronic Pipettes (25-300 µL, 30-300 µL), 2 sets of each size																									
B	-	-	-	Automatic Pipettes	Single Channel Electronic Pipettes (0.2 -10 µL, 10-20 µL, 20-200 µL, 100-1000 µL), 2 sets of each size																									
B	-	-	-	Automatic Pipettes	8 and 12-Channel Electronic Pipettes (25-300 µL, 30-300 µL), 2 sets of each size																									
B				Sterilized Filter Tips for Manual Pipettes or Automatic Pipettes	Sterilized Filter Pipette Tips are required for ELISA and PCR tests																									
B	-	-	-	Refrigerated Microcentrifuge	Benchtop Refrigerated General-Purpose Centrifuge																									
B	-	-	-	Refrigerated Microcentrifuge	Benchtop Refrigerated Microcentrifuge (1.5 mL - 2.0 mL tubes only)																									

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						ELECTRICAL																
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	ELECTRICAL DESCRIPTION	HP	VOLTAGE	PHASE	AMPS	KVA	FIELD CONNECTION	CLASS OF POWER	BACK-UP POWER / UPS	DATA INTEGRATION (PCS, MES, BAS, EMS, N/A)	UNIT COST	QUANTITY	INSTALLATION FACTOR	ESTIMATED TOTAL COST	LEAD TIME (WEEKS ARO)	ESTIMATION SOURCE	NOTES
Microbiology Lab																						
B	-	-	-	Automated Cell Counter	Automated Cell Viability Counter	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$78,525	-	Vendor	Typically 5-12% discount off list price. Price includes reagent pack for start-up, concentration control, focus control, 10 µm polystyrene microsphere package, installation with basic training, and IQ/OQ.
B	-	-	-	Isolator	4 ft PharmaGard ES Total Exhaust Aseptic Containment Isolator	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$24,844	-	Vendor	
B	-	-	-	Benchtop Scale	Precision Balance 610 mg x 1 mg	-	-	100-240 V @ 50-60 Hz	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$2,995	-	Vendor	
B	-	-	-	Water Bath	Water Bath	-	-	120V @ 60 Hz	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$1,300	-	HISTORY - Consultant Estimate	
B	-	-	-	Spectrophotometer	Double Beam UV-Vis Spectrophotometer	-	-	110/220 V @ 50/60 Hz	-	-	-	-	-	UPS	-	-	-	-	$9,597	-	Vendor	
QC LAB																						
B	-	-	-	-80°C Freezer - 3	-80°C Ultra-Low Freezer	-	-	115 V @ 60 Hz	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$23,190	4	Vendor	Given Model Number was possibly incorrect. Used the TSX50086A model.
B	-	-	-	Biosafety Cabinet	4 ft Class II, Type A2 Biological Safety Cabinet	-	-	230 V @ 50 Hz	-	-	-	-	-	UPS	-	-	-	-	$14,560	-	Vendor	
B	-	-	-	Benchtop Scale	Precision Balance 610 mg x 1 mg	-	-	100-240 V @ 50-60 Hz	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$2,995	-	Vendor	
B	-	-	-	Water Bath	Precision General Purpose Water Bath	-	-	120V @ 60 Hz	-	-	-	-	-	BACK-UP POWER	-	-	-	-	$2,013	-	Vendor	
B	-	-	-	Spectrophotometer	Double Beam UV-Vis Spectrophotometer	-	-	110/220 V @ 50/60 Hz	-	-	-	-	-	UPS	-	-	-	-	$9,597	-	Vendor	
B	-	-	-	Western Blot Apparatus	Western Blot Apparatus									BACK-UP POWER					$2,250		Vendor	Includes 100-120 V/220-240 V semi-dry electrophoretic transfer cell, agarose gel support frame, extra thick blot paper in 4 sheet sizes. Price includes frieght cost.
B	-	-	-	High Performance Liquid Chromatography (HPLC)	High Performance Liquid Chromatography (HPLC)									UPS					$70,000		Vendor	
B	-	-	-	High Performance Liquid Chromatography (HPLC) Fluorescence Detector	High Performance Liquid Chromatography (HPLC) Fluorescence Detector									UPS					$90,000		Vendor	High-Performance Liquid Chromatography (HPLC) Accessory.
B	-	-	-	Microscope	Inverted Microscope with manual components, one-deck standard configuration									BACK-UP POWER					$55,422		Vendor	Price includes a manual stage, nosepiece, well plate holder, slide holder, dish holder, 5 fluorite objectives, 4 phase contrast annuluses, 4 differential interference contrast (DIC) prisms, 1 phase contrast/DIC condenser, C-mount adapter for the addition of a camera if required.
B	-	-	-	Osmometer	Single Sample Micro-Osmometer									UPS					$48,459		Vendor	Price includes instrument installation with customer training, 4 years service contract, IQ/OQ, dot-matrix printer, and paper roll for dot-matrix printer. Note: Advanced Instruments Model 3300 Micro-Osmometer is no longer sold.
B	-	-	-	Labelling Equipment	Label Maker														$485		Vendor	
B	-	-	-	ELISA Microplate Reader with Temperature Control	ELISA Microplate Reader with Temperature Control (Wavelength Range: 190 nm - 1000 nm)									UPS					$25,835		Vendor	Molecular Devices partners with VWR for plate reader distribution in Canada.
B	-	-	-	Oven (100-400 °C) for depyrogenization	Heratherm Advanced Protocol Security Mechanical Convection Oven (temperature range: 5 °C to 330 °C)									BACK-UP POWER					$5,893		Vendor	
B	-	-	-	Automated Cell Counter	Automated Cell Viability Counter									BACK-UP POWER					$78,525		Vendor	Typically 5-12% discount off list price. Price includes reagent pack for start-up, concentration control, focus control, 10 µm polystyrene microsphere package, installation with basic training, and IQ/OQ.
B	-	-	-	Shaker Incubator with CO_2 Control	Shaker Incubator									BACK-UP POWER					$29,700	13-17	Vendor	
B	-	-	-	Imaging System	Chemiluminescence and Fluorescence Detection									BACK-UP POWER					$53,681		Vendor	Price includes 21 CFR Part 11, IQ/OQ, and 1 year warranty.
B	-	-	-	Capillary Electrophoresis	Capillary Electrophoresis									UPS					$100,000		Vendor	
B	-	-	-	Polymerase Chain Reaction (PCR) System with Thermal Gradient	Reverse Transcription Polymerase Chain Reaction (PCR) with Thermal Gradient									BACK-UP POWER					$9,318		Vendor	Reverse Transcription PCR - need to amplify DNA, in-vitro testing of reverse transcriptase in tubes to detect DNA impurities. Reverse transcription will be done using kits. Price of Thermal Cycler includes IQ/OQ. Total price includes $777 for Sub-Cell GT Horizontal Electrophoresis System to run the PCR products in agarose gel and $2,769 for PowerPac Universal Power Supply for the electrophoresis system.
B	-	-	-	Sterilization Autoclave	Fisherbrand SterilElite Tabletop Autoclave									BACK-UP POWER					$12,987		Vendor	
B	-	-	-	Manual Pipettes	Single Channel Electronic Pipettes (0.2 -10 µL, 10-20 µL, 20-200 µL, 100-1000 µL), 2 sets of each size														$625		Vendor	Listed price range are based on unit prices for 1 manual pipette of each size. Multiply price by 2 for 2 sets of each size.
B	-	-	-	Manual Pipettes	8 and 12-Channel Electronic Pipettes (25-300 µL, 30-300 µL), 2 sets of each size														$1,510 - $1,860		Vendor	Listed price range are based on unit prices for 1 manual pipette of each size. Multiply price by 2 for 2 sets of each size.
B	-	-	-	Automatic Pipettes	Single Channel Electronic Pipettes (0.2 -10 µL, 10-20 µL, 20-200 µL, 100-1000 µL), 2 sets of each size														$1,335 - $1,360		Vendor	Listed price range are based on unit prices for 1 electronic pipette of each size. Multiply price by 2 for 2 sets of each size.
B	-	-	-	Automatic Pipettes	8 and 12-Channel Electronic Pipettes (25-300 µL, 30-300 µL), 2 sets of each size														$2,390 - $3,405		Vendor	Listed price range are based on unit prices for 1 electronic pipette of each size. Multiply price by 2 for 2 sets of each size.
B				Sterilized Filter Tips for Manual Pipettes or Automatic Pipettes	Sterilized Filter Pipette Tips are required for ELISA and PCR tests														$109.50 - $169.50		Vendor	Listed price range are based on unit prices for 1 box of filtered and sterilized pipette tips of each size. Different boxes contain different quantities of pipette tips.
B	-	-	-	Refrigerated Microcentrifuge	Benchtop Refrigerated General-Purpose Centrifuge									BACK-UP POWER					$30,628		Vendor	Typically 40% discount off list price. Package includes one swinging bucket, 4 x 750 mL rotor; four 7 x 50 mL conical tube adapters; four 14 x 15 mL conical tube adapters; and two sets of microplate carriers. Price includes two sets of microplate covers, 2 sets of round bucket covers, and IQ/OQ.
B	-	-	-	Refrigerated Microcentrifuge	Benchtop Refrigerated Microcentrifuge (1.5 mL - 2.0 mL tubes only)									BACK-UP POWER					$18,911		Vendor	Typically, 40% discount off list price. Price does not include IQ/OQ because the unit does not offer any traceability so it is usually not required.

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EQUIPMENT INFORMATION

REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	Area	ROOM	NEW / EXISTING	MFG.	MODEL NUMBER	SPECIFICATION NO.	BID PACKAGE NO.	DIMENSIONS	MAX Weight	FURNISHED BY	INSTALLED BY	FIXED OR PORTABLE
B	-	-	-	Purified Water (PW) System	Milli-Q IQ 7005 Water Purification System	QC Lab	1117	NEW	Millipore Sigma	ZIQ7005T0	-	-	Purification Unit: 38 cm D x 31.5 cm W x 49.8 cm H (15" D x 12.4" W x 19.6" H), Storage Tank: 50.3 cm D x 40 cm W x 41.5 cm H (19.8" D x 15.7" W x 16.3" H)	Purification Unit: 26.0 kg (57 lb) Max. Operating, Storage Tank: 25 L			
B	-	-	-	Static Incubator 35 °C (temperature control between 32 °C - 38 °C)	Heratherm Advanced Protocol Microbiological Incubator (temperature range: 5 °C to 75 °C)	QC Lab	1117	NEW	Thermo Fisher Scientific	Catalogue Number: 51028064H	-	-	56.5 cm D x 64 cm W x 82 cm H (22.2" D x 25.2" W x 32.3" H) 117 L	51 kg (112 lb)			
B	-	-	-	Laminar Air Flow Hood (part of the in vitro testing in the QC lab)	Vertical Laminar Flow Hood	QC Lab	1117	NEW	NuAire	NU-140-430	-	-	813 mm D x 965 mm W x 1473 mm H (32" D x 38" W x 58" H)	136 kg (300 lb)			
B	-	-	-	Liquid N_2 Cell Storage Tank 200L + Additional Volume for Back-Up for the viral vectors line of production	Liquid Nitrogen Cryogenic Cell Storage, 6 racks	QC Lab	1117	NEW	Thermo Fisher Scientific	CryoPlus 1 Model Number: 7400	-	-	26 cm D x 21.5 cm W x 41 cm H (66" D x 54.6" W x 104.1" H) 90 L	117.9 kg (260 lb)			
B	-	-	-	Liquid N_2 Cell Storage Tank 200L + Additional Volume for Back-Up for the viral vectors line of production	Liquid Nitrogen Cryogenic Cell Storage, 6 racks	QC Lab	1117	NEW	Thermo Fisher Scientific	CryoPlus 1 Model Number: 7400	-	-	26 cm D x 21.5 cm W x 41 cm H (66" D x 54.6" W x 104.1" H) 90 L	117.9 kg (260 lb)			
Accessories																	
A	-	-	-	Total Organic Carbon (TOC) Analyzer	Shimadzu TOC-LCSH Analyzer	TBD	TBD	EXISTING	Mandel	Model - TOC-LCSH Catalog - SZ-638-91105-22	-	-	340 mm W x 660 mm D x 480 mm H	Approx. 35 kg	-	-	-
A	-	-	-	Benchtop Balance	High Capacity Benchtop Balance	TBD	TBD	EXISTING	Sartorius	MCE3620015-2SOO-0	-	-	400 mm W x 412 mm L x 126-159 mm H	15.8 - 17.1 kg	-	-	-
A	-	-	-	Viable Monitoring Device - 1	Compliant Air Sampler Air Filter	TBD	TBD	EXISTING	EMD Millipore	MAS-100 NT 1.17274.0001 with Filter	-	-	290 mm W x 160 mm L x 230 mm H	7.5 kg (without sampling head)	-	-	-
A	-	-	-	Viable Monitoring Device - 2	Compliant Air Sampler Air Filter	TBD	TBD	EXISTING	EMD Millipore	MAS-100 NT 1.17274.0001 with Filter	-	-	290 mm W x 160 mm L x 230 mm H	7.5 kg (without sampling head)	-	-	-
A	-	-	-	Viable Monitoring Device - 3	PMS minicapt Mobile Microbial Air Sampler100lpm	TBD	TBD	EXISTING	Alpha Controls	790045-0100	-	-	145 mm W x 150 mm D x 260 mm H	2.1 kg	-	-	-
A	-	-	-	Benchtop Stirrer - 1	Benchtop 7" x 7" Stirrer	TBD	TBD	EXISTING	VWR Intl. LLC	Model - VWR 7 x 7 Cer stirrer 120v pro Catalog - 97042-706	-	-	250 mm W x 376 mm D x 109 mm H	5.4 kg	-	-	-
A	-	-	-	Benchtop Stirrer - 2	Benchtop 7" x 7" Stirrer	TBD	TBD	EXISTING	VWR Intl. LLC	Model - VWR 7 x 7 Cer stirrer 120v pro Catalog - 97042-706	-	-	250 mm W x 376 mm D x 109 mm H	5.4 kg	-	-	-
A	-	-	-	pH-Meter - 1	Benchtop pH/Conductivity Multiparameter Benchtop Meter	TBD	TBD	EXISTING	Fisher Scientific	Model - Orion Versa Star Pro Meter Catalog - VSTAR-50	-	-	240 mm W x 282 mm D x 95 mm H	1.15 kg	-	-	-
A	-	-	-	pH-Meter - 2	Benchtop pH/Conductivity Multiparameter Benchtop Meter	TBD	TBD	EXISTING	Fisher Scientific	Model - Orion Versa Star Pro Meter Catalog - VSTAR-50	-	-	240 mm W x 282 mm D x 95 mm H	1.15 kg	-	-	-
A	-	-	-	Pressure MAT	Pressure MAT Sensor Monior	TBD	TBD	EXISTING	pendoTECH	PMAT3P	-	-	199.6 mm W 57.2 mm D x 113.5 mm H	0.65 kg	-	-	-
A	-	-	-	MiniCapt Compressed Gas Kit	PMS minicapt Compressed Gas Kit 1001lpm - Microbial Monitoring Accesory	TBD	TBD	EXISTING	Alpha Controls	Model - R05232.RNLA Catalog - 90790051	-	-	152 mm W x 102 mm D x 216 mm H	1.86 kg	-	-	-
A	-	-	-	Water Bath	Thermo Scientific Precision Criculating (TSPC) Water Bath	TBD	TBD	EXISTING	Fisher Scientific	TSCIR89	-	-	1160 mm W x 546 mm L x 300 mm H	Not Specified	-	-	-
A	-	-	-	EM Particulate Monitor -1	Met-One or similar	TBD	TBD	NEW	Met One	Aerocet 531S	-	-	102mm W x 54 mm D x 159 mm H	0.9 kg (2.0 lbs)	-	-	-
A	-	-	-	EM Particulate Monitor -2	Met-One or similar	TBD	TBD	NEW	Met One	Aerocet 531S	-	-	102mm W x 54 mm D x 159 mm H	0.9 kg (2.0 lbs)	-	-	-
A	-	-	-	EM Particulate Monitor -3	Met-One or similar	TBD	TBD	NEW	Met One	Aerocet 531S	-	-	102mm W x 54 mm D x 159 mm H	0.9 kg (2.0 lbs)	-	-	-

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						PROCESS UTILITIES																											
						HOT WFI HWFI		PURIFIED WATER PW		CIP		CLEAN STEAM CS		CLEAN STEAM CONDENSATE CSC		NITROGEN N_2			OXYGEN O_2			CABRON DIOXIDE CO_2			PROCESS AIR CCA			INSTRUMENT AIR IA			HEAT XFER FLUID (S/R)	
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	LPM	PSIG	LPM	PSIG	LPM	PSIG	kg/h	PSIG	kg/h	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	SCFM	CFM	PSIG	GPM	PSIG
B	-	-	-	Purified Water (PW) System	Milli-Q IQ 7005 Water Purification System																												
B	-	-	-	Static Incubator 35 °C (temperature control between 32 °C - 38 °C)	Heratherm Advanced Protocol Microbiological Incubator (temperature range: 5 °C to 75 °C)																												
B	-	-	-	Laminar Air Flow Hood (part of the in vitro testing in the QC lab)	Vertical Laminar Flow Hood																												
B	-	-	-	Liquid N_2 Cell Storage Tank 200L + Additional Volume for Back-Up for the viral vectors line of production	Liquid Nitrogen Cryogenic Cell Storage, 6 racks																												
B	-	-	-	Liquid N_2 Cell Storage Tank 200L + Additional Volume for Back-Up for the viral vectors line of production	Liquid Nitrogen Cryogenic Cell Storage, 6 racks																												
Accessories																																	
A	-	-	-	Total Organic Carbon (TOC) Analyzer	Shimadzu TOC-LCSH Analyzer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Benchtop Balance	High Capacity Benchtop Balance	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Viable Monitoring Device - 1	Compliant Air Sampler Air Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Viable Monitoring Device - 2	Compliant Air Sampler Air Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Viable Monitoring Device - 3	PMS minicapt Mobile Microbial Air Sampler100lpm	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Benchtop Stirrer - 1	Benchtop 7" x 7" Stirrer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Benchtop Stirrer - 2	Benchtop 7" x 7" Stirrer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	pH-Meter - 1	Benchtop pH/Conductivity Multiparameter Benchtop Meter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	pH-Meter - 2	Benchtop pH/Conductivity Multiparameter Benchtop Meter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Pressure MAT	Pressure MAT Sensor Monior	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	MiniCapt Compressed Gas Kit	PMS minicapt Compressed Gas Kit 1001lpm - Microbial Monitoring Accesory	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Water Bath	Thermo Scientific Precision Criculating (TSPC) Water Bath	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	EM Particulate Monitor -1	Met-One or similar	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	EM Particulate Monitor -2	Met-One or similar	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	EM Particulate Monitor -3	Met-One or similar	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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						PLANT UTILITES																					AUTOMATION		
						PLANT STEAM PS		PLANT STEAM CONDENSATE		DOMESTIC COLD WATER (T=60°F) CW		PROCESS CHILLED WATER		RELIEF VENT PV			INTAKE AIR	EXHAUST			SANITARY SEWER SAN		PROCESS WASTE PW		BIOWASTE BIOD		HEAT LOAD			
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	kg/h	PSIG	kg/h	PSIG	LPM	PSIG	LPM	PSIG	SCFM	CFM	PSIG	SCFM	SCFM	CFM	PSIG	LPM	PSIG	LPM	PSIG	LPM	PSIG	kW	CONTROL (OEM, PCS, BAS, N/A)	QUANTITY	BMS or SCADA
B	-	-	-	Purified Water (PW) System	Milli-Q IQ 7005 Water Purification System																								
B	-	-	-	Static Incubator 35 °C (temperature control between 32 °C - 38 °C)	Heratherm Advanced Protocol Microbiological Incubator (temperature range: 5 °C to 75 °C)																								
B	-	-	-	Laminar Air Flow Hood (part of the in vitro testing in the QC lab)	Vertical Laminar Flow Hood																								
B	-	-	-	Liquid N_2 Cell Storage Tank 200L + Additional Volume for Back-Up for the viral vectors line of production	Liquid Nitrogen Cryogenic Cell Storage, 6 racks																								
B	-	-	-	Liquid N_2 Cell Storage Tank 200L + Additional Volume for Back-Up for the viral vectors line of production	Liquid Nitrogen Cryogenic Cell Storage, 6 racks																								
Accessories																													
A	-	-	-	Total Organic Carbon (TOC) Analyzer	Shimadzu TOC-LCSH Analyzer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Benchtop Balance	High Capacity Benchtop Balance	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Viable Monitoring Device - 1	Compliant Air Sampler Air Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Viable Monitoring Device - 2	Compliant Air Sampler Air Filter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Viable Monitoring Device - 3	PMS minicapt Mobile Microbial Air Sampler100lpm	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Benchtop Stirrer - 1	Benchtop 7" x 7" Stirrer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Benchtop Stirrer - 2	Benchtop 7" x 7" Stirrer	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	pH-Meter - 1	Benchtop pH/Conductivity Multiparameter Benchtop Meter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	pH-Meter - 2	Benchtop pH/Conductivity Multiparameter Benchtop Meter	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Pressure MAT	Pressure MAT Sensor Monior	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	MiniCapt Compressed Gas Kit	PMS minicapt Compressed Gas Kit 1001lpm - Microbial Monitoring Accesory	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	Water Bath	Thermo Scientific Precision Criculating (T5PC) Water Bath	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	EM Particulate Monitor -1	Met-One or similar	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	EM Particulate Monitor -2	Met-One or similar	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A	-	-	-	EM Particulate Monitor -3	Met-One or similar	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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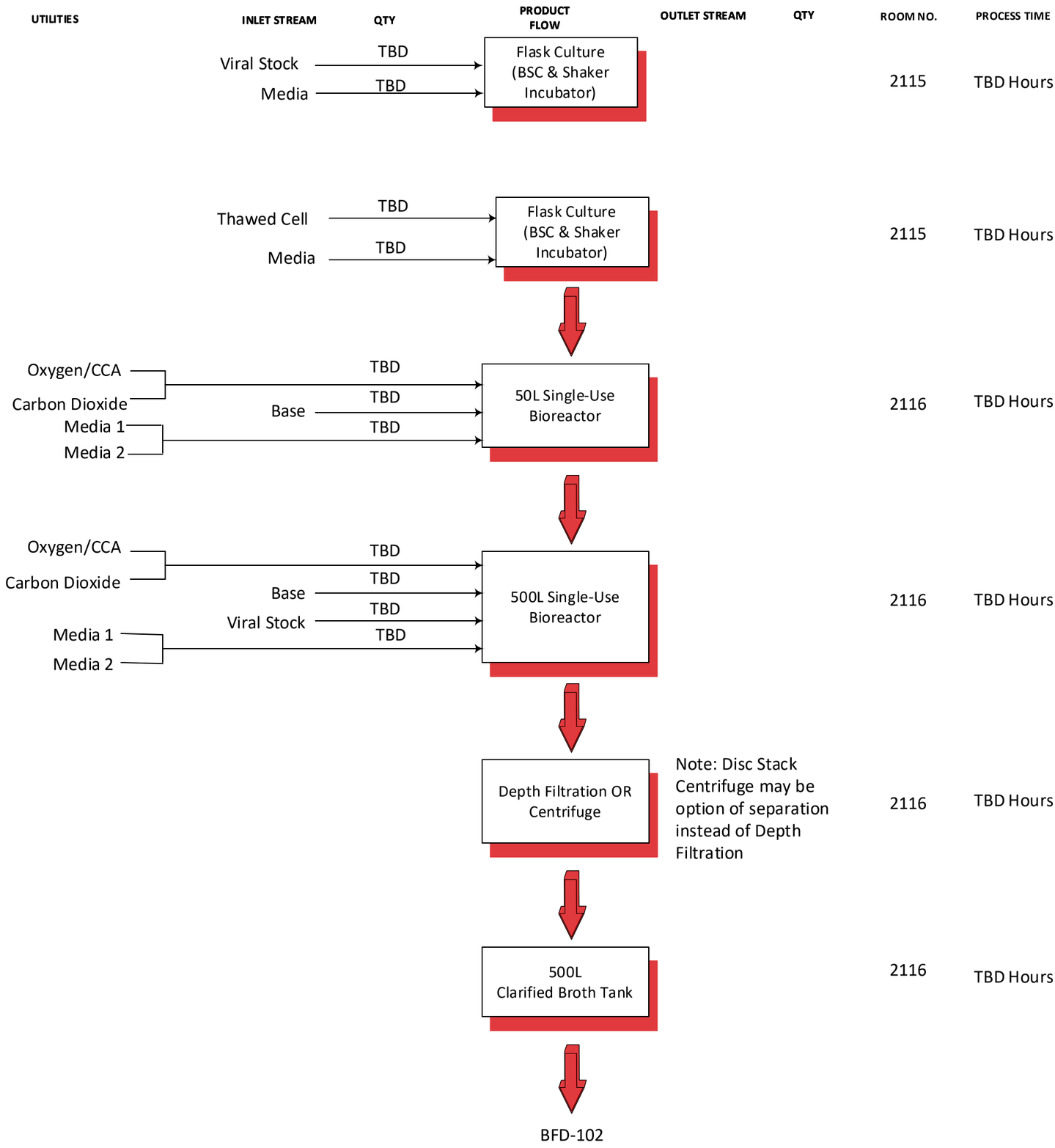
						ELECTRICAL																
REV.	TAG	PID No.	BFD No.	EQUIPMENT NAME	DESCRIPTION	ELECTRICAL DESCRIPTION	HP	VOLTAGE	PHASE	AMPS	KVA	FIELD CONNECTION	CLASS OF POWER	BACK-UP POWER / UPS	DATA INTEGRATION (PCS, MES, BAS, EMS, N/A)	UNIT COST	QUANTITY	INSTALLATION FACTOR	ESTIMATED TOTAL COST	LEAD TIME (WEEKS ARO)	ESTIMATION SOURCE	NOTES
B	-	-	-	Purified Water (PW) System	Milli-Q IQ 7005 Water Purification System									BACK-UP POWER + UPS					$35,000 - $40,000		Vendor	Milli-Q System includes a storage tank which can store reverse osmosis (RO) water.
B	-	-	-	Static Incubator 35 °C (temperature control between 32 °C - 38 °C)	Heratherm Advanced Protocol Microbiological Incubator (temperature range: 5 °C to 75 °C)									BACK-UP POWER					$3,187		Vendor	
B	-	-	-	Laminar Air Flow Hood (part of the in vitro testing in the QC lab)	Vertical Laminar Flow Hood									UPS					$10,988		Vendor	
B	-	-	-	Liquid N_2 Cell Storage Tank 200L + Additional Volume for Back-Up for the viral vectors line of production	Liquid Nitrogen Cryogenic Cell Storage, 6 racks									BACK-UP POWER					$14,983		Vendor	
B	-	-	-	Liquid N_2 Cell Storage Tank 200L + Additional Volume for Back-Up for the viral vectors line of production	Liquid Nitrogen Cryogenic Cell Storage, 6 racks									BACK-UP POWER					$14,983		Vendor	
Accessories																						
A	-	-	-	Total Organic Carbon (TOC) Analyzer	Shimadzu TOC-LCSH Analyzer	-	-	-	-	-	-	-	-	UPS	-	-	-	-	TBD	TBD	-	
A	-	-	-	Benchtop Balance	High Capacity Benchtop Balance	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	No results when looking for this specific catalog number. Used CUBIS II Datasheet with 36201S Model as the Basis.
A	-	-	-	Viable Monitoring Device - 1	Compliant Air Sampler Air Filter	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
A	-	-	-	Viable Monitoring Device - 2	Compliant Air Sampler Air Filter	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
A	-	-	-	Viable Monitoring Device - 3	PMS minicapt Mobile Microbial Air Sampler100lpm	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
A	-	-	-	Benchtop Stirrer - 1	Benchtop 7" x 7" Stirrer	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
A	-	-	-	Benchtop Stirrer - 2	Benchtop 7" x 7" Stirrer	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
A	-	-	-	pH-Meter - 1	Benchtop pH/Conductivity Multiparameter Benchtop Meter	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
A	-	-	-	pH-Meter - 2	Benchtop pH/Conductivity Multiparameter Benchtop Meter	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
A	-	-	-	Pressure MAT	Pressure MAT Sensor Monior	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
A	-	-	-	MiniCapt Compressed Gas Kit	PMS minicapt Compressed Gas Kit 100lpm - Microbial Monitoring Accesory	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
A	-	-	-	Water Bath	Thermo Scientific Precision Criculating (TSPC) Water Bath	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	
A	-	-	-	EM Particulate Monitor -1	Met-One or similar	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	Alternative Met One Device is "Swift 6.0 Flow Meter"
A	-	-	-	EM Particulate Monitor -2	Met-One or similar	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	Alternative Met One Device is "Swift 6.0 Flow Meter"
A	-	-	-	EM Particulate Monitor -3	Met-One or similar	-	-	-	-	-	-	-	-	BACK-UP POWER	-	-	-	-	TBD	TBD	-	Alternative Met One Device is "Swift 6.0 Flow Meter"

UPSTREAM PROCESS – Monoclonal Antibodies , GRADE 'C', Biocontainment N/A



CLIENT/PROJECT TITLE:	ISSUE	REV.	DATE	ENGINEER	NK	DRAWING No.
PROJECT NRC	OWNER REVIEW ISSUE	A	11MAR2021	DESIGNER	-	**BFD-101**
	OWNER REVIEW ISSUE	B	12MAR2021	DRAWN BY	NN	
BLOCK FLOW DIAGRAM DRUG SUBSTANCE – PROPAGATION & HARVEST	CONCEPT ISSUE	C	21APR2021	SCALE	NONE	

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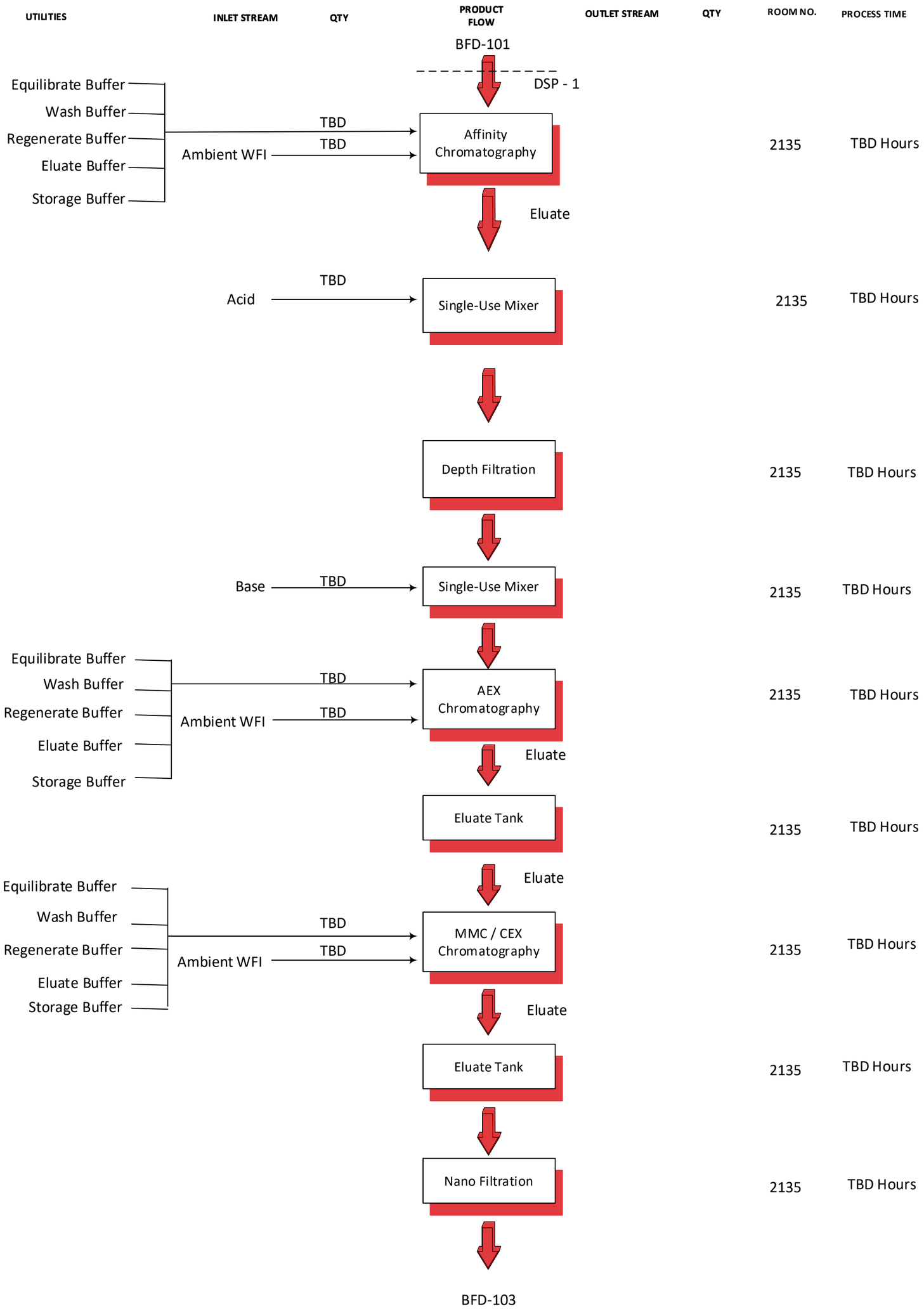
DOWNSTREAM PROCESS – Monoclonal Antibodies GRADE 'C' CL2, Biocontainment N/A



CLIENT/PROJECT TITLE:	ISSUE	REV.	DATE	ENGINEER	NK	DRAWING No.
PROJECT NRC	OWNER REVIEW ISSUE	A	11MAR2021	DESIGNER	-	**BFD-102**
BLOCK FLOW DIAGRAM DRUG PRODUCT – FILTRATION / PURIFICATION / CHROMATOGRAPHY	OWNER REVIEW ISSUE	B	12MAR2021	DRAWN BY	NN	
	CONCEPT ISSUE	C	21APR2021	SCALE	NONE	

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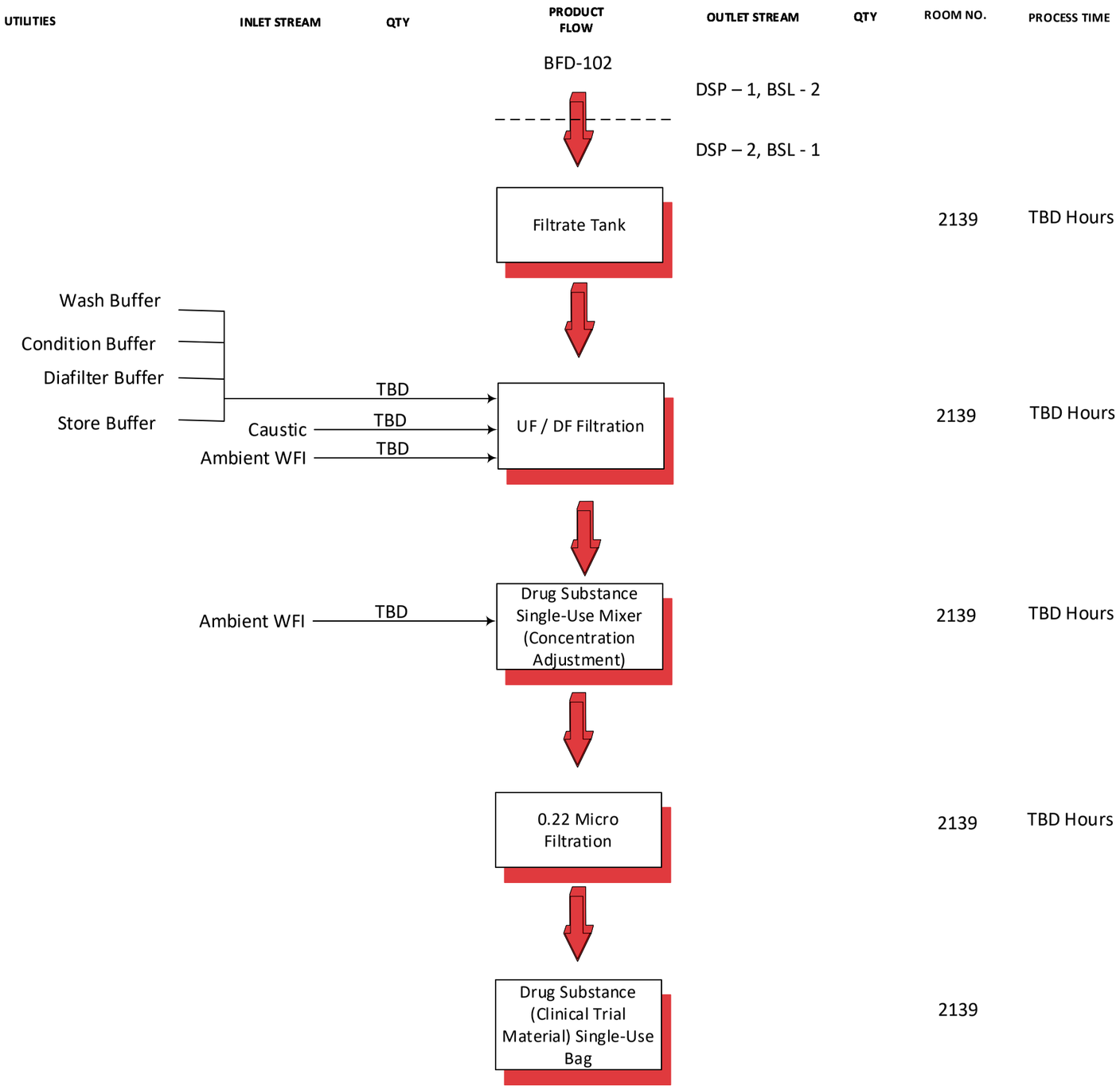
DOWNSTREAM PROCESS – Monoclonal Antibodies GRADE 'C' CL2, Biocontainment N/A



CLIENT/PROJECT TITLE:	ISSUE	REV.	DATE	ENGINEER	NK	DRAWING No.
PROJECT NRC	OWNER REVIEW ISSUE	A	11MAR2021	DESIGNER	-	**BFD-103**
BLOCK FLOW DIAGRAM DRUG PRODUCT – FILTRATION / FILLING	OWNER REVIEW ISSUE	B	12MAR2021	DRAWN BY	NN	
	CONCEPT ISSUE	C	21APR2021	SCALE	NONE	

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Drawing List NRC Project 21090.01

PROJECT – NRC 21090.01 DRAWING NUMBER	DRAWING TITTLE	ISSUE DATE 26MAR2021	06APR2021	21APR2021	-	-	-	-	-
		ISSUE DESCRPITION INITIAL DRAFT	Owner review issue	CONCEPT ISSUE	-	-	-	-	-
PFD-001	LEAD SHEET	X	X	X					
PFD-100	PFD DRAWING LIST	X	X	X					
PFD-101	VIRAL STOCK PREPARATION	X	X	X					
PFD-102	CELL THAW & INCUBATION	X	X	X					
PFD-103	CELL CULTURE GROWTH - SEPARATION	X	X	X					
PFD-104	CHROMATOGRAPHY - FILTRATION	X	X	X					
PFD-105	PURIFICATION	X	X	X					
PFD-106	FILTRATION	X	X	X					
PFD-107	FILTRATION & STORAGE	X	X	X					

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DRAWING No. **PFD-100**

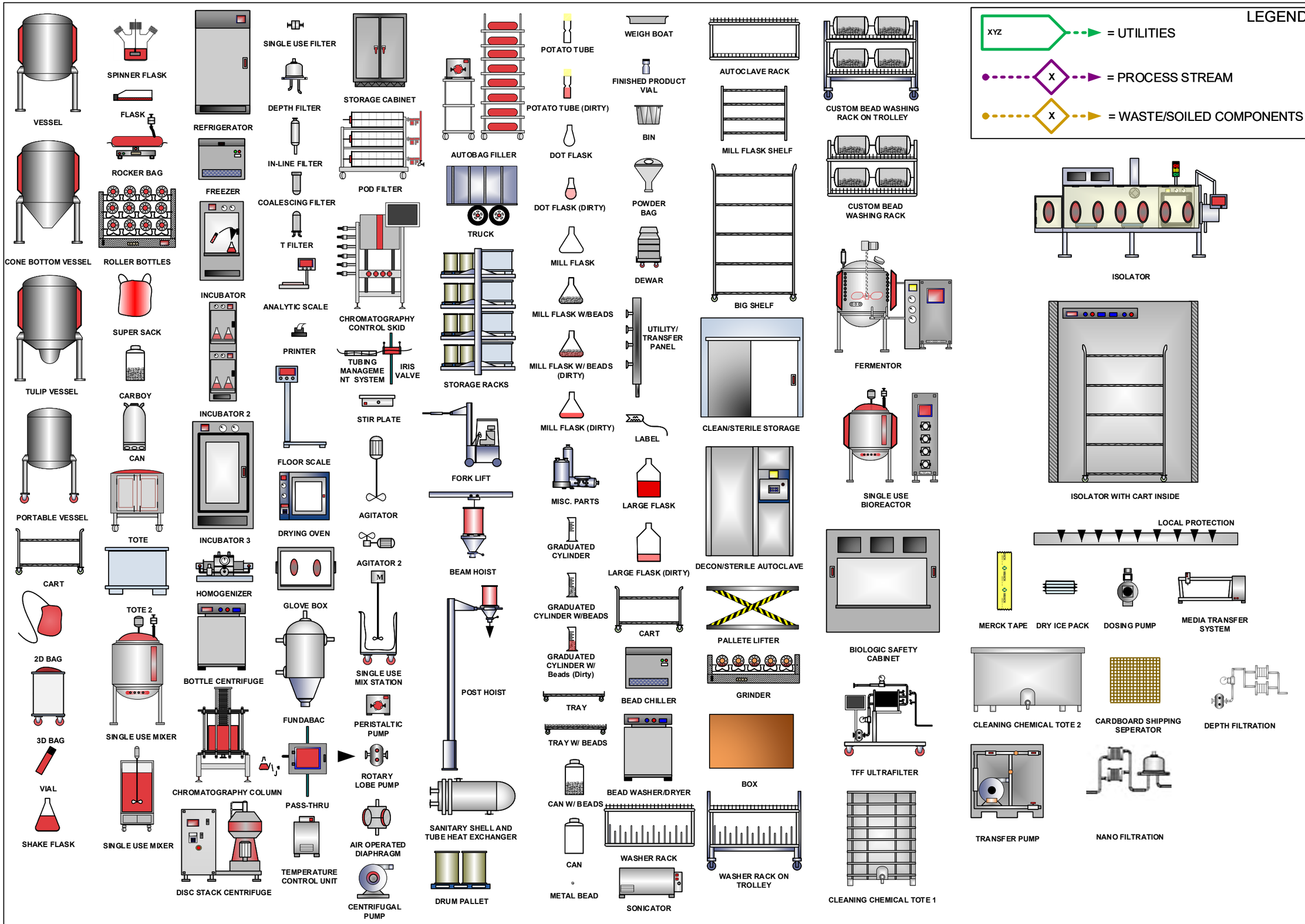
ENGINEER	NK					
DESIGNER	-					
DRAWN BY	SC					
SCALE	NONE					

REV.	DATE	ISSUE
A	26MAR2021	Initial Draft
B	06APR2021	Owner Review Issue
C	21APR2021	Concept Issue

CLIENT/PROJECT TITLE:

NRC Project 21090.01

mAb - Process Flow Diagram Drawing List



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DRAWING No.	PFD-001
NK	-
ENGINEER	SC
DESIGNER	NONE
DRAWN BY	
SCALE	

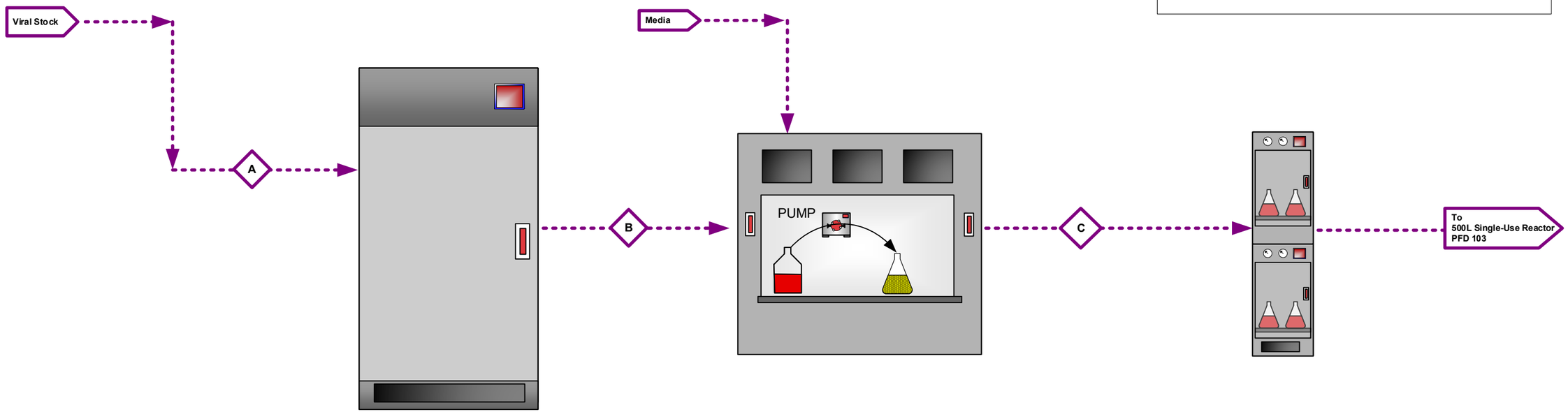
REV.	DATE	ISSUE
A	01APR2021	Initial Draft
B	06APR2021	Owner Review Issue
C	21APR2021	Concept Issue

CLIENT/PROJECT TITLE:

NRC PROJECT 21090.01

Process Flow Diagram Lead Sheet

Room Number. 2115, Classification : Grade C, Biocontainment : N/A



2-8°C REFRIGERATOR
FREEZER ROOM 2128

BIO SAFETY CABINET

SHAKER INCUBATOR

A Viral Stock Storage: Viral stock is stored in “2 – 8°C” refrigerator. Within enclosed system, viral stock is weighed based on the batch requirements.

B Seed Cell Inoculation: Seed vials (cells) are sub-cultured with media in the flask in the Bio Safety Cabinet. Media is dispensed into flasks under laminar flow hood. Temperature is monitored during process. Seed vial & media mixture are weighed based on batch requirements.

C Viral Stock Incubation: Viral stock is incubated in the Shaker Incubator

A) Viral Stock Storage		
Bottle Size	TBD	mL
Bottle Quantity	TBD	Bottles/Batch
Process Time	TBD	Hours
Process Temperature	4	°C

B) Viral Stock Transfer		
Bottle Size	TBD	mL
Bottle Quantity	TBD	Bottles/Batch
Media	TBD	mL/ Batch
Process Time	TBD	Hours
Process Temperature	TBD	°C

C) Incubation		
Bottle Size	TBD	mL
Bottle Quantity	TBD	Bottles/Batch
Media	TBD	mL/ Batch
Process Time	TBD	Hours
Process Temperature	37	°C

Notes:
1. Raw material, quantities and process parameters are process dependent.
2. Quantities shown are based on typical process as per Process definition.

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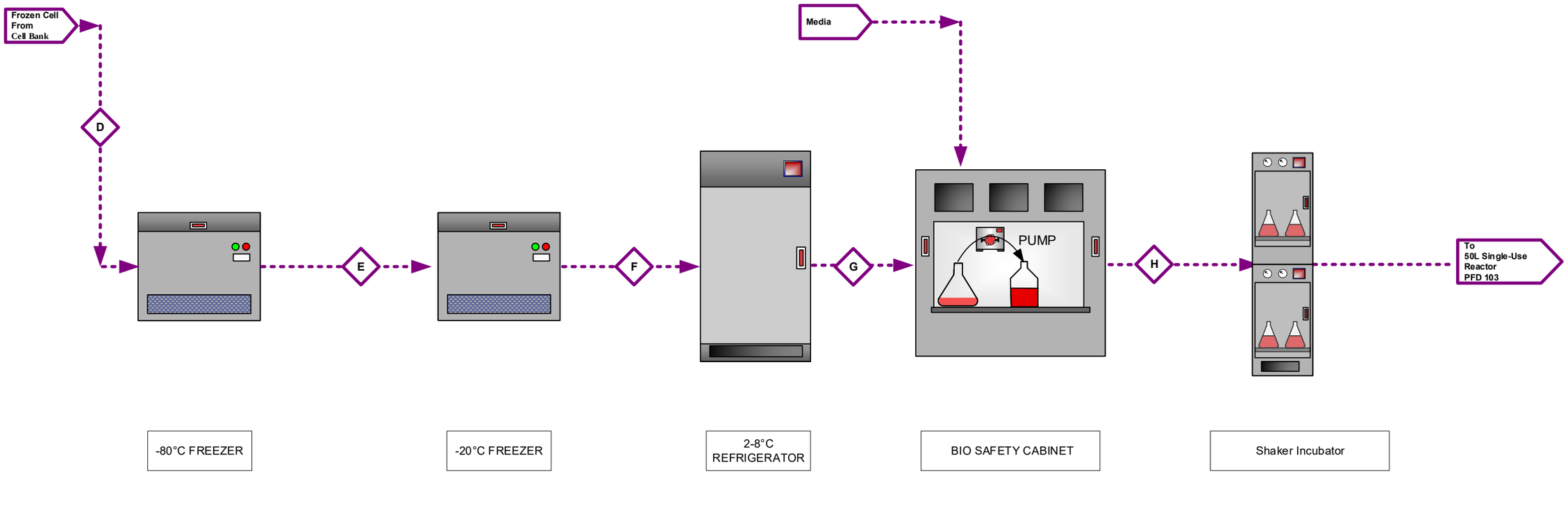
PFD-101

ISSUE	REV.	DATE	ENGINEER	NK
Initial Draft	A	01APR2021	DESIGNER	-
Owner review issue	B	06APR2021	DRAWN BY	SC
Concept Issue	C	21APR2021	SCALE	NONE

NRC Project 21090.01

Process Flow Diagram
Viral Stock Preparation

Room Number. 2115, Classification : Grade C, Biocontainment : N/A



D Cell Thawing: Frozen Cell is transferred to "-80°C" freezer from cryogenic storage tank. Within enclosed system, Cells are weighed based on batch requirements. Temperature is monitored during this process.

E Cell Thawing: Frozen Cell is transferred from "-80°C" to "-20°C" freezer. Within enclosed system, Cells are weighed based on batch requirements. Temperature is monitored during this process.

F Cell Thawing: Cells are transferred from "-20°C" to "2 – 8°C" refrigerator. Within enclosed system, Cells are weighed based on batch requirements. Temperature is monitored during this process.

G Seed Cell Inoculation: Seed vials (cells) are sub-cultured with media in the flask under Bio Safety Cabinet. Media is dispensed into flasks under laminar flow hood. Temperature is monitored during process. Seed vial & media mixture are weighed as per the batch record.

H Seed Cell Incubation: Seed Vials are incubated in the shaker Incubator

D) Frozen Cells Thaw		
Bottle Size	TBD	mL
Bottle Quantity	TBD	Bottles/ Batch
Process Time	TBD	Hours
Process Temperature	-80	°C

E) Frozen Cells Thaw		
Bottle Size	TBD	mL
Bottle Quantity	TBD	Bottles/ Batch
Process Time	TBD	Hours
Process Temperature	-20	°C

F) Frozen Cells Thaw		
Bottle Size	TBD	mL
Bottle Quantity	TBD	Bottles/ Batch
Process Time	TBD	Hours
Process Temperature	4	°C

G) Vial Transfer		
Bottle Size	TBD	mL
Bottle Quantity	TBD	Bottles/ Batch
Media	TBD	mL/ Batch
Process Time	TBD	Hours
Process Temperature	37	°C

H) Incubation		
Bottle Size	TBD	mL
Bottle Quantity	TBD	Bottles/ Batch
Media	TBD	mL/ Batch
Process Time	TBD	Hours
Process Temperature	37	°C

Notes:
1. Raw material, quantities and process parameters are process dependent.
2. Quantities shown are based on typical process as per Process Definition.

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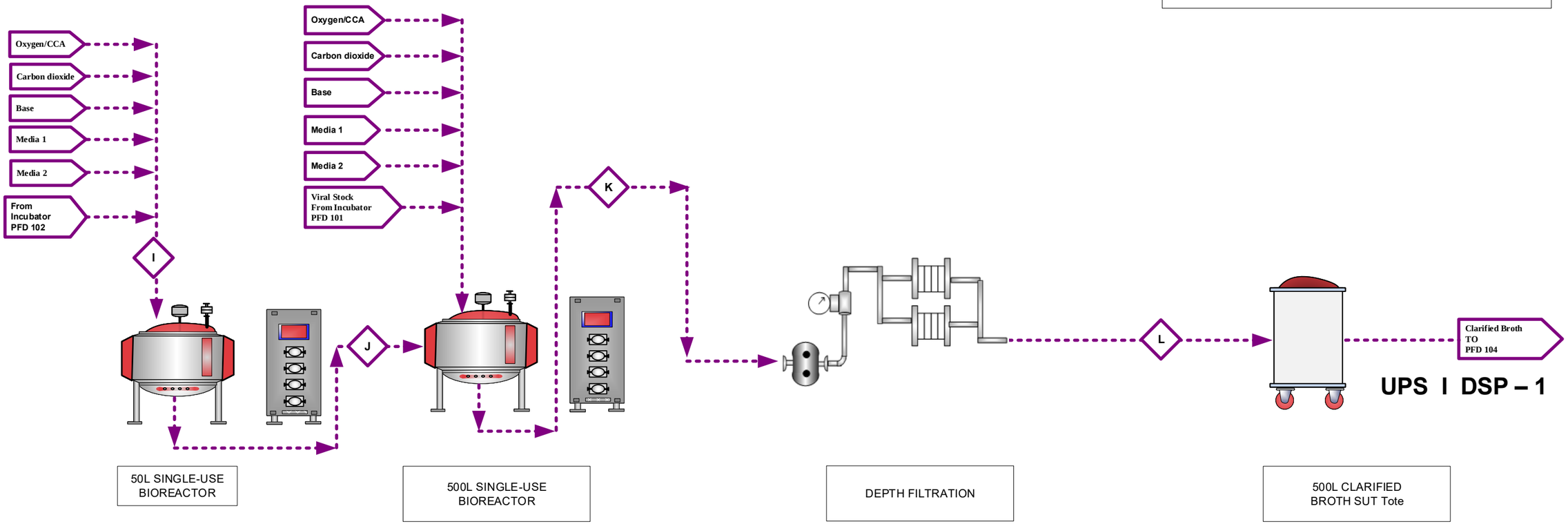
PFD-102

ISSUE	REV.	DATE	ENGINEER	NK
Initial Draft	A	01APR2021	DESIGNER	-
Qwner Review Issue	B	06APR2021	DRAWN BY	SC
Concept Issue	C	21APR2021	SCALE	NONE

NRC Project 21090.01

Process Flow Diagram
Cell Thaw & Incubation

Room Number. 2116, Classification : Grade C, Biocontainment : N/A



I Cell Culture: Media are transferred aseptically to bioreactor system. DO & pH are maintained using Oxygen/CCA, Carbon dioxide & base solution. Sub-cultured cells are transferred to 50L single use bioreactor. Media addition can be in two steps to maintain ratio to culture. Cell density and bioreactor temperature are monitored during process.

I) Cell Culture		
Seed Bottle Size	TBD	mL
Seed Quantity	4	L/Batch
Media - 1	20	L/ Batch
Media - 2	16	L/ Batch
Oxygen/CCA	TBD	LPM
CO2	TBD	LPM
Base	0.02	L/ Batch
Process Time	TBD	Hours
Process Temperature	37	°C

J Cell Culture: Media are transferred aseptically to bioreactor system. DO & pH are maintained using Oxygen/CCA, Carbon dioxide & base solution. Sub-cultured cells are transferred to 500L single use bioreactor. Cells shall grow until target cell density is reached. Media addition can be in two steps to maintain ratio to culture. Cell density and bioreactor temperature are monitored during process.

J) Cell Culture		
Cell Culture Quantity	40	L/Batch
Viral Stock	4	L/ Batch
Media - 1	200	L/ Batch
Media - 2	160	L/ Batch
Oxygen/CCA	TBD	LPM
CO2	TBD	LPM
Base	0.10	L/ Batch
Process Time	TBD	Hours
Process Temperature	37	°C

K Cell Clarification: Lysed cell culture shall be harvested using depth filtration.

K) Cell Clarification		
Harvest Quantity	TBD	Kgs/Batch
Harvest feed flowrate	TBD	LPM
Process Time	TBD	Hours
Process Temperature	TBD	°C

L Broth SUT Tote: Clarified broth is harvested into broth SUT Tote which will be used to feed clarified culture to downstream process.

L) Broth SUT Tote		
Clarified Broth Quantity	TBD	Kgs/Batch
Process Time	TBD	Hours
Process Temperature	TBD	°C

Notes:
1. Raw material, quantities and process parameters are process dependent.
2. Quantities shown are based on typical process as per Process Definition.

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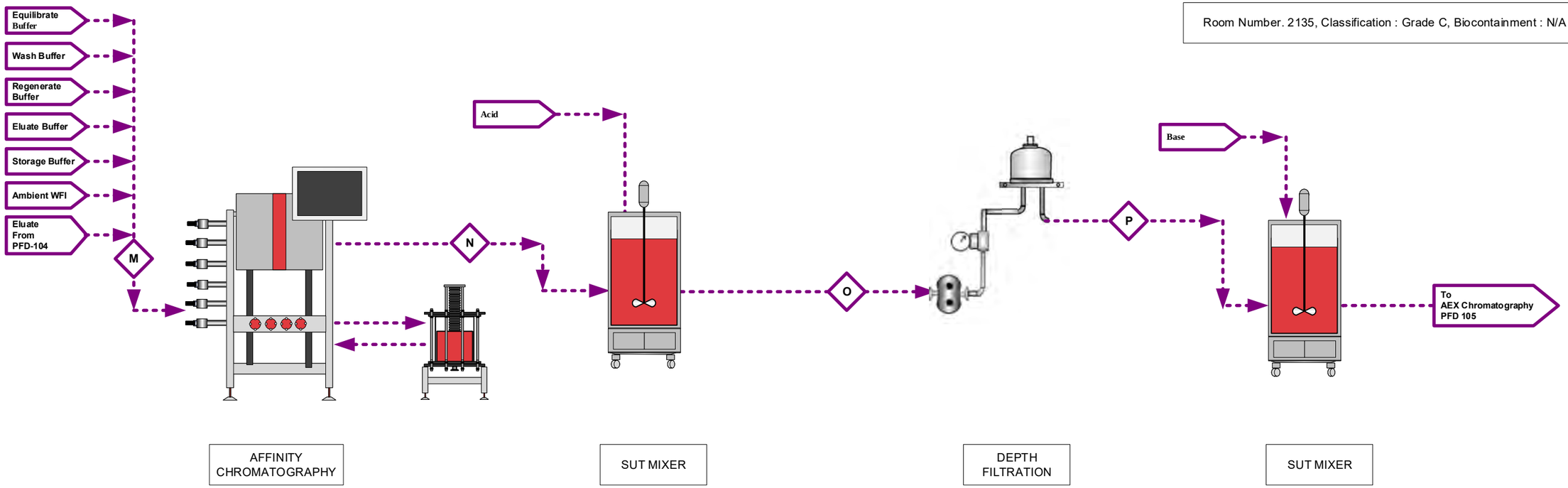
PFD-103

ISSUE	REV.	DATE	ENGINEER	NK
Initial Draft	A	01APR2021	DESIGNER	-
Owner Review Issue	B	06APR2021	DRAWN BY	SC
Concept Issue	C	21APR2021	SCALE	NONE

NRC Project 21090.01

Process Flow Diagram
Cell Culture Growth - Separation

Room Number. 2135, Classification : Grade C, Biocontainment : N/A



M Purification: Affinity chromatography is performed to reduce the residual host cell and residual host cell DNA content.

N Virus Inactivation & Removal: Eluate is collected in the SUT Mixer. Acid is added using peristaltic pump for virus inactivation. Low pH is maintained for certain duration to inactivate all potential virus.

O Filtration: Acidic eluate solution is filtered using depth filtration skid to remove debris.

P Neutralization: Base solution is added to adjust filtrate to neutral pH. Osmolarity is adjusted to prepare for polishing.

M) Affinity Chromatography		
Broth Quantity	TBD	Kgs/Batch
Broth Feed rate	TBD	LPM
Equilibrate Buffer	159	L/ Batch
Wash Buffer	190	L/ Batch
Regenerate Buffer	159	L/ Batch
Eluate Buffer	95	L/ Batch
Storage Buffer	64	L/ Batch
Caustic	127	L/ Batch
Ambient WFI	95	L/ Batch
Process Time	TBD	Hours
Process Temperature	TBD	°C

N) Virus Inactivation		
Eluate Quantity	TBD	Kgs/Batch
Acid	5	L/ Batch
Agitator Speed	TBD	RPM
pH	TBD	
Process Time	TBD	Hours
Process Temperature	TBD	°C

O) Filtration		
Eluate Quantity	TBD	Kgs/Batch
pH	TBD	
Process Time	TBD	Hours
Process Temperature	TBD	°C

P) Neutralization		
Eluate Quantity	TBD	Kgs/Batch
Base	5	L/ Batch
Agitator Speed	TBD	RPM
pH	7	
Process Time	TBD	Hours
Process Temperature	TBD	°C

Notes:
1. Raw material, quantities and process parameters are process dependent.
2. Quantities shown are based on typical process as per Process Definition.

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PFD-104

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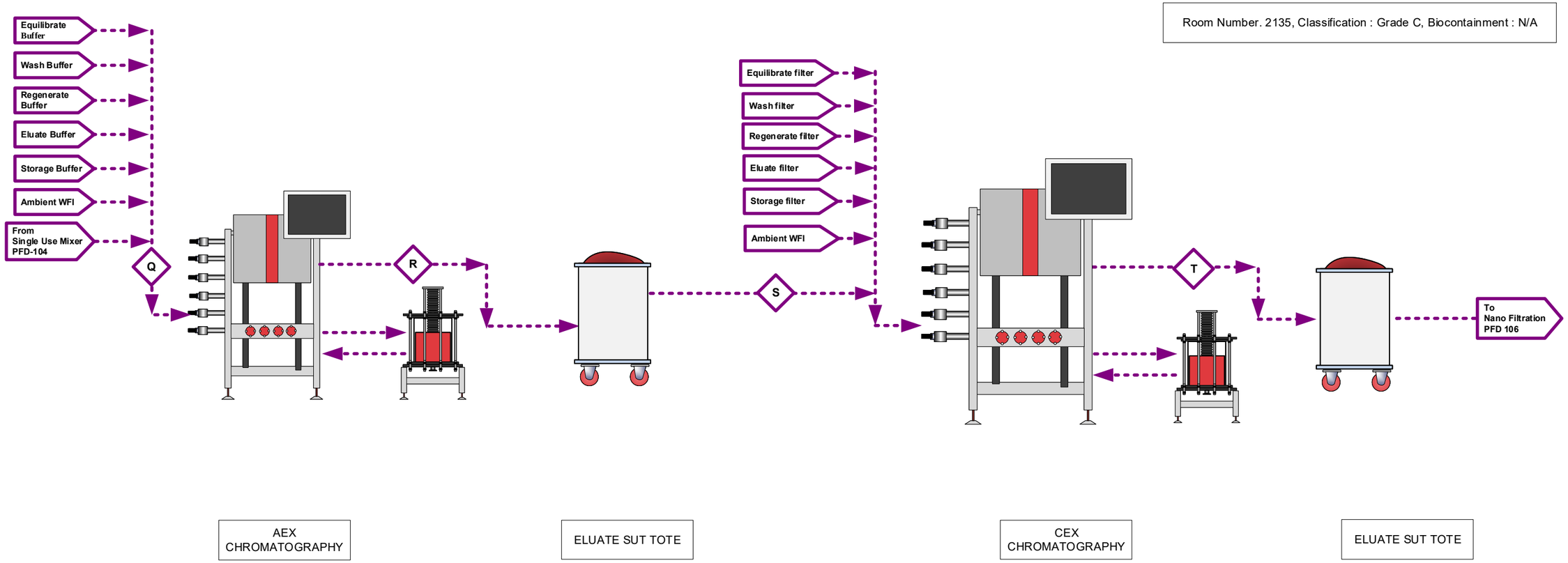
NRC Project 21090.01

Process Flow Diagram
Chromatography-Filtration

Room Number. 2135, Classification : Grade C, Biocontainment : N/A



Q Purification: Anion Exchange chromatography is performed to polish filtrate.

Q) AEX Chromatography		
Eluate Quantity	TBD	Kgs/Batch
Eluate Feed rate	TBD	LPM
Equilibrate Buffer	151	L/ Batch
Wash Buffer	101	L/ Batch
Regenerate Buffer	75	L/ Batch
Eluate Buffer	75	L/ Batch
Storage Buffer	75	L/ Batch
Caustic	75	L/ Batch
Ambient WFI	75	L/ Batch
Process Time	TBD	Hours
Process Temperature	TBD	°C

R Eluate SUT Tote: Eluate is stored in the Eluate SUT Tote from AEX chromatography.

R) Eluate SUT Tote		
Eluate Quantity	TBD	Kgs/Batch
pH	7	
Process Time	TBD	Hours
Process Temperature	TBD	°C

S Purification: Cation Exchange chromatography is performed to polish eluate.

S) CEX Chromatography		
Eluate Quantity	TBD	Kgs/Batch
Eluate Feed rate	TBD	LPM
Equilibrate Buffer	151	L/ Batch
Wash Buffer	101	L/ Batch
Regenerate Buffer	75	L/ Batch
Eluate Buffer	101	L/ Batch
Storage Buffer	75	L/ Batch
Caustic	75	L/ Batch
Ambient WFI	75	L/ Batch
Process Time	TBD	Hours
Process Temperature	TBD	°C

T Eluate SUT Tote: Eluate is stored in the Eluate SUT tote from CEX chromatography.

T) Eluate SUT Tote		
Eluate Quantity	TBD	Kgs/Batch
pH	7	
Process Time	TBD	Hours
Process Temperature	TBD	°C

Notes:
1. Raw material, quantities and process parameters are process dependent.
2. Quantities shown are based on typical process as per Process Definition.

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PFD-105

ENGINEER	NK
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SCALE	NONE
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REV.	DATE	ISSUE
A	01APR2021	Initial Draft
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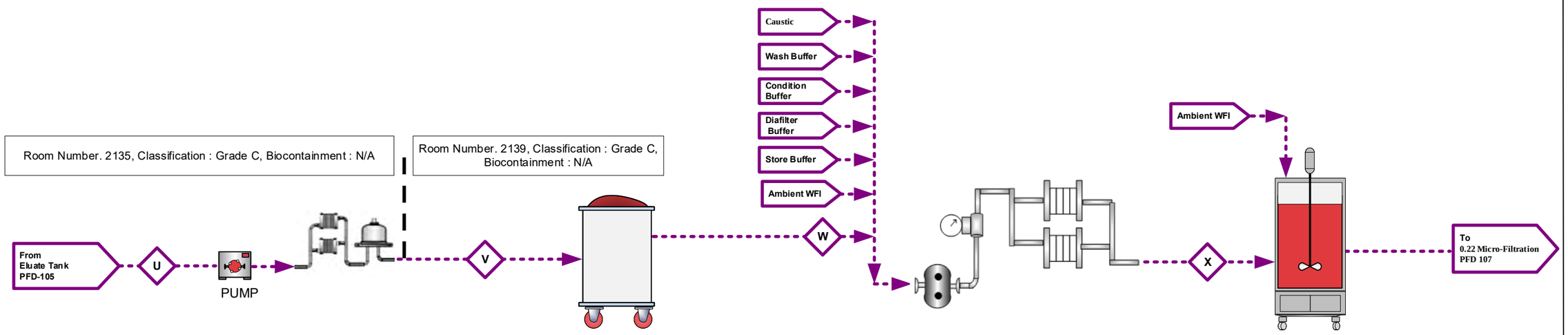
C	21APR2021	Concept Issue

NRC Project 21090.01

Process Flow Diagram
Purification



NANO FILTRATION

FILTRATE SUT TOTE

UF/DF FILTRATION

DRUG SUBSTANCE SUT MIXER

U Purification: Eluate/Product is purified from inactivated virus using Nano filtration.

V Filtrate SUT Tote: Filtrate is received from Nano filtration skid and stored in the Filtrate SUT Tote.

W UF/DF Filtration: Filtrate is diafiltered as part of final formulation step.

X Concentration Adjustment: Product is collected in the SUT Mixer where concentration is verified and adjusted, as required.

U) Purification		
Eluate Quantity	TBD	Kgs/Batch
pH	TBD	
Process Time	TBD	Hours
Process Temperature	TBD	°C

V) Filtrate SUT Tote		
Filtrate Quantity	TBD	Kgs/Batch
pH	7	
Process Time	TBD	Hours
Process Temperature	TBD	°C

W) UF/DF Filtration		
Filtrate Quantity	TBD	Kgs/Batch
Filtrate Feed rate	TBD	LPM
Condition Buffer	TBD	L/ Batch
Wash Buffer	TBD	L/ Batch
Diafilter Buffer	1552	L/ Batch
Storage Buffer	200	L/ Batch
Caustic	400	L/ Batch
Ambient WFI	800	L/ Batch
Process Time	TBD	Hours
Process Temperature	TBD	°C

X) Concentration Adjustment		
Product Quantity	TBD	Kgs/Batch
Product Assay	TBD	%
Agitator Speed	TBD	RPM
Ambient WFI	2	L/Batch
Process Time	TBD	Hours
Process Temperature	TBD	°C

Notes:
1. Raw material, quantities and process parameters are process dependent.
2. Quantities are shown based on typical process as per process definition.

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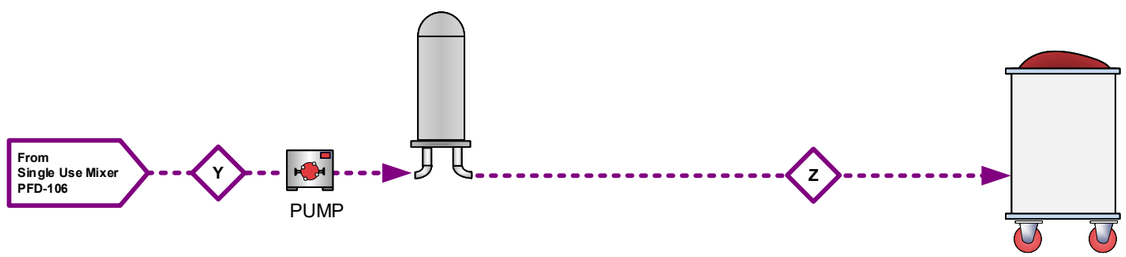
PFD-106

ISSUE	REV.	DATE	ENGINEER	NK
Initial Draft	A	01APR2021	DESIGNER	-
Owner Review Issue	B	06APR2021	DRAWN BY	SC
Concept Issue	C	21APR2021	SCALE	NONE

NRC Project 21090.01

Process Flow Diagram Filtration

Room Number. 2139, Classification : Grade C, Biocontainment : N/A



0.22 MICRO-FILTRATION

DRUG SUBSTANCE SUT MOBILE BAG

Y — Filtration: Concentrated product is passed through 0.22 micron sterilizing grade filter.

Z — Drug Substance/Product Storage Bag: Finished product/ clinical drug substance is stored in the SUT Mobile bag. Product bag is moved to cold room for storage.

Y) Filtration		
Product Flowrate	TBD	LPM
Pressure, inlet	TBD	Psig
Process Time	TBD	Hours
Process Temperature	TBD	°C

Z) Drug Substance Storage		
Product Quantity	TBD	Kgs/Batch
Hold Time	TBD	hours
Process Temperature	TBD	°C
Storage Temperature	2-8	°C

Notes:
1. Raw material, quantities and process parameters are process dependent.
2. Quantities are shown based on typical process as per Process Definition.

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REV.	DATE	ENGINEER	NK
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C	21APR2021	SCALE	NONE

PFD-107

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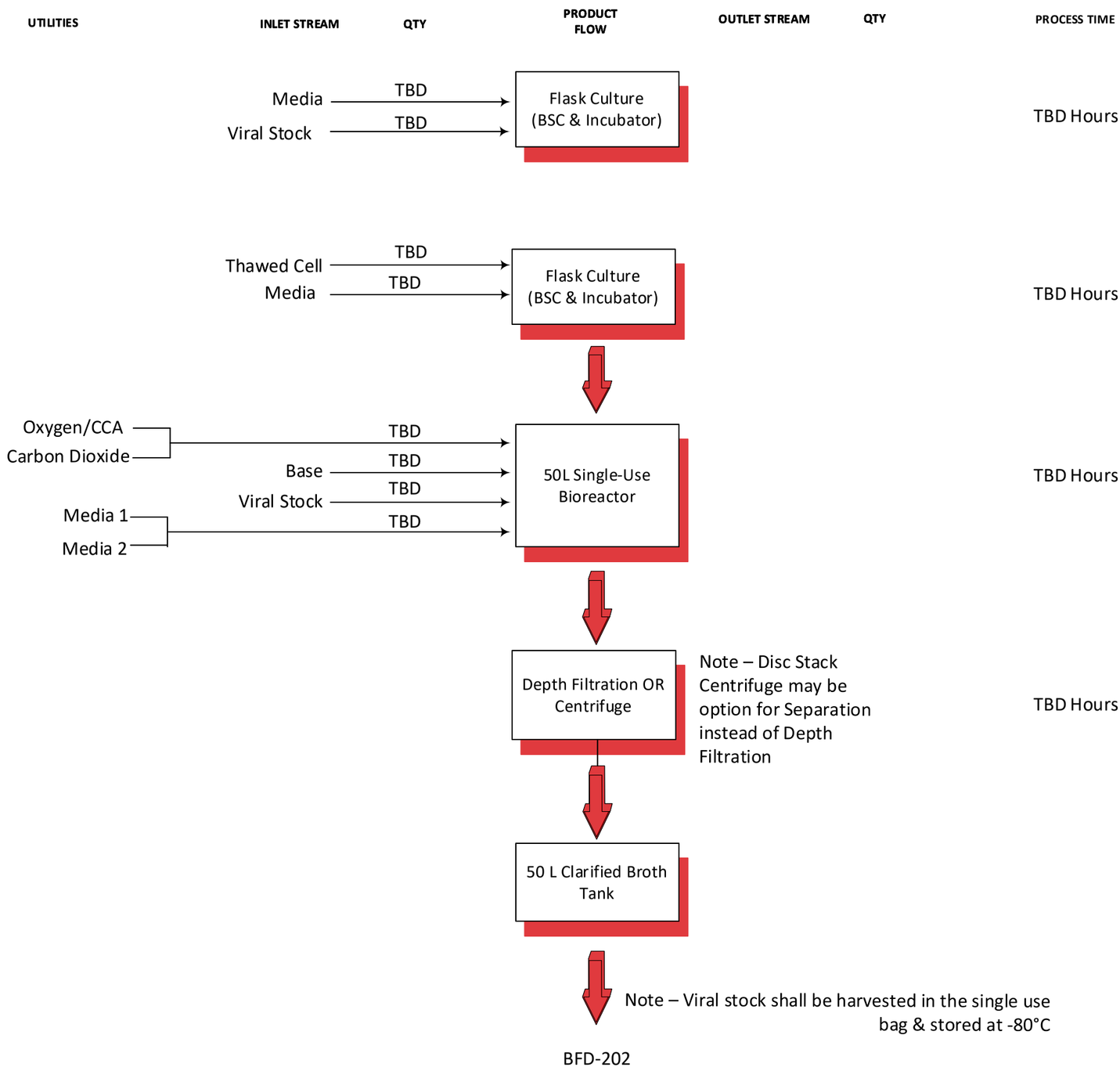
NRC Project 21090.01

Process Flow Diagram
Filtration & Storage

UPSTREAM PROCESS – Viral Vector Room Number 2108, Classification: Grade C, Biocontainment: BL2



CLIENT/PROJECT TITLE:	ISSUE	REV.	DATE	ENGINEER	NK	DRAWING No.
PROJECT NRC	OWNER REVIEW ISSUE	A	11MAR2021	DESIGNER	-	**BFD-201**
	OWNER REVIEW ISSUE	B	12MAR2021	DRAWN BY	NN	
BLOCK FLOW DIAGRAM DRUG SUBSTANCE – PROPAGATION & HARVEST	CONCEPT ISSUE	C	21APR2021	SCALE	NONE	

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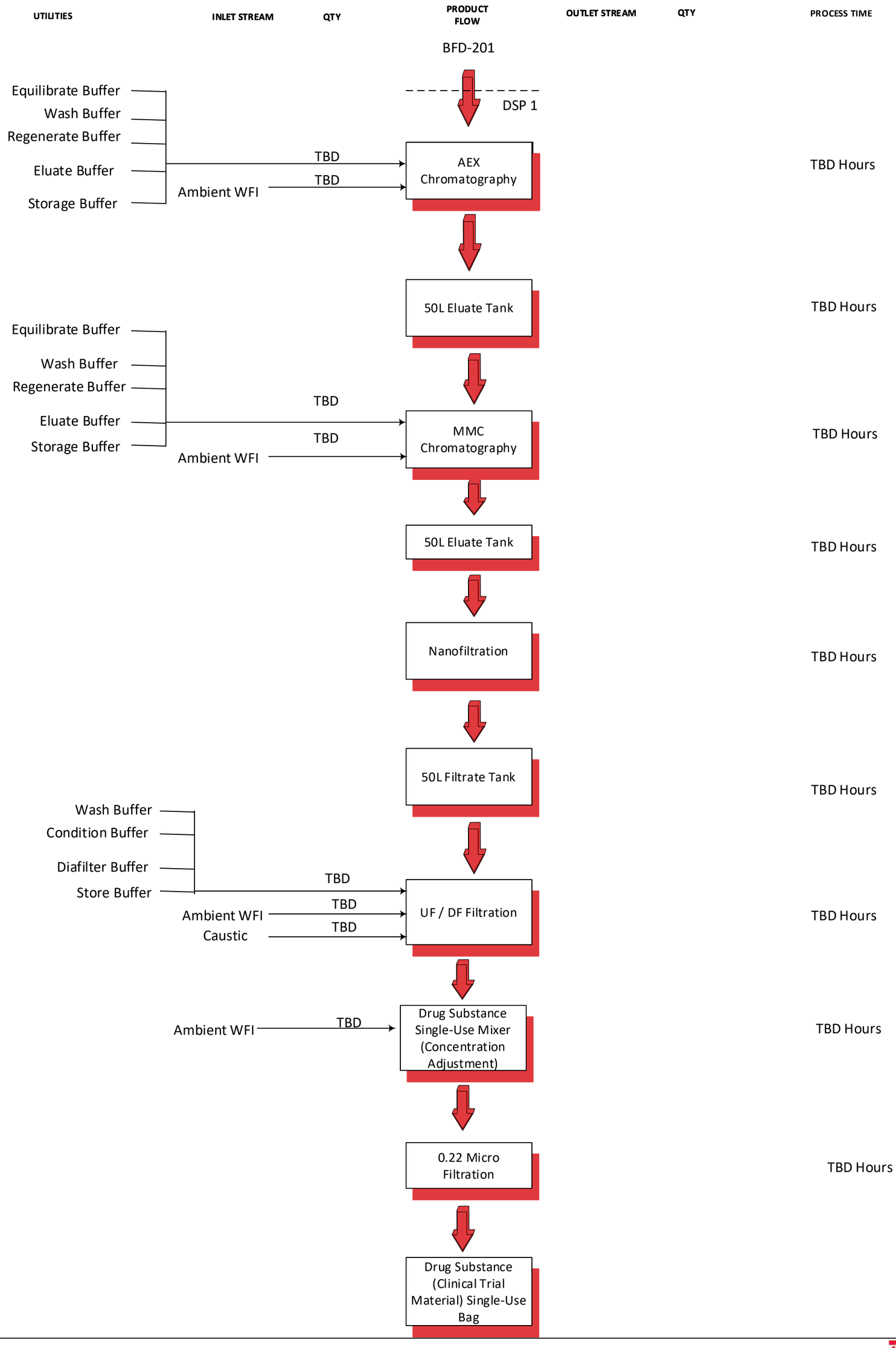
DOWNSTREAM PROCESS – Viral Vector Room Number 2108, Classification: Grade C, Biocontainment: BL2



CLIENT/PROJECT TITLE:	ISSUE	REV.	DATE	ENGINEER	NK	DRAWING No.
PROJECT NRC	OWNER REVIEW ISSUE	A	10MAR2021	DESIGNER	-	**BFD-202**
BLOCK FLOW DIAGRAM DRUG PRODUCT – FILTRATION / PURIFICATION / CHROMATOGRAPHY	OWNER REVIEW ISSUE	B	12MAR2021	DRAWN BY	NN	
	CONCEPT ISSUE	C	21APR2021	SCALE	NONE	

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Drawing List NRC PROJECT 21090.01

PROJECT – NRC 21090.01 DRAWING NUMBER	DRAWING TITTLE									
		ISSUE DATE	26MAR2021	06APR2021	21APR2021	-	-	-	-	-
		ISSUE DESCRPITION	INITIAL DRAFT	OWNER REVIEW ISSUE	CONCEPT ISSUE	-	-	-	-	-
PFD-001	LEAD SHEET		X	X	X					
PFD-200	PFD DRAWING LIST		X	X	X					
PFD-201	VIRAL STOCK PREPARATION		X	X	X					
PFD-202	CELL THAW & INCUBATION		X	X	X					
PFD-203	CELL CULTURE GROWTH - SEPRATION		X	X	X					
PFD-204	CHROMATOGRAPHY		X	X	X					
PFD-205	FILTRATION		X	X	X					
PFD-206	FILTRATION AND STORAGE		X	X	X					

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DRAWING No. **PFD-200**

ENGINEER	NK
DESIGNER	-
DRAWN BY	SC
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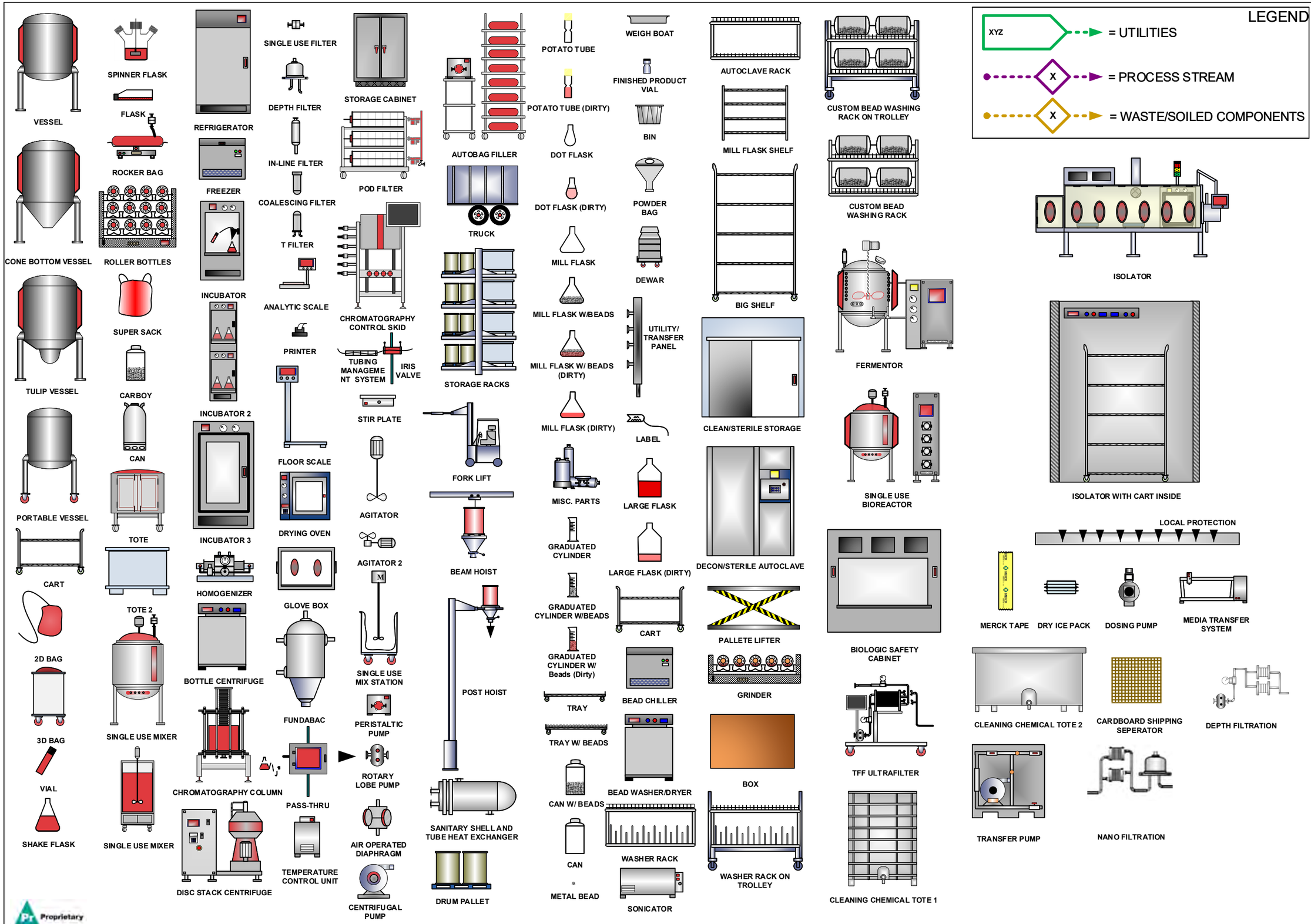
A	26MAR2021	Initial Draft
B	06APR2021	Owner Review Issue
C	21APR2021	Concept Issue

CLIENT/PROJECT TITLE:
NRC Project 21090.01

Viral Vector - Process Flow Diagram Drawing List

Pr Proprietary



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DRAWING No.	PFD-001
NK	-
ENGINEER	SC
DESIGNER	NONE
DRAWN BY	CND21090.01
SCALE	-
PROJECT #	
CLIENT PROJECT #	

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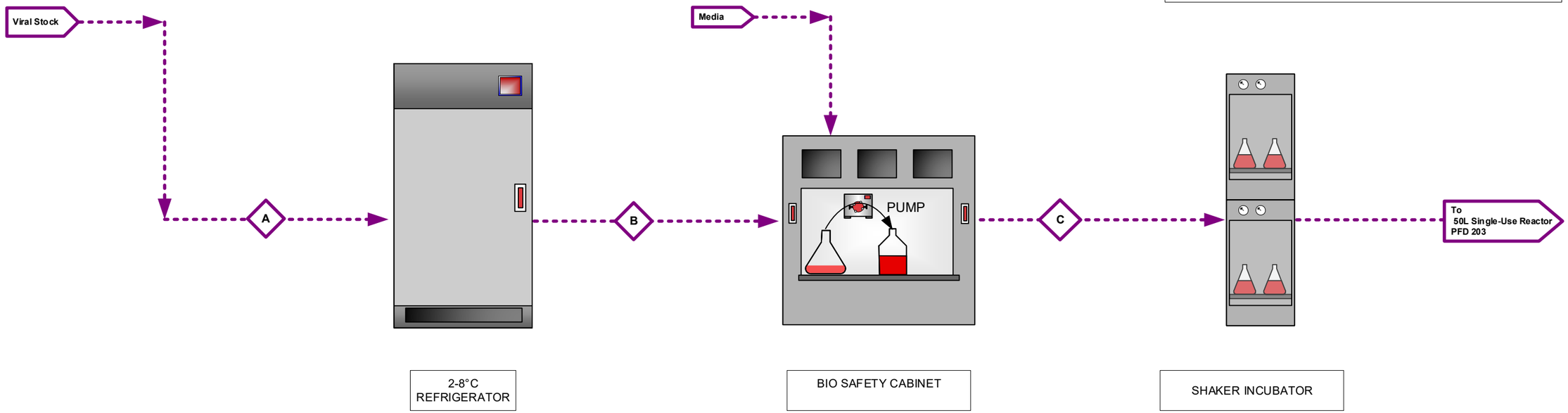
C	21APR2021	Concept Issue

CLIENT/PROJECT TITLE: **NRC PROJECT 21090.01**

Process Flow Diagram Lead Sheet

Room Number. 2108, Classification : Grade C, Biocontainment : BL2



A Viral Stock Storage: Viral stock is stored in “2 – 8°C” refrigerator.
Within enclosed system, viral stock is weighed based on the batch requirement.
Temperature is monitored during this process.

B Viral Stock Incubation: Viral stock is sub-cultured with media in the flask under Bio Safety Cabinet.
Media is dispensed into flasks under laminar flow hood.
Temperature is monitored during this process.
Viral stock & media mixture are weighed based on the batch requirement.

C Viral Stock Incubator: Viral stock is Incubated in the shaker Incubator

A) Viral Stock Storage		
Bottle Size	TBD	mL
Bottle Quantity	TBD	Bottles/Batch
Process Time	TBD	Hours
Process Temperature	4	°C

B) Viral Stock Transfer		
Bottle Size	TBD	mL
Bottle Quantity	TBD	Bottles/Batch
Media	TBD	mL/ Batch
Process Time	TBD	Hours
Process Temperature	37	°C

C) Incubation		
Bottle Size	TBD	mL
Bottle Quantity	TBD	Bottles/Batch
Media	TBD	mL/ Batch
Process Time	TBD	Hours
Process Temperature	37	°C

Notes:
1. Raw material, quantities and process parameters are process dependent.
2. Quantities shown are based on typical process as per Process Definition.

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PFD-201

ENGINEER	NK
DESIGNER	-
DRAWN BY	SC
SCALE	NONE
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CLIENT PROJECT #	

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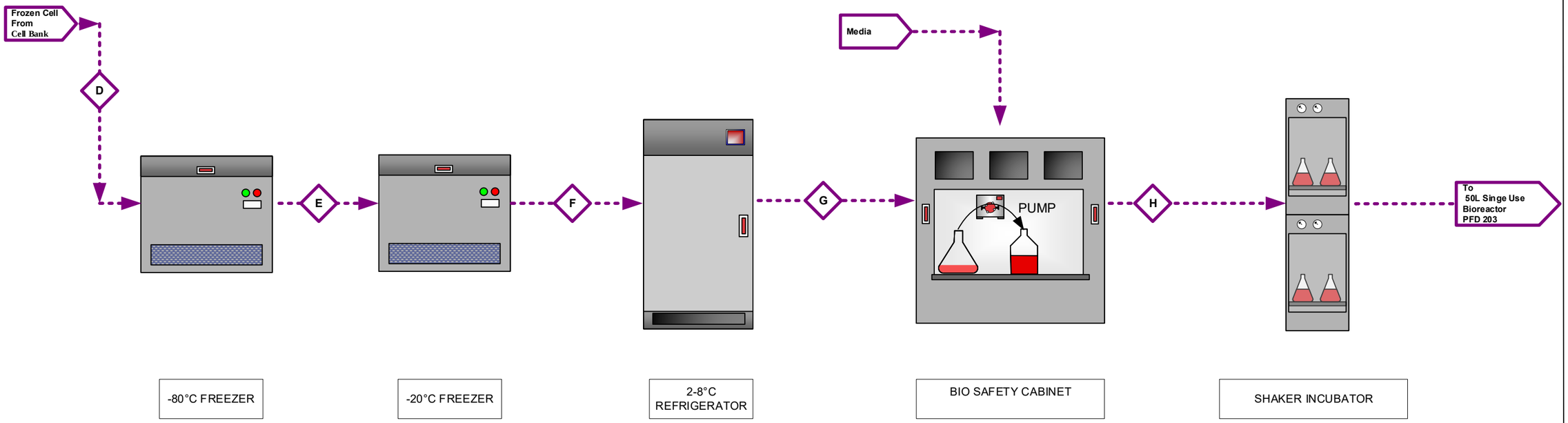
A	01APR2021	Initial Draft
B	06APR2021	Owner Review Issue
C	21APR2021	Concept Issue

NRC Project 21090.01

Process Flow Diagram
Viral Stock Preparation

Room Number. 2108, Classification : Grade C, Biocontainment : BL2



D Cell Thawing: Frozen Cell is transferred to "-80°C" freezer from cryogenic storage tank.
Within enclosed system, Cells are weighed based on batch requirement.
Temperature is monitored during this process.

E Cell Thawing: Frozen Cell is transferred from "-80°C" to "-20°C" freezer.
Within enclosed system, Cells are weighed based on the batch requirement.
Temperature is monitored during this process.

F Cell Thawing: Cells is transferred from "-20°C" to "2 – 8°C" refrigerator.
Within enclosed system, Cells are weighed based on the batch requirement.
Temperature is monitored during this process.

G Seed Cell Inoculation: Seed vials (cells) are sub-cultured with media in the flask under Bio Safety Cabinet.
Media is dispensed into flasks under laminar flow hood. Temperature is monitored during process.
Seed vial & media mixture are weighed as per the batch record.

H Seed Cell Incubation: Seed vials are incubated in the shaker Incubator.

D) Frozen Cells Thaw		
Bottle Size	TBD	mL
Bottle Quantity	TBD	Bottles/ Batch
Process Time	TBD	Hours
Process Temperature	-80	°C

E) Frozen Cells Thaw		
Bottle Size	TBD	mL
Bottle Quantity	TBD	Bottles/ Batch
Process Time	TBD	Hours
Process Temperature	-20	°C

F) Frozen Cells Thaw		
Bottle Size	TBD	mL
Bottle Quantity	TBD	Bottles/ Batch
Process Time	TBD	Hours
Process Temperature	4	°C

G) Vial Transfer		
Bottle Size	TBD	mL
Bottle Quantity	TBD	Bottles/ Batch
Media	TBD	mL/ Batch
Process Time	TBD	Hours
Process Temperature	37	°C

H) Incubation		
Bottle Size	TBD	mL
Bottle Quantity	TBD	Bottles/ Batch
Media	TBD	mL/ Batch
Process Time	TBD	Hours
Process Temperature	37	°C

Notes:
1. Raw material, quantities and process parameters are process dependent.
2. Quantities shown are based on typical process as per Process Definition.

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PFD-202

ENGINEER	NK
DESIGNER	-
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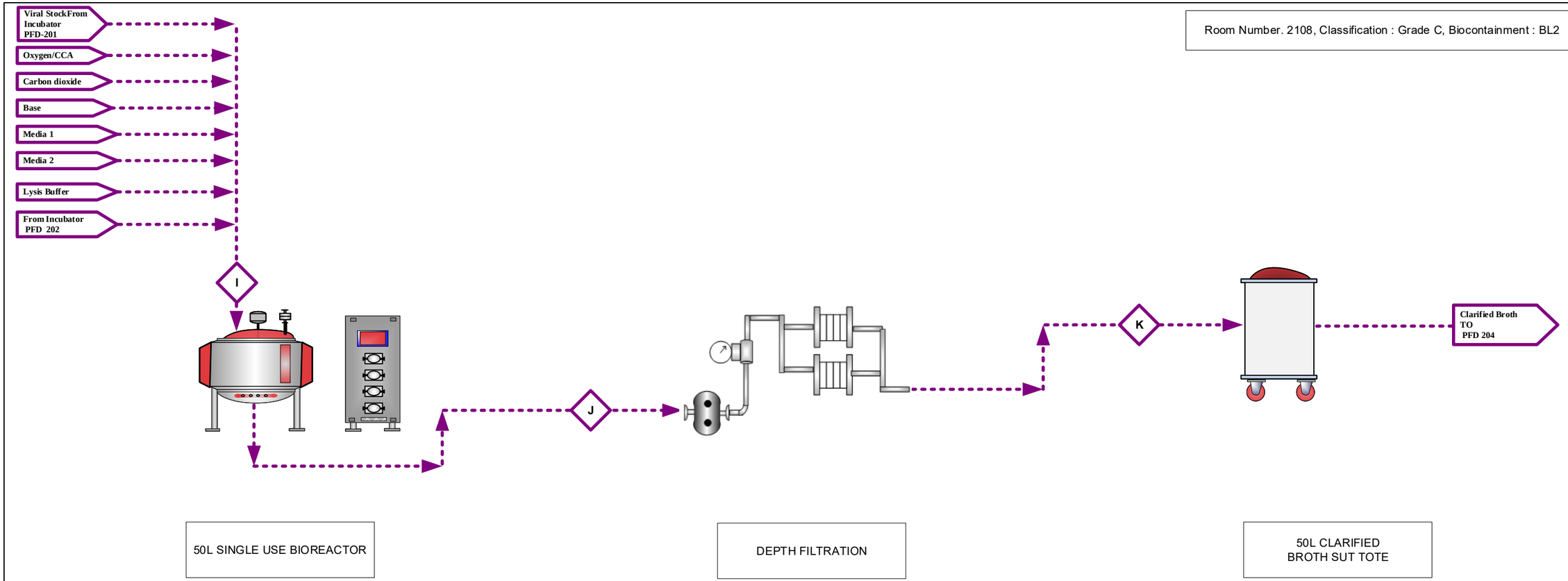
CLIENT PROJECT #	

ISSUE	DATE	REV.
Initial Draft	01APR2021	A
Owner Review Issue	06APR2021	B
Concept Issue	21APR2021	C

NRC Project 21090.01

Process Flow Diagram
Cell Thaw & Incubation

Room Number. 2108, Classification : Grade C, Biocontainment : BL2



I — Cell Culture: Media are transferred aseptically to bioreactor system. DO & pH are maintained using Oxygen/CCA, Carbon dioxide & base solution. Sub-cultured cells are transferred to 50L single use bioreactor. Media addition can be in two steps to maintain ratio to culture. Cell density and bioreactor temperature are monitored during process.

J — Cell Clarification: Lysed cell culture shall be harvested using depth filtration.

K — Broth SUT Tote: Clarified broth is harvested into broth SUT Tote which will be used to feed clarified culture to downstream process.

I) Cell Culture		
Seed Bottle Size	TBD	mL
Seed Quantity	4	L/Batch
Viral Stock	4	L/ Batch
Media - 1	20	L/ Batch
Media - 2	8	L/ Batch
Lysis buffer	4	L/Batch
Oxygen/CCA	TBD	LPM
CO2	TBD	LPM
Base	0.02	L/ Batch
Process Time	TBD	Hours

J) Cell Clarification		
Harvest Quantity	TBD	Kgs/Batch
Harvest feed flowrate	TBD	LPM
Process Time	TBD	Hours
Process Temperature	TBD	°C

K) Broth SUT Tote		
Clarified Broth Quantity	TBD	Kgs/Batch
Process Time	TBD	Hours
Process Temperature	TBD	°C

Notes:
1. Raw material, quantities and process parameters are process dependent.
2. Quantities shown are based on typical process as per process Definition.

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PFD-203

ENGINEER	NK		
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Initial Draft	01APR2021	A
Owner Review Issue	06APR2021	B
Concept Issue	21APR2021	C

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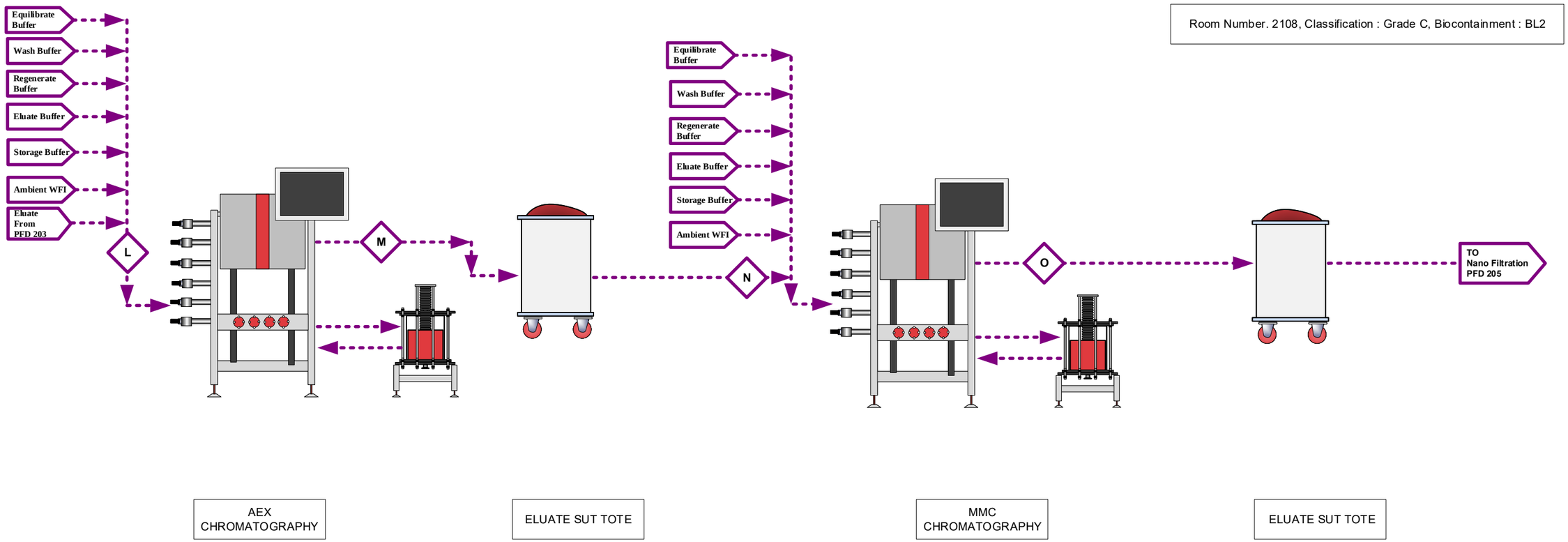
Process Flow Diagram
Cell Culture Growth - Sepration

Room Number. 2108, Classification : Grade C, Biocontainment : BL2



L — Purification: Anion Exchange chromatography is performed to polish clarified broth.

M — Eluate SUT Tote: Eluate from AEX chromatography is stored in the Eluate SUT Tote.

N — Purification: Multi mode chromatography is performed to polish eluate content.

O — Eluate SUT Tote: Eluate is stored in the Eluate SUT Tote from MMC chromatography.

L) AEX Chromatography		
Eluate Quantity	TBD	Kgs/Batch
Eluate Feed rate	TBD	LPM
Equilibrate Buffer	75	L/ Batch
Wash Buffer	101	L/ Batch
Regenerate Buffer	75	L/ Batch
Eluate Buffer	75	L/ Batch
Storage Buffer	75	L/ Batch
Caustic	75	L/ Batch
Ambient WFI	75	L/ Batch
Process Time	TBD	Hours
Process Temperature	TBD	°C

M) Eluate SUT Tote		
Eluate Quantity	TBD	Kgs/Batch
pH	7	
Process Time	TBD	Hours
Process Temperature	TBD	°C

N) MMC Chromatography		
Eluate Quantity	TBD	Kgs/Batch
Eluate Feed rate	TBD	LPM
Equilibrate Buffer	151	L/ Batch
Wash Buffer	101	L/ Batch
Regenerate Buffer	75	L/ Batch
Eluate Buffer	75	L/ Batch
Storage Buffer	75	L/ Batch
Caustic	75	L/ Batch
Ambient WFI	75	L/ Batch
Process Time	TBD	Hours
Process Temperature	TBD	°C

O) Eluate SUT Tote		
Eluate Quantity	TBD	Kgs/Batch
pH	7	
Process Time	TBD	Hours
Process Temperature	TBD	°C

Notes:
1. Raw material, quantities and process parameters are process dependent.
2. Quantities shown are based on typical process as per Process Definition.

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PFD-204

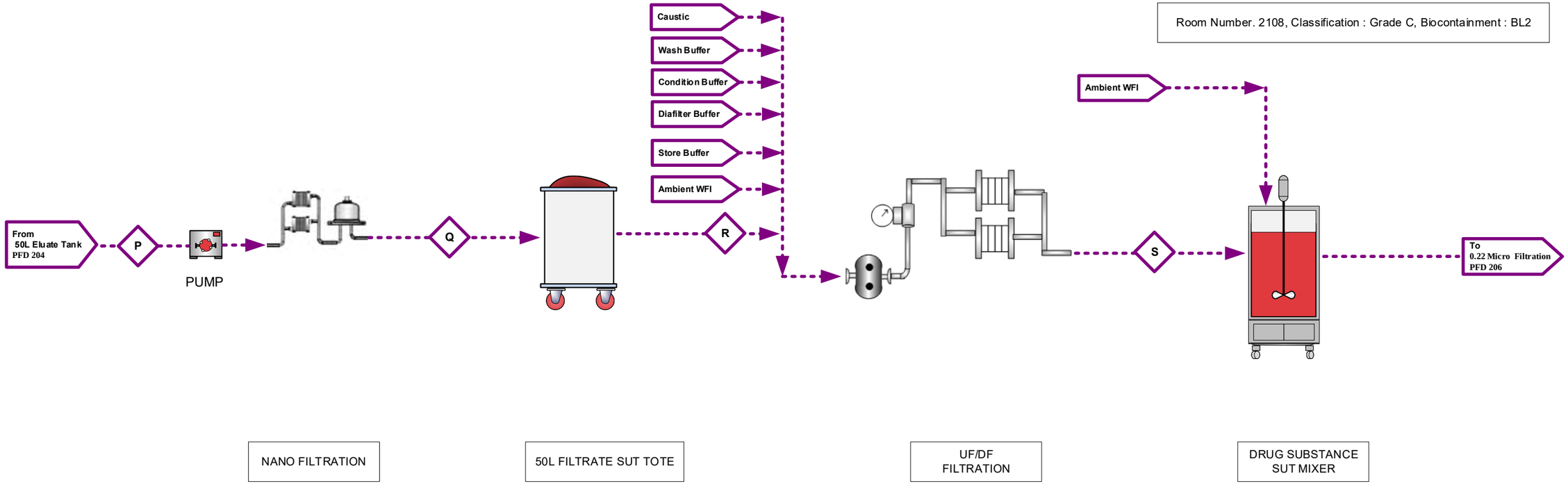
ENGINEER	NK	REV.	DATE
DESIGNER	-	A	01APR2021
DRAWN BY	SC	B	06APR2021
SCALE	NONE	C	21APR2021
PROJECT#	CND21090.01		
CLIENT PROJECT #			

ISSUE
Initial Draft
Owner Review Issue
Concept Issue

NRC Project 21090.01

Process Flow Diagram Chromatography

Room Number. 2108, Classification : Grade C, Biocontainment : BL2



P Purification: Eluate/Product is purified using Nano filtration.

Q Filtrate SUT TOTE: Filtrate is stored in the Filtrate SUT Tote from Nano filtration skid.

R UF/DF Filtration: Filtrate is diafiltered as part of final formulation step.

S Concentration Adjustment: Product is collected in the SUM where concentration is verified and adjusted, as required.

P) Purification		
Eluate Quantity	TBD	Kgs/Batch
pH	TBD	
Process Time	TBD	Hours
Process Temperature	TBD	°C

Q) Filtrate SUT Tote		
Filtrate Quantity	TBD	Kgs/Batch
pH	7	
Process Time	TBD	Hours
Process Temperature	TBD	°C

R) UF/DF Filtration		
Filtrate Quantity	TBD	Kgs/Batch
Filtrate Feed rate	TBD	LPM
Condition Buffer	TBD	L/ Batch
Wash Buffer	TBD	L/ Batch
Diafilter Buffer	539	L/ Batch
Storage Buffer	200	L/ Batch
Caustic	400	L/ Batch
Ambient WFI	800	L/ Batch
Process Time	TBD	Hours
Process Temperature	TBD	°C

S) Concentration Adjustment		
Product Quantity	TBD	Kgs/Batch
Product Assay	TBD	%
Agitator Speed	TBD	RPM
Ambient WFI	2	L/Batch
Process Time	TBD	Hours
Process Temperature	TBD	°C

Notes:
1. Raw material, quantities and process parameters are process dependent.
2. Quantities shown are based on typical process as per Process Definition.

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PFD-205

ENGINEER	NK
DESIGNER	-
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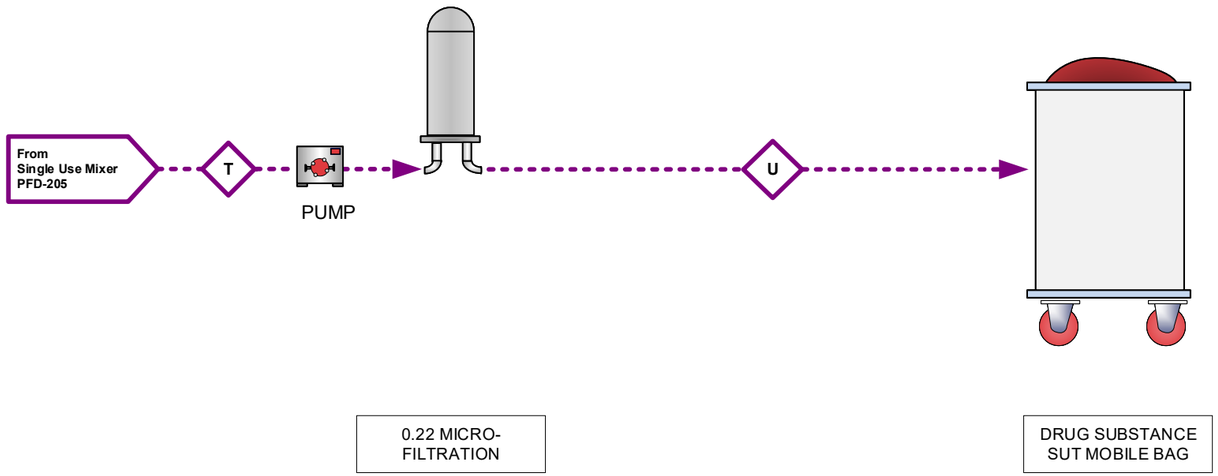
SCALE	NONE
PROJECT#	CND21090.01
CLIENT PROJECT #	

ISSUE	DATE	REV.
Initial Draft	01APR2021	A
Owner Review Issue	06APR2021	B
Concept Issue	21APR2021	C

NRC Project 21090.01

Process Flow Diagram
Filtration

Room Number. 2108, Classification : Grade C, Biocontainment : BL2



T — Filtration: Concentrated product is passed through 0.22 micron filter.

U — Drug Substance/Product Storage Bag: Finished product/ clinical drug substance is stored in the SUT Mobile bag. Product bag is moved to Cold room for storage.

T) Filtration		
Product Flowrate	TBD	LPM
Pressure, inlet	TBD	Psig
Process Time	TBD	Hours
Process Temperature	TBD	°C

U) Drug Substance Storage		
Product Quantity	TBD	Kgs/Batch
Hold Time	TBD	hours
Process Temperature	TBD	°C
Storage Temperature	2-8	°C

Notes:
1. Raw material, quantities and process parameters are process dependent.
2. Quantities shown are based on typical process as per Process Definition.

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PFD-206

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Owner Review Issue	B	06APR2021
Concept Issue	C	21APR2021

NRC Project 21090.01

Process Flow Diagram
Filtration and Storage

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VIRAL STOCK, CELL THAWING & PREPARATION, AND BIOREACTORS

PRODUCT PARAMETERS

	Volume	Mass	Concentration
	L	g	g/L
Product input	400	800	2.000
Product output	400	800	2.002
Waste	0		

STEP PARAMETERS

STEP NAME	SOLUTION		VIRAL STOCK PREPARATION				CELL THAWING & PREPARATION								BIOREACTORS			
			2-8 °C REFRIGERATOR		SEED FLASKS (SHAKER INCUBATOR 1)		-80 °C FREEZER		-20 °C FREEZER		2-8 °C REFRIGERATOR		SEED FLASKS (SHAKER INCUBATOR 2)		50 L SUB		500 L SUB	
			PRODUCT	SOLUTIONS	PRODUCT	SOLUTIONS	PRODUCT	SOLUTIONS	PRODUCT	SOLUTIONS	PRODUCT	SOLUTIONS	PRODUCT	SOLUTIONS	PRODUCT	SOLUTIONS	PRODUCT	SOLUTIONS
	TYPE	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Seed / Product			4		4		4		4		4		4		4.0		40.2	
Media		444.83		10.0		10.0		10		10		10		10		36.0		358.8
Feed	7% of total BR volume																	
Medical Air	maximum TBD																	
Oxygen	maximum TBD																	
CO2	maximum TBD																	
Nitrogen	maximum TBD																	
Acid																		
Base		0.75														0.15		0.60
Antifoam		0.12														0.02		0.10
WFI	WFI																	
			14		14		14.0		14.0		14.0		14.0		40.2		400	

PROCESS PARAMETERS

Step yield	100%
2-8 °C Refrigerator	1 d
Seed Flasks (Shaker Incubator 1)	2 d
-80 °C Freezer	1 d
-20 °C Freezer	1 d
2-8 °C Refrigerator	1 d

Note: Viral stock preparation occurs at the same time as the cell thawing and preparation so it is not included in the total time.

DEPTH FILTRATION & CLARIFIED BROTH

PRODUCT PARAMETERS

	Volume	Mass	Concentration
	L	g	g/L
Product input	400	800	2.002
Product output	421	760	1.807
Waste	525		

PROCESS PARAMETERS

Step yield	95%
Normalized flowrate, LMH	50 L/(m²·h)
Basis: Depth 1, m²	3 m²
Flowrate	150 L/h
Pre-process time	2.33 h
Process time	2.80 h
Post-process time	1.17 h
Total time	6.30 h

SOLUTION VOLUMES

SOLUTION	VOLUME
	L
BROTH 1	196
WFI	350

STEP PARAMETERS

STAGE	LOAD CAPACITY	REQUIRED	PER FILTER	FILTERS	TOTAL AREA	HOLD-UP		FLUSH		EQUILIBRATION		CHASE		POST-USE FLUSH	
								WFI		BROTH 1		BROTH 1		WFI	
	L/m²	m²	m²	qty	m²	L/m²	L	L/m²	L	L/m²	L	L/m²	L	L/m²	L
Depth 1	150	2.664666667	3	1	3	3	9	25	75	25	75	3.3	9.9	25	75
Depth 2	150	2.664666667	3	1	3	3	9	25	75	25	75	3.3	9.9	25	75
Bioburden	500	0.7994	1	1	1	1	1	25	25	25	25	1.1	1.1	25	25
					7				175		175		20.9		175

AFFINITY CHROMATOGRAPHY

PRODUCT PARAMETERS

	Volume	Mass	Concentration
	L	g	g/L
Product input	421	760	1.807
Product output	95	684	7.168
Waste	1,502		

PROCESS PARAMETERS

Step yield	90%
Column diameter	45.00 cm
Bed height	20.00 cm
Bed volume	31.81 L
Binding Capacity (90% of maximum)	27 g/L
Total Capacity	859 g
Runs required per batch	1.00
Pre-process time	0.64 h
Process time	1.46 h
Post-process time	0.81 h
Total time	2.91 h

STEP PARAMETERS

CHROMATOGRAPHY STEPS				PER COLUMN			PER BATCH		
STEP NAME	SOLUTION	VELOCITY	FLOWRATE	CV	VOLUME	TIME	RUNS	VOLUME	TIME
		cm/h	L/h		L	h	qty	L	h
Pre-use cleaning	0.1 M NaOH	345	549	3	95	0.17	1	95	0.17
Pre-use flush	WFI	345	549	3	95	0.17	1	95	0.17
Equilibration	AFF 1	345	549	5	159	0.29	1	159	0.29
Load	Product	345	549	13	421	0.77	1	421	0.77
Chase	AFF 1	345	549	3	95	0.17	1	95	0.17
Wash 1	AFF 2	345	549	3	95	0.17	1	95	0.17
Wash 2	AFF 3	345	549	3	95	0.17	1	95	0.17
Elution	AFF 4	345	549	3	95	0.17	1	95	0.17
Strip / Wash / Regen	AFF 1	345	549	5	159	0.29	1	159	0.29
Post-use cleaning / sani	0.1 M NaOH	345	549	4	127	0.23	1	127	0.23
Post-use flush	WFI	345	549	3	95	0.17	1	95	0.17
Store	19% Ethanol	345	549	2	64	0.12	1	64	0.12
					1,598	2.91		1,598	2.91

SOLUTION VOLUMES

SOLUTION	COLUMN	BATCH
	L	L
0.1 M NaOH	223	223
AFF 1	414	414
AFF 2	95	95
AFF 3	95	95
AFF 4	95	95
19% Ethanol	64	64
WFI	191	191

VIRUS INACTIVATION & NEUTRALIZATION

PRODUCT PARAMETERS

	Volume	Mass	Concentration
	L	g	g/L
Product input	95	684	7.168
Product output	106	684	6.456
Waste	105		

pH PARAMETERS

SOLUTION ADDITION		BUFFER			PRODUCT
STEP NAME	SOLUTION	STOCK	SOLUTION	VOLUME	VOLUME
		%	%	L	L
Acid		100	5.0	5.02	100
Base		100	5.0	5.29	106

Mix in one SUM

Transfer

Hold in SUM

PROCESS PARAMETERS

Step yield	100%
Normalized flowrate, LMH	50 L/(m²·h)
Inactivation time	2.00 h
Filter area	1 m²
Flowrate	50 L/h
Pre-process time	1.50 h
Process time	2.22 h
Post-process time	0.50 h
Total time	6.22 h

SOLUTION VOLUMES

SOLUTION	VOLUME
	L
Buffer 1	55.5
WFI	50

FILTRATION PARAMETERS

STAGE	LOAD CAPACITY	REQUIRED	PER FILTER	FILTERS	TOTAL AREA	HOLD-UP		FLUSH		EQUILIBRATION		CHASE		POST-USE FLUSH	
								WFI		Buffer 1		Buffer 1		WFI	
	L/m²	m²	m²	qty	m²	L/m²	L	L/m²	L	L/m²	L	L/m²	L	L/m²	L
Depth 1	150	0.636172512	1	1	1	5	5	25	25	35	35	5.5	5.5	25	25
Depth 2	150	0.636172512	1	1	1	5	5	25	25	35	35	5.5	5.5	25	25
Bioburden	500	0.21	1	1	1	5	5	25	25	50	50	5.5	5.5	25	25
									25		50		5.5		25

ANION EXCHANGE CHROMATOGRAPHY

PRODUCT PARAMETERS

	Volume	Mass	Concentration
	L	g	g/L
Product input	106	684	6.456
Product output	75	670	8.890
Waste	810		

PROCESS PARAMETERS

Step yield	98%
Column diameter	40.00 cm
Bed height	20.00 cm
Bed volume	25.13 L
Binding Capacity	55 g/L
Total Capacity	1382 g
Runs required per batch	1.00
Pre-process time	0.80 h
Process time	0.75 h
Post-process time	0.80 h
Total time	2.35 h

STEP PARAMETERS

CHROMATOGRAPHY STEPS				PER COLUMN			PER BATCH		
STEP NAME	SOLUTION	VELOCITY	FLOWRATE	CV	VOLUME	TIME	RUNS	VOLUME	TIME
		cm/h	L/h		L	h	qty	L	h
Pre-use cleaning	0.1 M NaOH	300	377	3	75	0.20	1	75	0.20
Pre-use flush	WFI	300	377	3	75	0.20	1	75	0.20
Equilibration	AEX 1	300	377	6	151	0.40	1	151	0.40
Load	Product	300	377	4	106	0.28	1	106	0.28
Wash 1	AEX 2	300	377	4	101	0.27	1	101	0.27
Wash 2							1		
Elution	AEX 3	300	377	3	75	0.20	1	75	0.20
Strip / Wash / Regen	AEX 1	300	377	3	75	0.20	1	75	0.20
Post-use cleaning / sani	0.1 M NaOH	300	377	3	75	0.20	1	75	0.20
Post-use flush	WFI	300	377	3	75	0.20	1	75	0.20
Store	19% Ethanol	300	377	3	75	0.20	1	75	0.20
					885	2.35		885	2.35

SOLUTION VOLUMES

SOLUTION	COLUMN	BATCH
	L	L
0.1 M NaOH	151	151
AEX 1	226	226
AEX 2	101	101
AEX 3	75	75
19% Ethanol	75	75
WFI	151	151

CATION EXCHANGE CHROMATOGRAPHY

PRODUCT PARAMETERS

	Volume	Mass	Concentration
	L	g	g/L
Product input	75	670	8.890
Product output	101	603	6.001
Waste	779		

PROCESS PARAMETERS

Step yield	90%
Column diameter	40.00 cm
Bed height	20.00 cm
Bed volume	25.13 L
Binding Capacity	60 g/L
Total Capacity	1508 g
Runs required per batch	1.00
Pre-process time	0.80 h
Process time	0.73 h
Post-process time	0.80 h
Total time	2.33 h

STEP PARAMETERS

CHROMATOGRAPHY STEPS				PER COLUMN			PER BATCH		
STEP NAME	SOLUTION	VELOCITY	FLOWRATE	CV	VOLUME	TIME	RUNS	VOLUME	TIME
		cm/h	L/h		L	h	qty	L	h
Pre-use cleaning	0.1 M NaOH	300	377	3	75	0.20	1	75	0.20
Pre-use flush	WFI	300	377	3	75	0.20	1	75	0.20
Equilibration + Chase	CEX 1	300	377	6	151	0.40	1	151	0.40
Load	Product	300	377	3	75	0.20	1	75	0.20
Wash 1	CEX 2	300	377	4	101	0.27	1	101	0.27
Wash 2							1		
Elution	CEX 3	300	377	4	101	0.27	1	101	0.27
Strip / Wash / Regen	CEX 1	300	377	3	75	0.20	1	75	0.20
Post-use cleaning / sani	0.1 M NaOH	300	377	3	75	0.20	1	75	0.20
Post-use flush	WFI	300	377	3	75	0.20	1	75	0.20
Store	19% Ethanol	300	377	3	75	0.20	1	75	0.20
					880	2.33		880	2.33

SOLUTION VOLUMES

SOLUTION	COLUMN	BATCH
	L	L
0.1 M NaOH	151	151
CEX 1	226	226
CEX 2	101	101
CEX 3	101	101
19% Ethanol	75	75
WFI	151	151

NANOFILTRATION

PRODUCT PARAMETERS

	Volume	Mass	Concentration
	L	g	g/L
Product input	101	603	6.001
Product output	134	597	4.451
Waste	337		

PROCESS PARAMETERS

Step yield	99%
Normalized flowrate, LMH	50 L/(m²·h)
Basis: Nanofilter	3.06 m²
Flowrate	153 L/h
Pre-process time	1.20 h
Process time	0.88 h
Post-process time	1.00 h
Total time	3.08 h

SOLUTION VOLUMES

SOLUTION	VOLUME
	L
NANO 1	64.26
WFI	306

STEP PARAMETERS

STAGE	LOAD CAPACITY	REQUIRED	PER FILTER	FILTERS	TOTAL AREA	HOLD-UP		FLUSH		EQUILIBRATION		CHASE		POST-USE FLUSH	
								WFI		NANO 1		NANO 1		WFI	
	L/m²	m²	m²	qty	m²	L/m²	L	L/m²	L	L/m²	L	L/m²	L	L/m²	L
Prefilter	500	0.201	0.2	2	0.4	10	4								
Nanofilter	50	2.011	1.53	2	3.06	10	30.6	50	153	10	30.6	11	33.66	50	153
Bioburden															
					3.46				153		30.6		33.66		153

ULTRAFILTRATION-DIAFILTRATION

PRODUCT PARAMETERS

	Volume	Mass	Concentration
	L	g	g/L
Product input	134	597	4.451
Product output	24	567	24
Waste	2,862		

PROCESS PARAMETERS

Step yield	95%
NMWL	30 kDa
Concentration	$m^2 \cdot h$
Diafiltration	26.84 $m^2 \cdot h$
Concentration	6.01 $m^2 \cdot h$
Optimization factor	32.85 $m^2 \cdot h$
Desired process time	4.00 h
Required area	8.21 m^2
Actual area	10.00 m^2
Pre-process time	1.17 h
Process time	3.28 h
Post-process time	1.17 h
Total time	5.62 h

SOLUTION VOLUMES

SOLUTION	VOLUME
	L
0.1 M NaOH	200
UF 1	1,552
WFI	800
0.5 M NaOH	200

CLEANING PARAMETERS

STEP NAME	SOLUTION	VOLUME		FLOWRATE		FLUX		PERMEATE
		L/m²	L	L/(m²·min)	L/min	L/(m²·h)	L/min	L
Pre-use flush	WFI	20	200	6	60	60	10.0	200
Pre-use clean	0.5 M NaOH	10	100	6	60	60	10.0	100
Pre-use flush	WFI	20	200	6	60	60	10.0	200
Equilibration	UF 1	20	200	6	60	60	10.0	200
Post-use flush	WFI	20	200	6	60	60	10.0	200
Post-use clean	0.5 M NaOH	10	100	6	60	60	10.0	100
Post-use flush	WFI	20	200	6	60	60	10.0	200
Store	0.1 M NaOH	20	200	6	60	60	10.0	200
			1400					1400

UF / DF PARAMETERS

	INPUT		FLOWRATE		FLUX		INITIAL	FINAL	CF	DIAVOLUMES	PERMEATE
	SOLUTION	L	L/(m²·min)	L/min	L/(m²·h)	L/min	L	L		N	L
Concentration	Product	134	4	40	50	8	134.19	134.19	1.00		
Diafiltration	UF 1	1,342	4	40	50	8	134.19	134.19	1.00	10.00	1,342
Concentration	Product		4	40	20	3	134.19	14.00	9.59		120
Chase	UF 1	10	4	40	30	5	14.00	24.00	0.58		
		1,486									1,462

CONCENTRATION ADJUSTMENT SINGLE USE MIXER

PRODUCT PARAMETERS

	Volume	Mass	Concentration
	L	g	g/L
Product input	24	567	23.641
Product output	26	562	21.605
Waste			

PROCESS PARAMETERS

Step yield	99%
Normalized flowrate, LMH	100 $L/(m^2 \cdot h)$
Basis: Bioburden	m^2
Flowrate	120 L/h
Pre-process time	h
Process time	0.20 h
Post-process time	h
Total time	0.20 h

SOLUTION VOLUMES

SOLUTION	VOLUME
	L
FILT 1	
WFI	2

STEP PARAMETERS

STAGE	LOAD CAPACITY	REQUIRED	PER FILTER	FILTERS	TOTAL AREA	HOLD-UP		FLUSH		EQUILIBRATION		CHASE		POST-USE FLUSH	
								WFI		FILT 1		FILT 1		WFI	
	L/m^2	m^2	m^2	qty	m^2	L/m^2	L	L/m^2	L	L/m^2	L	L/m^2	L	L/m^2	L

0.22 µm MICROFILTRATION

PRODUCT PARAMETERS

	Volume	Mass	Concentration
	L	g	g/L
Product input	26	562	21.605
Product output	28	556	19.720
Waste	2		

PROCESS PARAMETERS

Step yield	99%
Normalized flowrate, LMH	50 LMH
Basis: Bioburden	0.2 m²
Flowrate	10 L/h
Pre-process time	0.30 h
Process time	2.82 h
Post-process time	h
Total time	3.12 h

SOLUTION VOLUMES

SOLUTION	VOLUME
	L
MICRO 1	2.2
WFI	2

STEP PARAMETERS

STAGE	LOAD CAPACITY	REQUIRED	PER FILTER	FILTERS	TOTAL AREA	HOLD-UP		FLUSH		EQUILIBRATION		CHASE		POST-USE FLUSH	
								WFI		MICRO 1		MICRO 1		WFI	
	L/m²	m²	m²	qty	m²	L/m²	L	L/m²	L	L/m²	L	L/m²	L	L/m²	L
Prefilter	500	0.052	0.2	1	0.2	5	1	5	1			5.5	1.1		
Bioburden	500	0.052	0.2	1	0.2	5	1	5	1			5.5	1.1		
					0.4				2				2.2		

VIRAL STOCK, CELL THAWING & PREPARATION, AND BIOREACTOR

PRODUCT PARAMETERS

	Volume	Mass	Concentration
	L	g	g/L
Product input	40	80	2.000
Product output	40	80	2.002
Waste	0		

STEP PARAMETERS

STEP NAME	SOLUTION		VIRAL STOCK PREPARATION				CELL THAWING & PREPARATION								BIOREACTOR	
			2-8 °C REFRIGERATOR		SEED FLASKS (SHAKER INCUBATOR 1)		-80 °C FREEZER		-20 °C FREEZER		2-8 °C REFRIGERATOR		SEED FLASKS (SHAKER INCUBATOR 2)		50 L SUB	
			PRODUCT	SOLUTIONS	PRODUCT	SOLUTIONS	PRODUCT	SOLUTIONS	PRODUCT	SOLUTIONS	PRODUCT	SOLUTIONS	PRODUCT	SOLUTIONS	PRODUCT	SOLUTIONS
	TYPE	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Seed / Product			4		4		4		4		4		4		4.0	
Media		81.8		10.0		10.0		10		10		10		10		31.8
Lysis Buffer for Viral Inactivation		4														4.0
Feed	7% of total BR volume															
Medical Air	maximum TBD															
Oxygen	maximum TBD															
CO2	maximum TBD															
Nitrogen	maximum TBD															
Acid																
Base		0.15														0.15
Antifoam		0.02														0.02
WFI	WFI															
			14		14		14.0		14.0		14.0		14.0		40.0	

PROCESS PARAMETERS

Step yield	100%
2-8 °C Refrigerator	1 d
Seed Flasks (Shaker Incubator 1)	2 d
-80 °C Freezer	1 d
-20 °C Freezer	1 d
2-8 °C Refrigerator	1 d

Note: Viral stock preparation occurs at the same time as the cell thawing and preparation so it is not included in the total time.

DEPTH FILTRATION & CLARIFIED BROTH

PRODUCT PARAMETERS

	Volume	Mass	Concentration
	L	g	g/L
Product input	40	80	2.002
Product output	48	76	1.594
Waste	205		

PROCESS PARAMETERS

Step yield	95%
Normalized flowrate, LMH	50 $L/(m^2 \cdot h)$
Basis: Depth 1, m^2	1 m^2
Flowrate	50 L/h
Pre-process time	3.00 h
Process time	0.95 h
Post-process time	1.10 h
Total time	5.05 h

SOLUTION VOLUMES

SOLUTION	VOLUME
	L
BROTH 1	83
WFI	130

STEP PARAMETERS

STAGE	LOAD CAPACITY	REQUIRED	PER FILTER	FILTERS	TOTAL AREA	HOLD-UP		FLUSH		EQUILIBRATION		CHASE		POST-USE FLUSH	
								WFI		BROTH 1		BROTH 1		WFI	
	L/m^2	m^2	m^2	qty	m^2	L/m^2	L	L/m^2	L	L/m^2	L	L/m^2	L	L/m^2	L
Depth 1	150	0.27	1	1	1	3	3	25	25	25	25	3.3	3.3	25	25
Depth 2	150	0.27	1	1	1	3	3	25	25	25	25	3.3	3.3	5	5
Bioburden	500	0.07994	1	1	1	1	1	25	25	25	25	1.1	1.1	25	25
					3				75		75		7.7		55

ANION EXCHANGE CHROMATOGRAPHY

PRODUCT PARAMETERS

	Volume	Mass	Concentration
	L	g	g/L
Product input	48	76	1.594
Product output	75	74	0.988
Waste	676		

PROCESS PARAMETERS

Step yield	98%
Column diameter	40.00 cm
Bed height	20.00 cm
Bed volume	25.13 L
Binding Capacity	55 g/L
Total Capacity	1382 g
Runs required per batch	1.00
Pre-process time	0.60 h
Process time	0.59 h
Post-process time	0.80 h
Total time	1.99 h

STEP PARAMETERS

CHROMATOGRAPHY STEPS				PER COLUMN			PER BATCH		
STEP NAME	SOLUTION	VELOCITY	FLOWRATE	CV	VOLUME	TIME	RUNS	VOLUME	TIME
		cm/h	L/h		L	h	qty	L	h
Pre-use cleaning	0.1 M NaOH	300	377	3	75	0.20	1	75	0.20
Pre-use flush	WFI	300	377	3	75	0.20	1	75	0.20
Equilibration	AEX 1	300	377	3	75	0.20	1	75	0.20
Load	Product	300	377	2	48	0.13	1	48	0.13
Wash 1	AEX 2	300	377	4	101	0.27	1	101	0.27
Wash 2							1		
Elution	AEX 3	300	377	3	75	0.20	1	75	0.20
Strip / Wash / Regen	AEX 1	300	377	3	75	0.20	1	75	0.20
Post-use cleaning / sani	0.1 M NaOH	300	377	3	75	0.20	1	75	0.20
Post-use flush	WFI	300	377	3	75	0.20	1	75	0.20
Store	19% Ethanol	300	377	3	75	0.20	1	75	0.20
					751	1.99		751	1.99

SOLUTION VOLUMES

SOLUTION	COLUMN	BATCH
	L	L
0.1 M NaOH	151	151
AEX 1	151	151
AEX 2	101	101
AEX 3	75	75
19% Ethanol	75	75
WFI	151	151

MIXED-MODE (MULTIMODAL) CHROMATOGRAPHY

PRODUCT PARAMETERS

	Volume	Mass	Concentration
	L	g	g/L
Product input	75	74	0.988
Product output	75	67	0.889
Waste	779		

PROCESS PARAMETERS

Step yield	90%
Column diameter	40.00 cm
Bed height	20.00 cm
Bed volume	25.13 L
Binding Capacity	60 g/L
Total Capacity	1508 g
Runs required per batch	1.00
Pre-process time	0.80 h
Process time	0.67 h
Post-process time	0.80 h
Total time	2.27 h

STEP PARAMETERS

CHROMATOGRAPHY STEPS				PER COLUMN			PER BATCH		
STEP NAME	SOLUTION	VELOCITY	FLOWRATE	CV	VOLUME	TIME	RUNS	VOLUME	TIME
		cm/h	L/h		L	h	qty	L	h
Pre-use cleaning	0.1 M NaOH	300	377	3	75	0.20	1	75	0.20
Pre-use flush	WFI	300	377	3	75	0.20	1	75	0.20
Equilibration + Chase	MMC 1	300	377	6	151	0.40	1	151	0.40
Load	Product	300	377	3	75	0.20	1	75	0.20
Wash 1	MMC 2	300	377	4	101	0.27	1	101	0.27
Wash 2							1		
Elution	MMC 3	300	377	3	75	0.20	1	75	0.20
Strip / Wash / Regen	MMC 1	300	377	3	75	0.20	1	75	0.20
Post-use cleaning / sani	0.1 M NaOH	300	377	3	75	0.20	1	75	0.20
Post-use flush	WFI	300	377	3	75	0.20	1	75	0.20
Store	19% Ethanol	300	377	3	75	0.20	1	75	0.20
					855	2.27		855	2.27

SOLUTION VOLUMES

SOLUTION	COLUMN	BATCH
	L	L
0.1 M NaOH	151	151
MMC 1	226	226
MMC 2	101	101
MMC 3	75	75
19% Ethanol	75	75
WFI	151	151

NANOFILTRATION

PRODUCT PARAMETERS

	Volume	Mass	Concentration
	L	g	g/L
Product input	75	67	0.889
Product output	84	66	0.792
Waste	168		

PROCESS PARAMETERS

Step yield	99%
Normalized flowrate, LMH	50 L/(m²·h)
Basis: Nanofilter	1.53 m²
Flowrate	77 L/h
Pre-process time	1.20 h
Process time	1.10 h
Post-process time	1.00 h
Total time	3.30 h

SOLUTION VOLUMES

SOLUTION	VOLUME
	L
NANO 1	23.715
WFI	153

STEP PARAMETERS

STAGE	LOAD CAPACITY	REQUIRED	PER FILTER	FILTERS	TOTAL AREA	HOLD-UP		FLUSH		EQUILIBRATION		CHASE		POST-USE FLUSH	
								WFI		NANO 1		NANO 1		WFI	
	L/m²	m²	m²	qty	m²	L/m²	L	L/m²	L	L/m²	L	L/m²	L	L/m²	L
Prefilter	500	0.151	0.2	1	0.2	5	1								
Nanofilter	50	1.508	1.53	1	1.53	5	7.65	50	76.5	10	15.3	5.5	8.415	50	76.5
Bioburden															
					1.73				76.5		15.3		8.415		76.5

ULTRAFILTRATION-DIAFILTRATION

PRODUCT PARAMETERS

	Volume	Mass	Concentration
	L	g	g/L
Product input	84	66	0.792
Product output	18	63	4
Waste	1,805		

PROCESS PARAMETERS

Step yield	95%
NMWL	30 kDa
Concentration	m^2·h
Diafiltration	6.71 m^2·h
Concentration	3.49 m^2·h
Optimization factor	10.20 m^2·h
Desired process time	4.00 h
Required area	2.55 m^2
Actual area	10.00 m^2
Pre-process time	1.17 h
Process time	1.02 h
Post-process time	1.17 h
Total time	3.35 h

SOLUTION VOLUMES

SOLUTION	VOLUME
	L
0.1 M NaOH	200
UF 1	539
WFI	800
0.5 M NaOH	200

CLEANING PARAMETERS

STEP NAME	SOLUTION	VOLUME		FLOWRATE		FLUX		PERMEATE
		L/m²	L	L/(m^2·min)	L/min	L/(m^2·h)	L/min	L
Pre-use flush	WFI	20	200	6	60	60	10.0	200
Pre-use clean	0.5 M NaOH	10	100	6	60	60	10.0	100
Pre-use flush	WFI	20	200	6	60	60	10.0	200
Equilibration	UF 1	20	200	6	60	60	10.0	200
Post-use flush	WFI	20	200	6	60	60	10.0	200
Post-use clean	0.5 M NaOH	10	100	6	60	60	10.0	100
Post-use flush	WFI	20	200	6	60	60	10.0	200
Store	0.1 M NaOH	20	200	6	60	60	10.0	200
			1400					1400

UF / DF PARAMETERS

	INPUT		FLOWRATE		FLUX		INITIAL	FINAL	CF	DIAVOLUMES	PERMEATE
	SOLUTION	L	L/(m^2·min)	L/min	L/(m^2·h)	L/min	L	L		N	L
Concentration	Product	84	2	20	50	8	83.81	83.81	1.00		
Diafiltration	UF 1	335	2	20	50	8	83.81	83.81	1.00	4.00	335
Concentration	Product		2	20	20	3	83.81	14.00	5.99		70
Chase	UF 1	4	2	20	30	5	14.00	18.00	0.78		
		423									405

CONCENTRATION ADJUSTMENT SINGLE USE MIXER

PRODUCT PARAMETERS

	Volume	Mass	Concentration
	L	g	g/L
Product input	18	63	3.502
Product output	20	62	3.121
Waste			

PROCESS PARAMETERS

Step yield	99%
Normalized flowrate, LMH	100 L/(m²·h)
Basis: Bioburden	m²
Flowrate	120 L/h
Pre-process time	h
Process time	0.15 h
Post-process time	h
Total time	0.15 h

SOLUTION VOLUMES

SOLUTION	VOLUME
	L
FILT 1	
WFI	2

STEP PARAMETERS

STAGE	LOAD CAPACITY	REQUIRED	PER FILTER	FILTERS	TOTAL AREA	HOLD-UP		FLUSH		EQUILIBRATION		CHASE		POST-USE FLUSH	
								WFI		FILT 1		FILT 1		WFI	
	L/m²	m²	m²	qty	m²	L/m²	L	L/m²	L	L/m²	L	L/m²	L	L/m²	L

0.22 µm MICROFILTRATION

PRODUCT PARAMETERS

	Volume	Mass	Concentration
	L	g	g/L
Product input	20	62	3.121
Product output	22	62	2.783
Waste	2		

PROCESS PARAMETERS

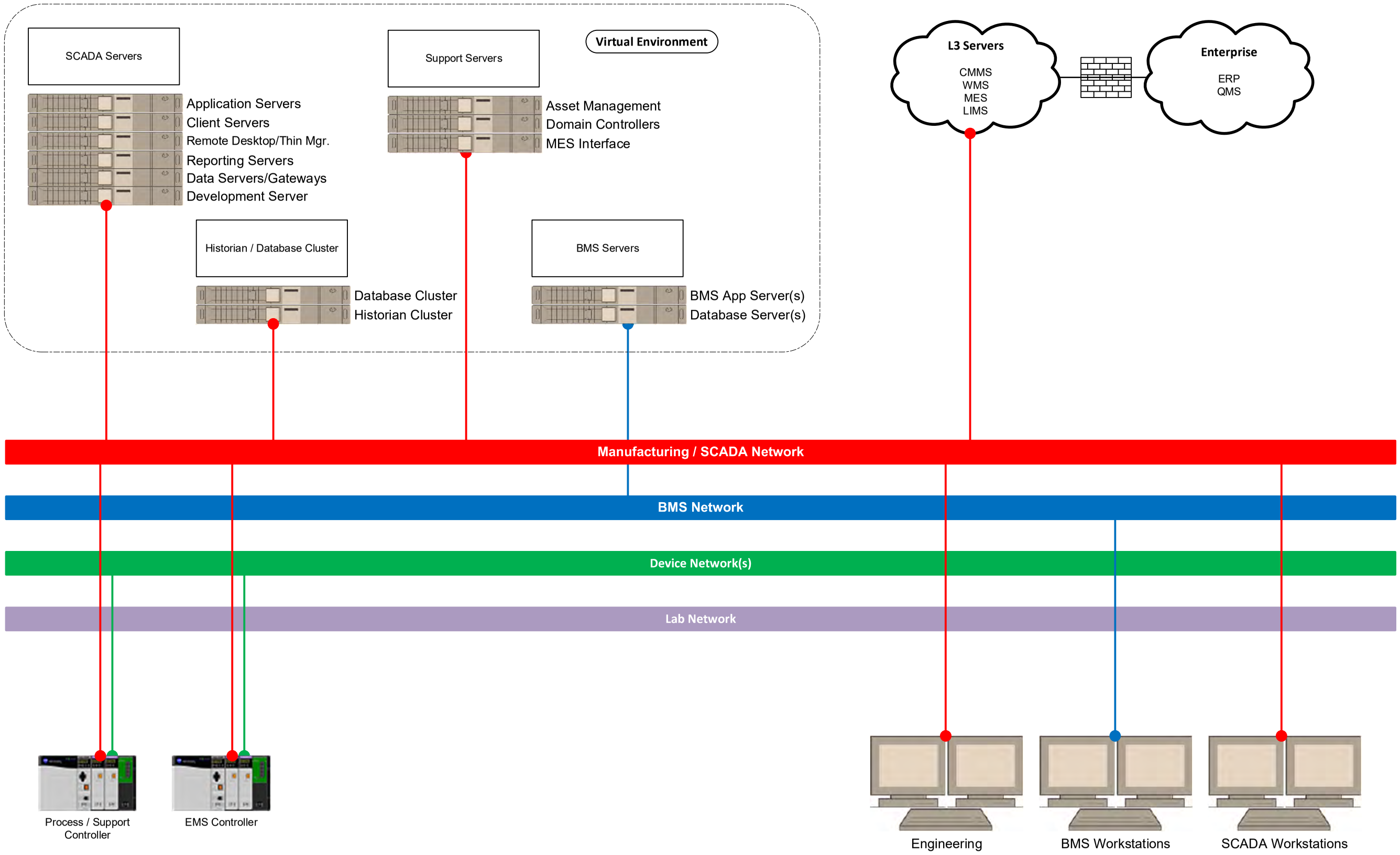
Step yield	99%
Normalized flowrate, LMH	50 L/(m²·h)
Basis: Bioburden	0.2 m²
Flowrate	10 L/h
Pre-process time	0.30 h
Process time	2.22 h
Post-process time	h
Total time	2.52 h

SOLUTION VOLUMES

SOLUTION	VOLUME
	L
MICRO 1	2.2
WFI	2

STEP PARAMETERS

STAGE	LOAD CAPACITY	REQUIRED	PER FILTER	FILTERS	TOTAL AREA	HOLD-UP		FLUSH		EQUILIBRATION		CHASE		POST-USE FLUSH	
								WFI		MICRO 1		MICRO 1		WFI	
	L/m²	m²	m²	qty	m²	L/m²	L	L/m²	L	L/m²	L	L/m²	L	L/m²	L
Prefilter	500	0.040	0.2	1	0.2	5	1	5	1			5.5	1.1		
Bioburden	500	0.040	0.2	1	0.2	5	1	5	1			5.5	1.1		
					0.4				2				2.2		



Overview

Notes:
1) Exact models/quantities of components to be detailed in DD. Images are only used for illustrative purposes only.

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DRAWING No.	21090-DES-AIC-DIA-001
E.C.	E.C.
ENGINEER	DESIGNER
J.J	DRAWN BY
NONE	SCALE
CND21090.01	PROJECT #
N/AP.	CLIENT PROJECT #
-	-

DATE	REV.	ISSUE
21APR2021	A	CONCEPT ISSUE
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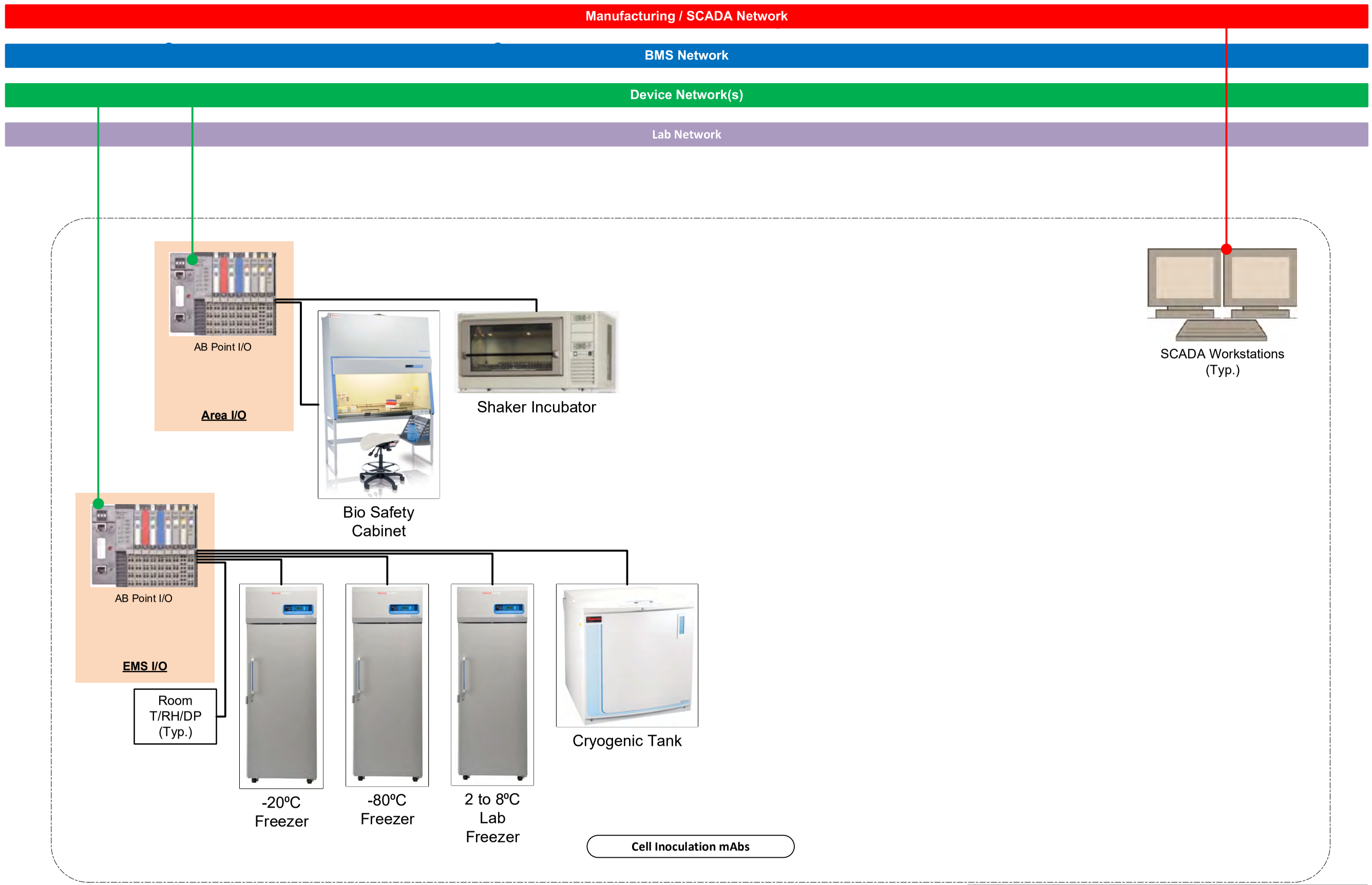
CLIENT/PROJECT TITLE:
National Research Council of Canada
Clinical Trial Manufacturing Facility

PRELIMINARY MANUFACTURING NETWORK ARCHITECTURE



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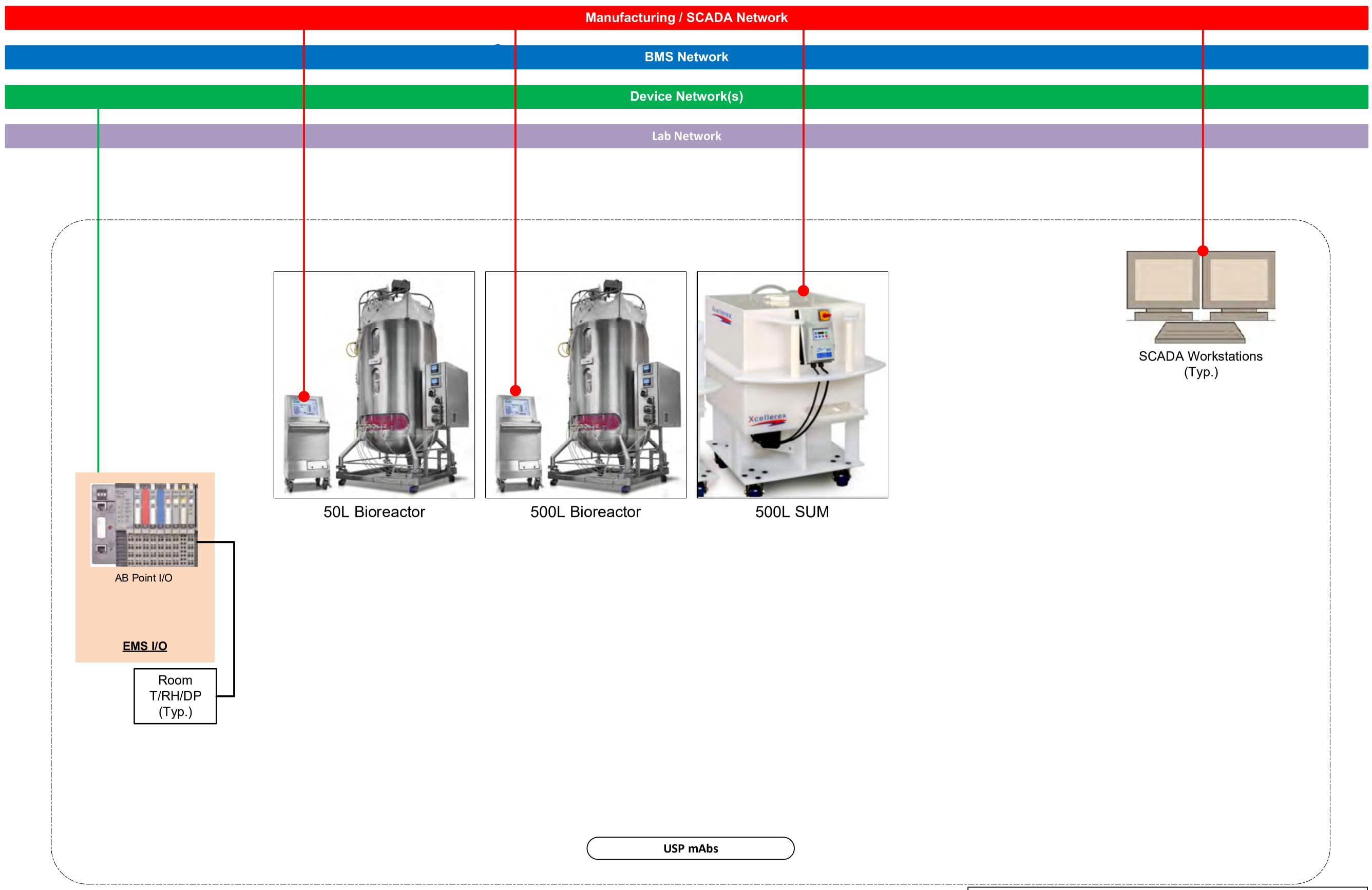

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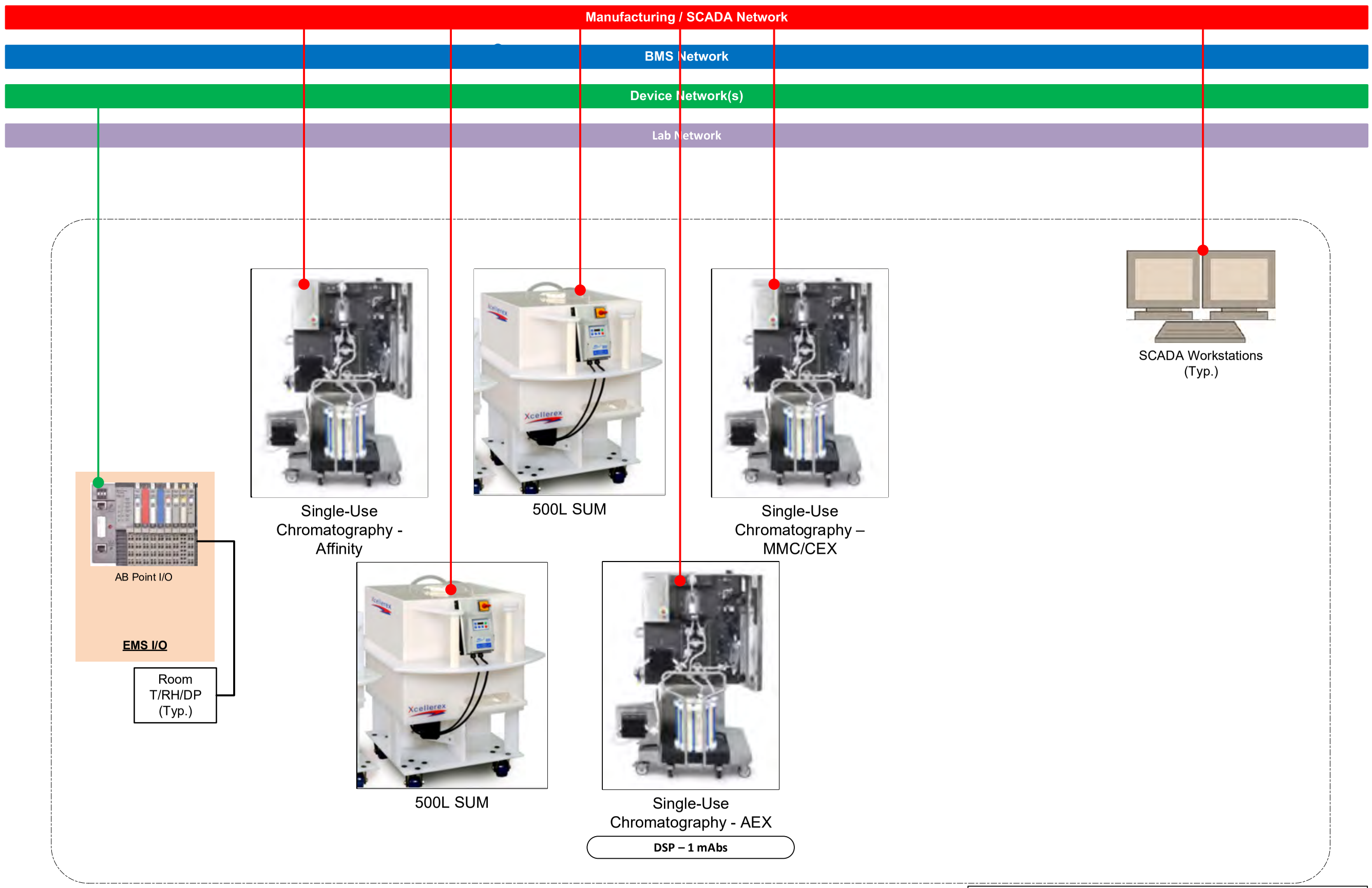

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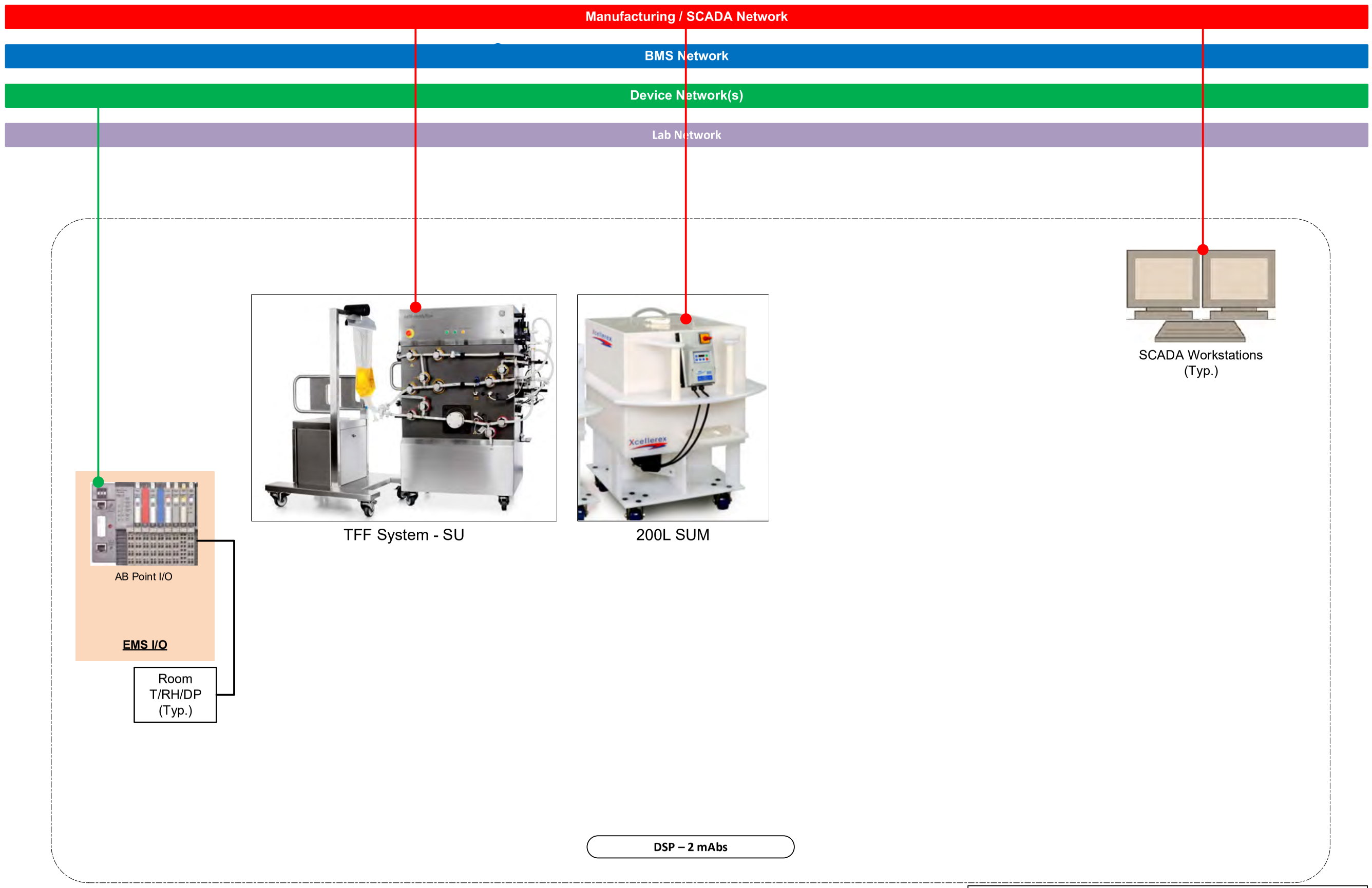

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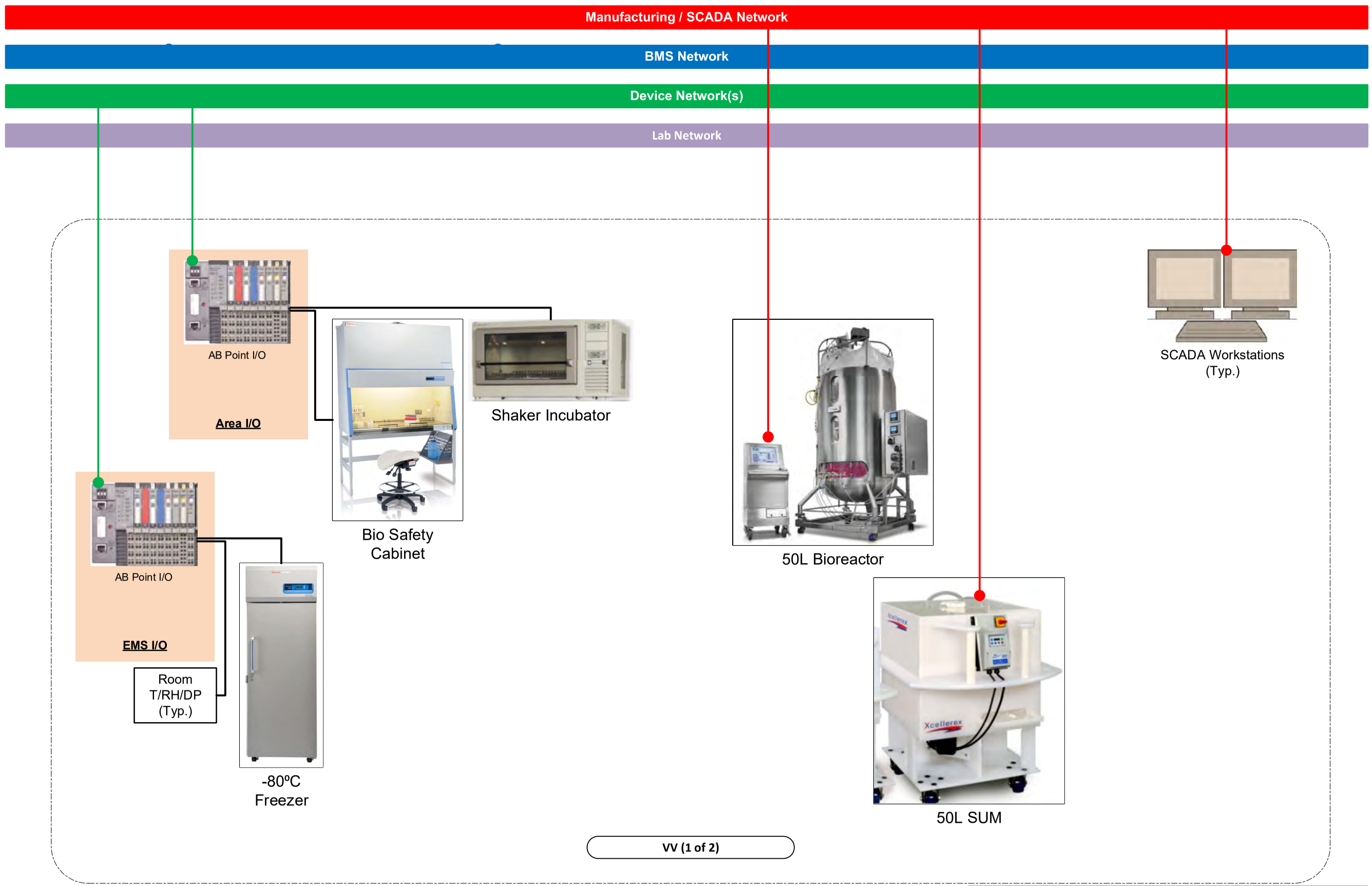

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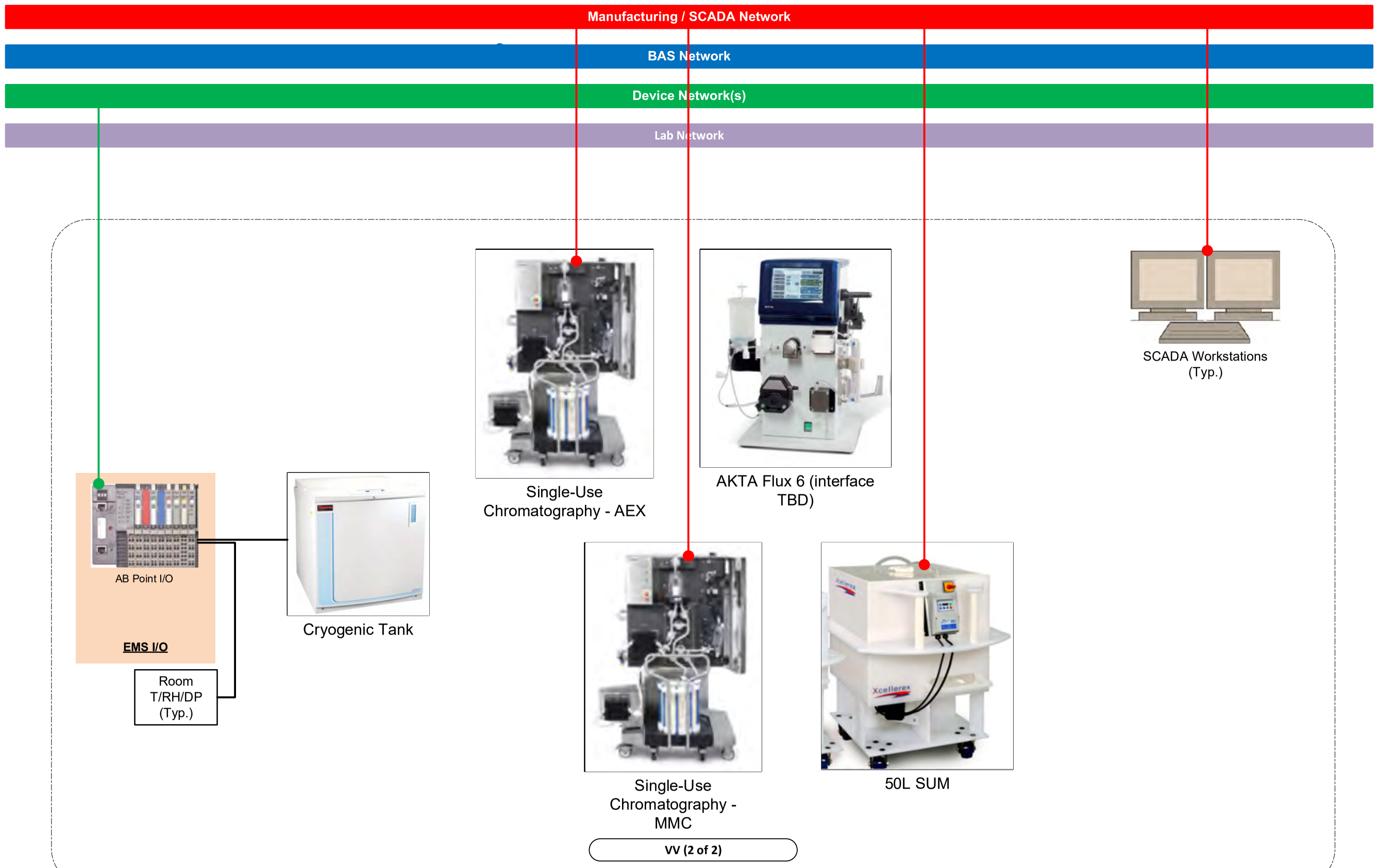

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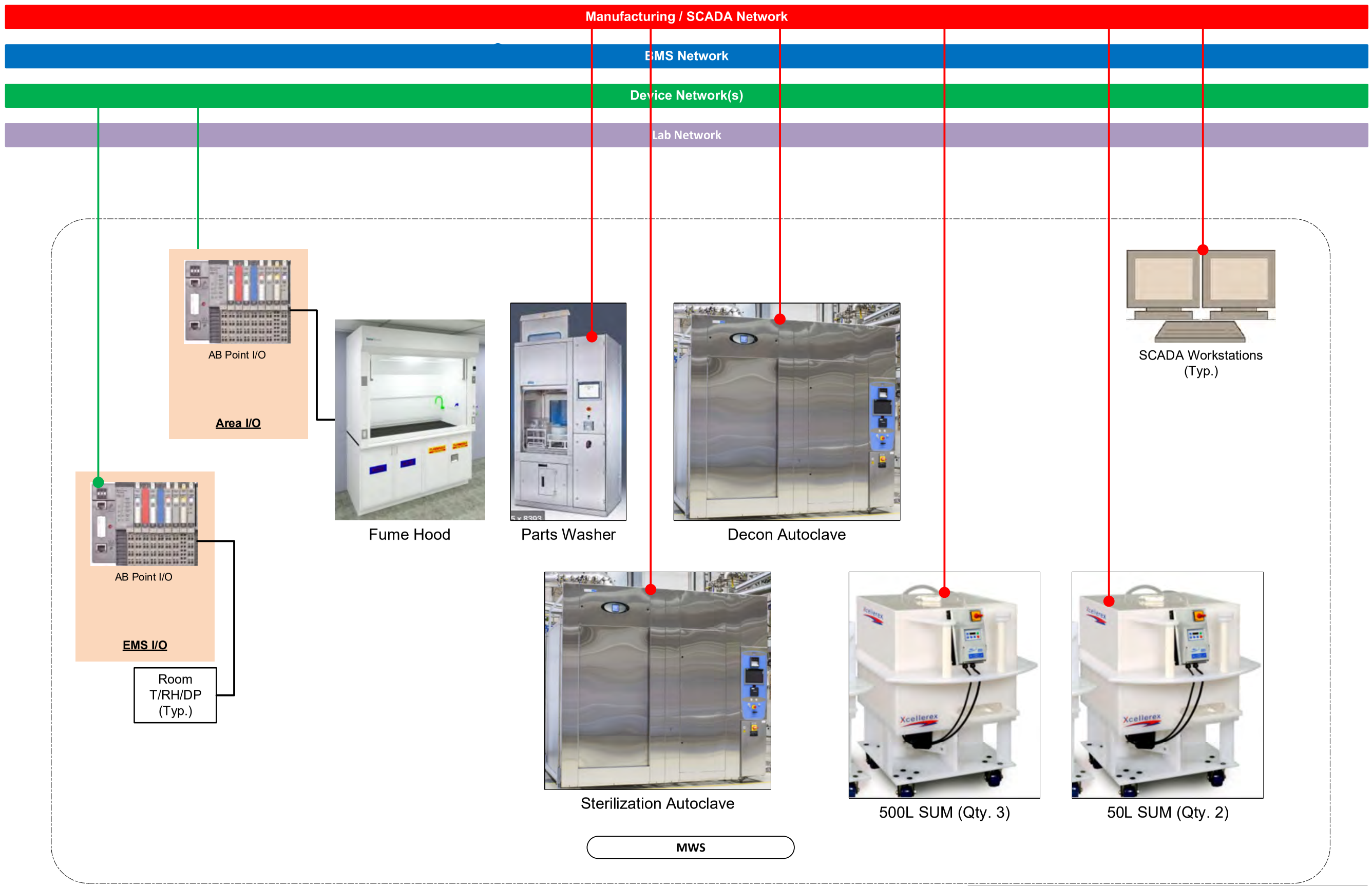

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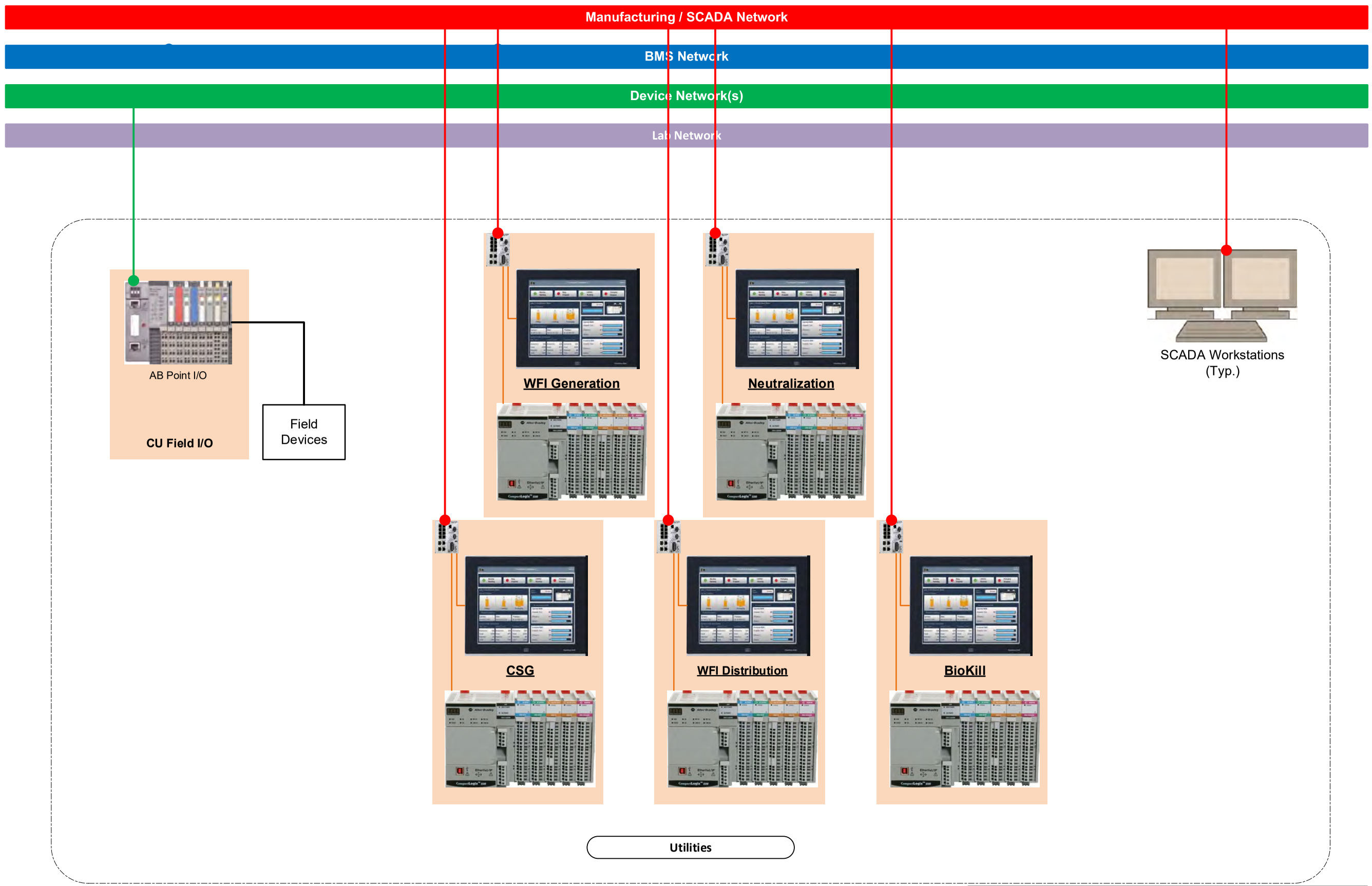

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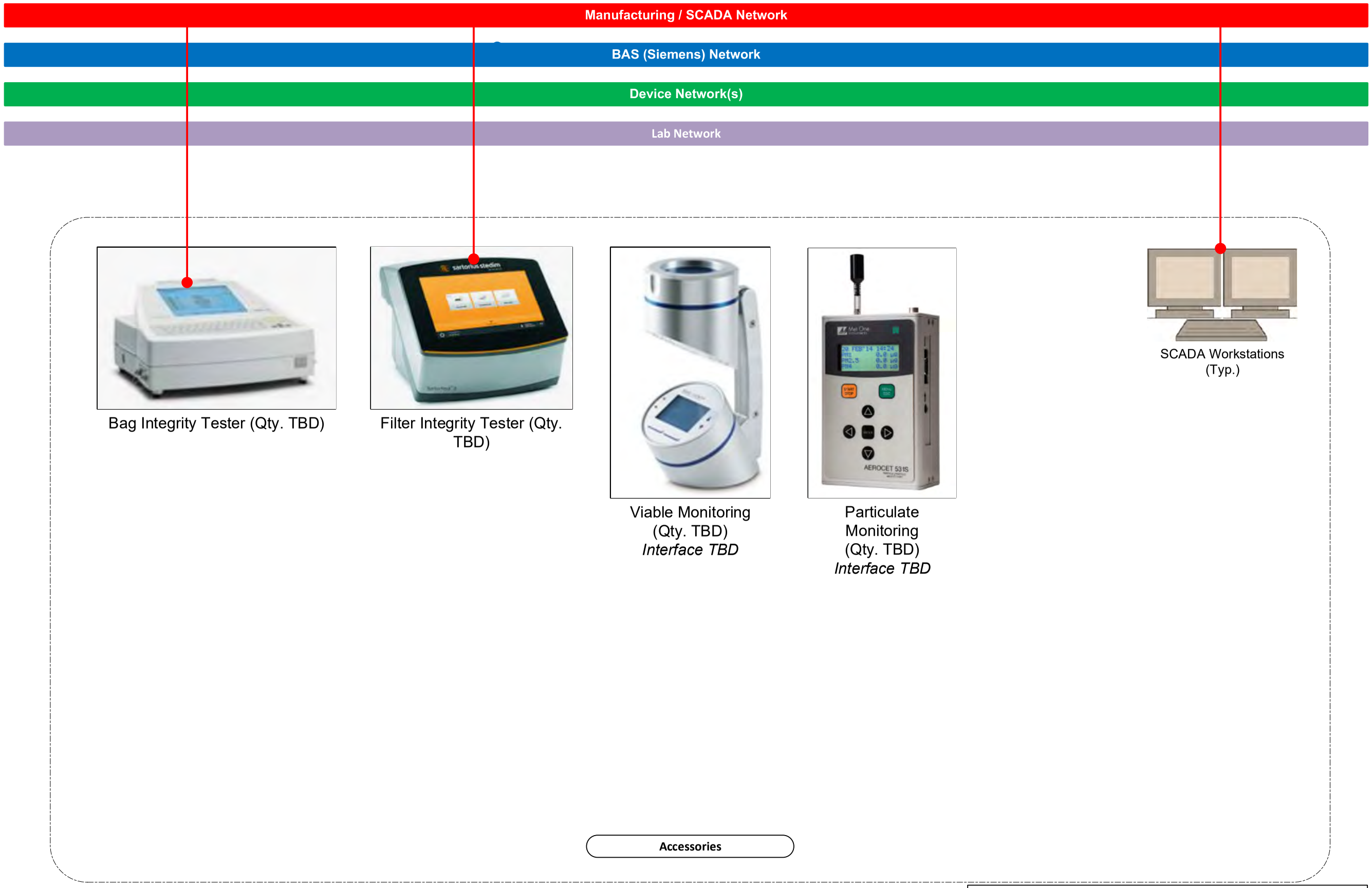

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Proprietary

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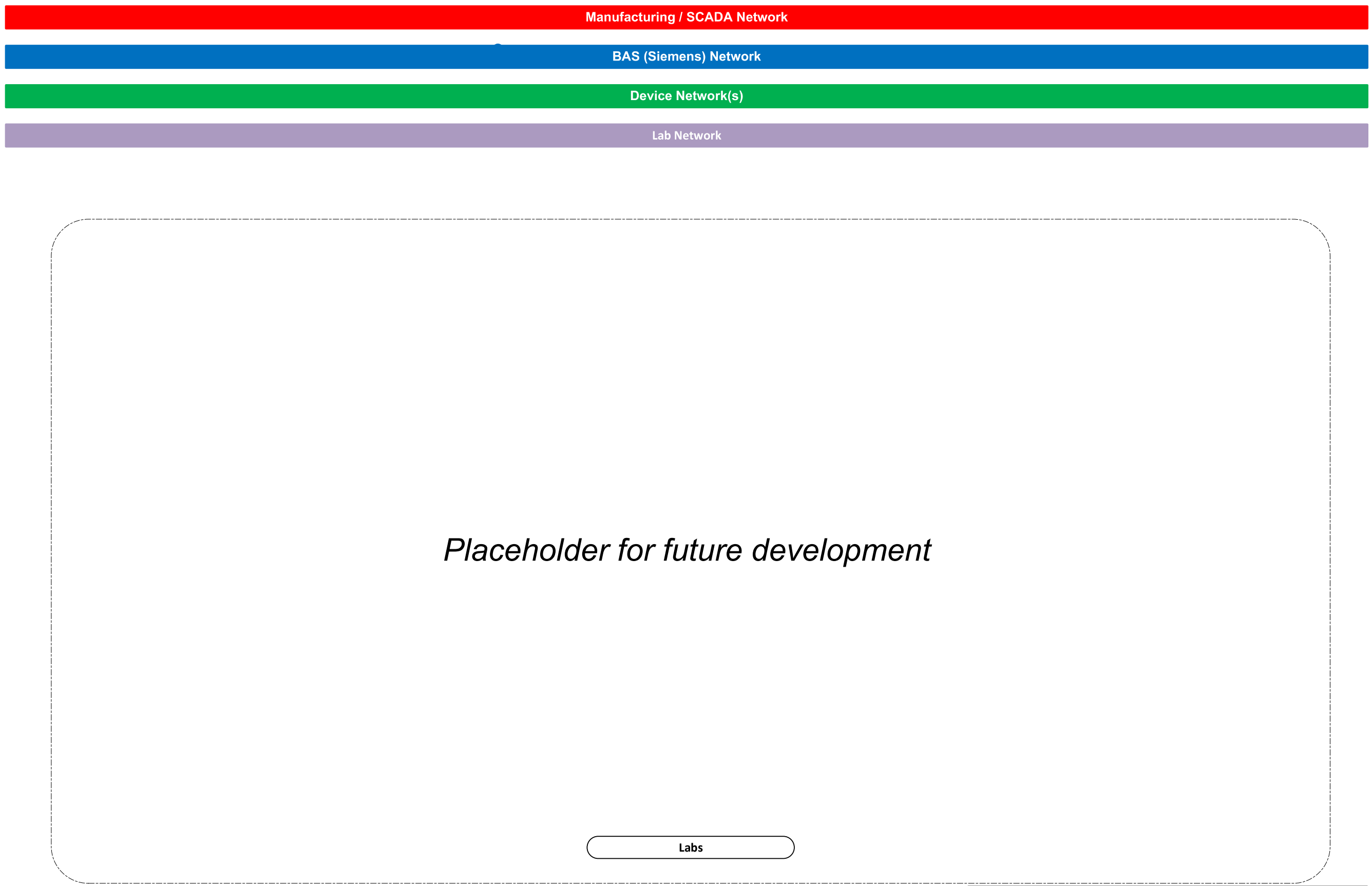

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PRELIMINARY MANUFACTURING NETWORK ARCHITECTURE

OPTION 3 - ROOM LIST WITH AREAS			
ROOM NO	**ROOM CLASSIFICATION**	**ROOM NAME**	**AREA**
FIRST FLOOR			
1100	UNCLASSIFIED	STAIR	136 SF
1101	UNCLASSIFIED	MUDROOM/ CORRIDOR	914 SF
1102	CONTROLLED NON CLASSIFIED	AIR LOCK	80 SF
1103	GRADE C	SAMPLING	277 SF
1104	GRADE C	PAL IN	52 SF
1105	GRADE D	PAL IN	52 SF
1106	GRADE D	MAL/ PAL OUT	64 SF
1107	GRADE C	WEIGH DESPENSE	346 SF
1108	GRADE D	MAL/ PAL OUT	66 SF
1109	GRADE C	PAL IN	52 SF
1110	GRADE D	PAL IN	52 SF
1111	UNCLASSIFIED	MENS	250 SF
1112	UNCLASSIFIED	WOMENS	250 SF
1113	UNCLASSIFIED	VIRAL VECTOR FEMALE LOCKERS	289 SF
1114	CONTROLLED NON CLASSIFIED	STAIRS	137 SF
1115	UNCLASSIFIED	VEST.	88 SF
1116	UNCLASSIFIED	VIRAL VECTOR MALE LOCKERS	289 SF
1117	CONTROLLED NON CLASSIFIED	QC LAB	705 SF
1118	GRADE D	MICRO LAB	197 SF
1119	UNCLASSIFIED	ELECTRICAL	1007 SF
1120	UNCLASSIFIED	IT	135 SF
1121	UNCLASSIFIED	MECHANICAL	1317 SF
1122	CONTROLLED NON CLASSIFIED	CNC CORRIDOR	712 SF
1123	UNCLASSIFIED	WASTE HANDLING	122 SF
1124	UNCLASSIFIED	JANITOR STORAGE	80 SF
1125	UNCLASSIFIED	CORRIDOR	1012 SF
1126	CONTROLLED NON CLASSIFIED	VEST.	35 SF
1127	UNCLASSIFIED	MALE LOCKER ROOM	269 SF
1128	CONTROLLED NON CLASSIFIED	STAIR	135 SF
1129	UNCLASSIFIED	VEST.	41 SF
1130	UNCLASSIFIED	FEMALE LOCKER ROOM	271 SF
1131	CONTROLLED NON CLASSIFIED	VEST.	46 SF
1132	UNCLASSIFIED	2-8	426 SF
1133	UNCLASSIFIED	WAREHOUSE	2132 SF
1134	UNCLASSIFIED	CLEAN UTILITIES	818 SF

1135	UNCLASSIFIED	BIO - KILL	827 SF
1136	UNCLASSIFIED	AIR LOCK	88 SF
1137	UNCLASSIFIED	WASTE NEUTRALIZATION	752 SF
1138	UNCLASSIFIED	STAIR	138 SF
1139	GRADE D	AIR LOCK	98 SF
1140	GRADE C	MAL IN	52 SF
1141	GRADE D	MAL IN	52 SF
1142	GRADE C	MAL IN	52 SF
1143	GRADE D	MAL IN	52 SF
SECOND FLOOR			
2100	UNCLASSIFIED	STAIR	136 SF
2101	GRADE D	RETURN CORRIDOR	3848 SF
2102	GRADE D	COMPONENT PREP	229 SF
2103	GRADE C	STERILE PREP	259 SF
2104	GRADE C	MAL/ PAL OUT	76 SF
2105	GRADE C	MAL/PAL OUT	129 SF
2106	GRADE D	AUTOCLAVE ROOM	74 SF
2107	GRADE D	MECH.	71 SF
2108	GRADE C	VIRAL VECTOR	1676 SF
2109	GRADE C	PAL OUT	69 SF
2110	GRADE C	PAL IN	60 SF
2111	GRADE C	MAL IN	112 SF
2112	GRADE C	VEST.	79 SF
2113	GRADE D	VEST.	48 SF
2114	CONTROLLED NON CLASSIFIED	ACCESS STAIR	137 SF
2115	GRADE C	CELL INOCULATION	374 SF
2116	GRADE C	UP STREAM	691 SF
2117	GRADE D	MAL/ PAL OUT	75 SF
2118	GRADE C	MAL/ PAL IN	87 SF
2119	GRADE C	MEDIA BUFFER PREP	604 SF
2120	GRADE D	MAL/ PAL OUT	96 SF
2121	GRADE C	MAL/ PAL IN	101 SF
2122	GRADE C	SUPPLY CORRIDOR	1213 SF
2123	GRADE D	MAL/ PAL OUT	114 SF
2124	GRADE C	CLEAN STORAGE	357 SF
2125	GRADE D	MAL/ PAL OUT	210 SF
2126	CONTROLLED NON CLASSIFIED	STAGING	224 SF
2127	CONTROLLED NON CLASSIFIED	STAIRS	135 SF

2128	GRADE C	FREEZER ROOM	210 SF
2129	GRADE D	MAL IN	86 SF
2130	GRADE D	PAL IN	86 SF
2131	GRADE C	MAL IN	124 SF
2132	GRADE C	PAL IN	124 SF
2133	GRADE D	STAGING	367 SF
2134	GRADE D	MAL/ PAL OUT	57 SF
2135	GRADE C	DOWN STREAM 1	1483 SF
2136	GRADE C	MAL/ PAL IN	103 SF
2137	GRADE C	MAL/ PAL IN	102 SF
2138	UNCLASSIFIED	STAIR	138 SF
2139	GRADE C	DOWN STREAM 2 & BULK FILL	762 SF
2140	GRADE D	MAL/ PAL OUT	75 SF
MECHANICAL PENTHOUSE			
4100	UNCLASSIFIED	MECHANICAL PENTHOUSE	11996 SF
4101	UNCLASSIFIED	IT CLOSET	51 SF
4102	UNCLASSIFIED	ELECTRICAL	97 SF
4103	UNCLASSIFIED	STAIR	138 SF
4104	UNCLASSIFIED	STAIR	136 SF

387 | 399

411 | 425

A CLASSIFICATION PLAN - FIRST FLOOR - OPTION 3
ASK-007 1" = 10'-0"

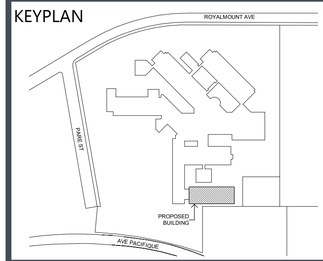
PROJECT
Clinical Trial Manufacturing Facility (CTMF)

LOCATION
6100 Royalmount Ave, Montreal, Quebec, H4P 2R2 Canada

LEGEND
AREA CLASSIFICATIONS

REST OF WORLD	US FDA
UNCLASSIFIED	UNCLASSIFIED
CONTROLLED/ NON-CLASS	CONTROLLED/ NON-CLASS
GRADE D	-
GRADE C	ISO 8
GRADE A AIR SUPPLY	LOCAL PROTECTION
GRADE B	ISO 7
GRADE A	ISO 5

PLAN LEGEND
VIRAL BOUNDARY

KEYPLAN


NEW CTMF CONCEPT STUDY

DRAWING TITLE
CLASSIFICATION PLAN - FIRST FLOOR - OPTION 3

PROJ #: CND21090.01
DWG #: ASK-007
SCALE: 1" = 10'-0"
DATE: 21-APR-2021 REV: A
DRAWN BY: AAS CHECKED BY: DBL

CLIENT
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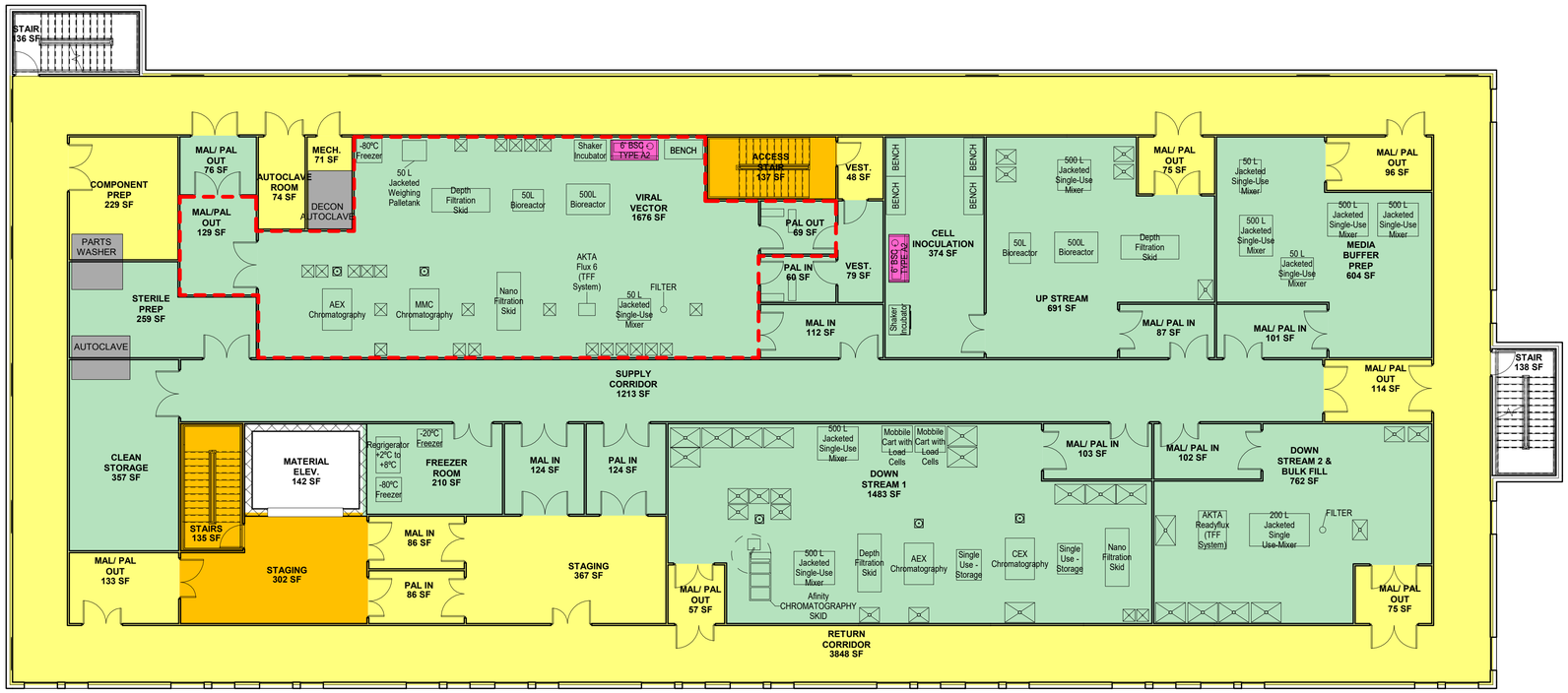


A CLASSIFICATION PLAN - SECOND FLOOR - OPTION 3

ASK-008 1" = 10'-0"

PROJECT
Clinical Trial Manufacturing Facility (CTMF)

LOCATION
6100 Royalmount Ave, Montreal, Quebec, H4P 2R2 Canada

LEGEND

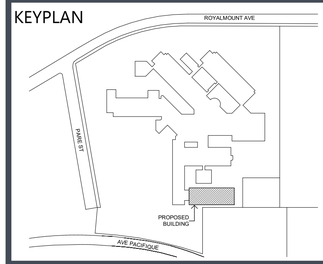
AREA CLASSIFICATIONS

REST OF WORLD	US FDA
UNCLASSIFIED	UNCLASSIFIED
CONTROLLED/ NON-CLASS	CONTROLLED/ NON-CLASS
GRADE D	-
GRADE C	ISO 8
GRADE A AIR SUPPLY	LOCAL PROTECTION
GRADE B	ISO 7
GRADE A	ISO 5

PLAN LEGEND

VIRAL BOUNDARY

KEYPLAN



NEW CTMF CONCEPT STUDY

DRAWING TITLE
CLASSIFICATION PLAN - SECOND FLOOR - OPTION 3

PROJ #: CND21090.01

DWG #: ASK-008

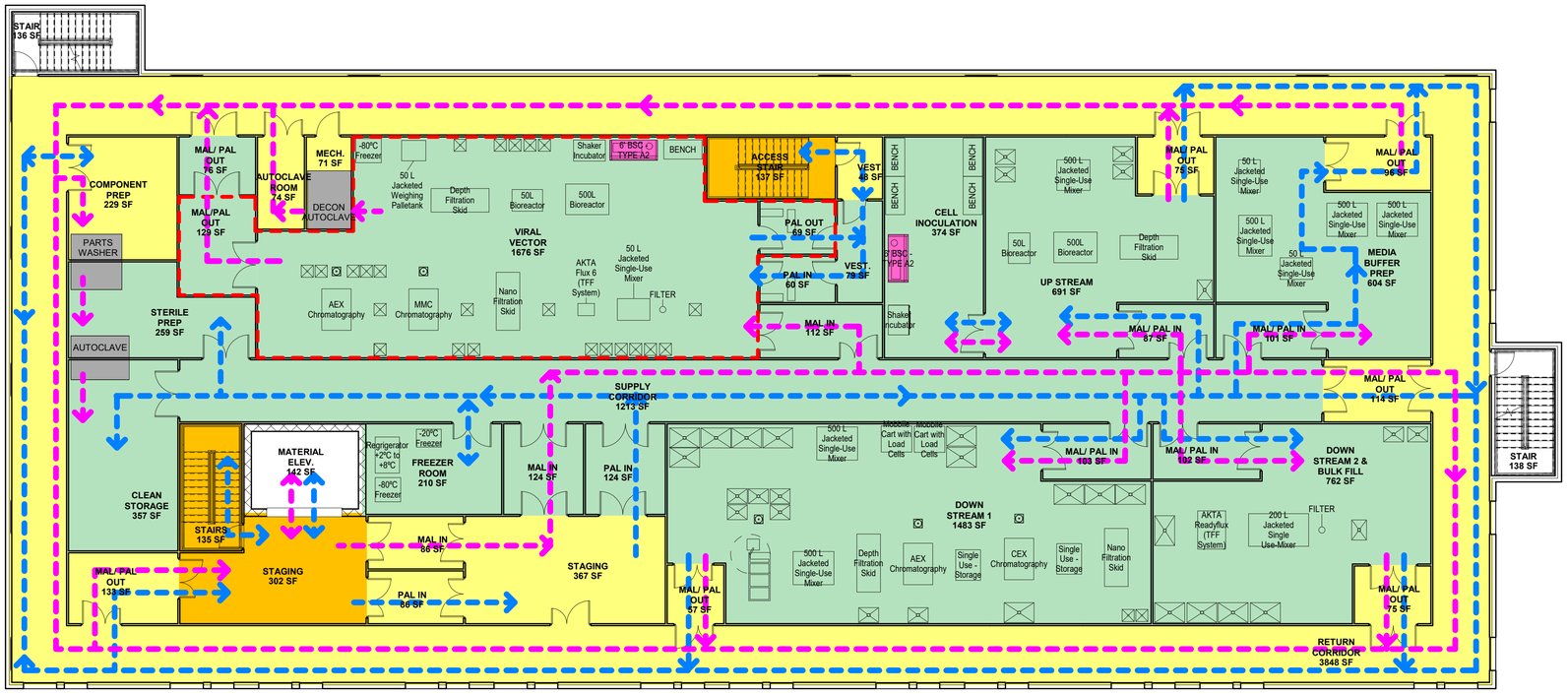
SCALE: 1" = 10'-0"

DATE: 21-APR-2021 REV: A

DRAWN BY: AAS CHECKED BY: DBL

CLIENT

National Research Council Canada Conseil national de recherches Canada



A FLOW PLAN - SECOND FLOOR - OPTION 3

ASK-009 1" = 10'-0"

PROJECT

Clinical Trial Manufacturing Facility (CTMF)

LOCATION

6100 Royalmount Ave, Montreal, Quebec, H4P 2R2 Canada

LEGEND

AREA CLASSIFICATIONS

REST OF WORLD	US FDA
UNCLASSIFIED	UNCLASSIFIED
CONTROLLED/ NON-CLASS	CONTROLLED/ NON-CLASS
GRADE D	-
GRADE C	ISO 8
GRADE A AIR SUPPLY	LOCAL PROTECTION
GRADE B	ISO 7
GRADE A	ISO 5

PLAN LEGEND

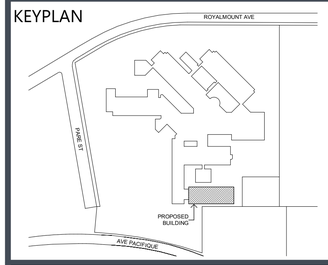
VIRAL BOUNDARY

FLOW DIAGRAMS LEGEND

MATERIAL FLOW

PERSONNEL FLOW

KEYPLAN



NEW CTMF CONCEPT STUDY

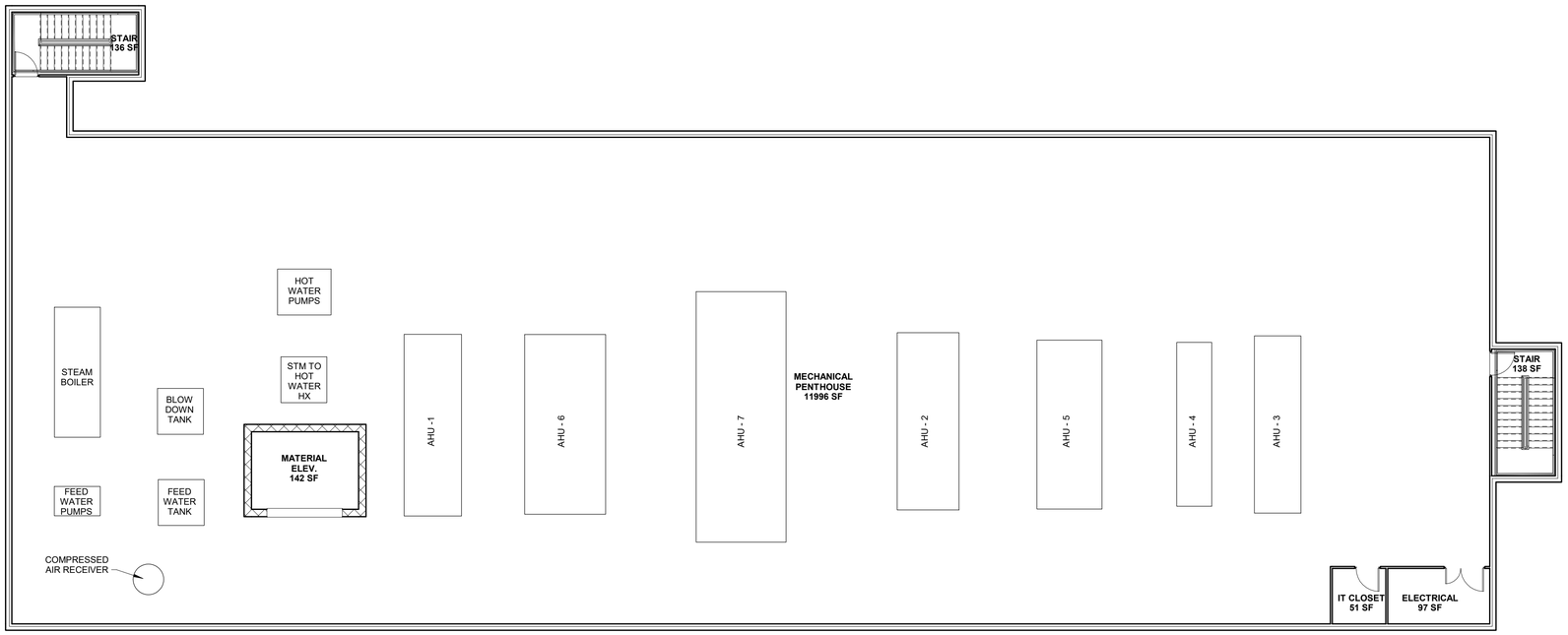
DRAWING TITLE

FLOW PLAN - SECOND FLOOR - OPTION 3

PROJ #:	CND21090.01
DWG #:	ASK-009
SCALE:	1" = 10'-0"
DATE: 21-APR-2021	REV: A
DRAWN BY: AAS	CHECKED BY: DBL

CLIENT

National Research Council Canada | Conseil national de recherches Canada



A MECHANICAL PENTHOUSE - OPTION 3

ASK-010 1" = 10'-0"

PROJECT

Clinical Trial Manufacturing Facility (CTMF)

LOCATION

6100 Royalmount Ave, Montreal, Quebec, H4P 2R2 Canada

LEGEND

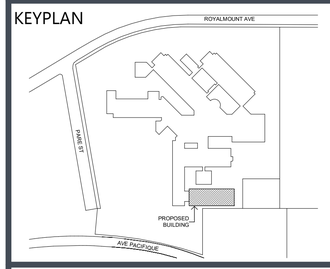
AREA CLASSIFICATIONS

REST OF WORLD	US FDA
UNCLASSIFIED	UNCLASSIFIED
CONTROLLED/ NON-CLASS	CONTROLLED/ NON-CLASS
GRADE D	-
GRADE C	ISO 8
GRADE A AIR SUPPLY	LOCAL PROTECTION
GRADE B	ISO 7
GRADE A	ISO 5

PLAN LEGEND

VIRAL BOUNDARY

KEYPLAN



NEW CTMF CONCEPT STUDY

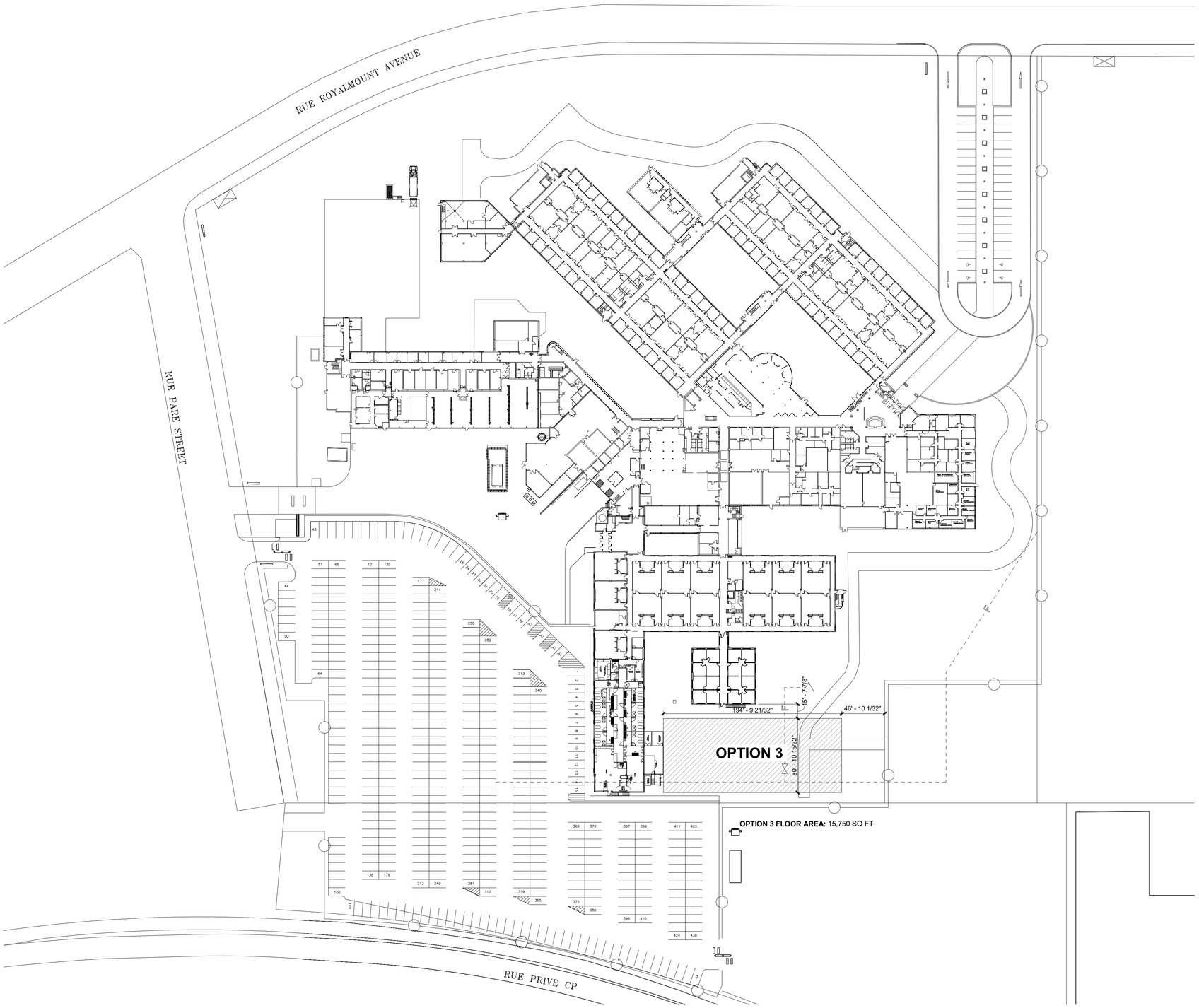
DRAWING TITLE

MECHANICAL PENTHOUSE PLAN - OPTION 3

PROJ #:	CND21090.01
DWG #:	ASK-010
SCALE:	1" = 10'-0"
DATE: 21-APR-2021	REV: A
DRAWN BY: AAS	CHECKED BY: DBL

CLIENT

National Research Council Canada / Conseil national de recherches Canada



A SITE PLAN - OPTION 3
ASK-011 1" = 60'-0"

PROJECT
Clinical Trial Manufacturing Facility (CTMF)

LOCATION
6100 Royalmount Ave, Montreal, Quebec, H4P 2R2 Canada

LEGEND
AREA CLASSIFICATIONS

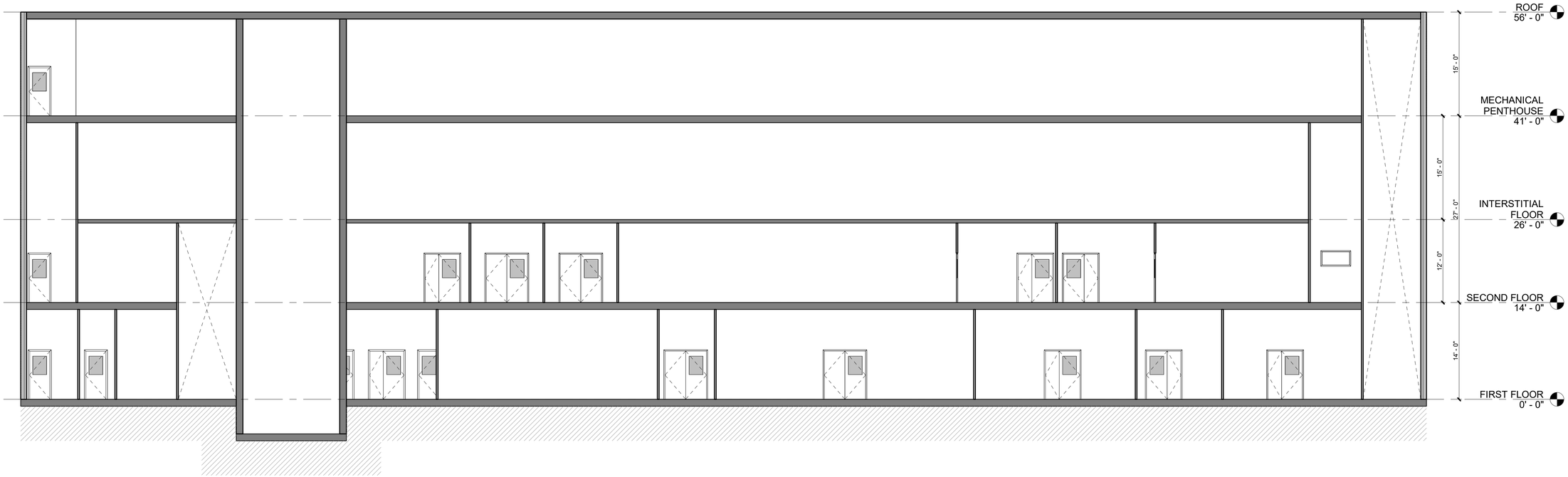
REST OF WORLD	US FDA
UNCLASSIFIED	UNCLASSIFIED
CONTROLLED/ NON-CLASS	CONTROLLED/ NON-CLASS
GRADE D	-
GRADE C	ISO 8
GRADE A AIR SUPPLY	LOCAL PROTECTION
GRADE B	ISO 7
GRADE A	ISO 5

NEW CTMF CONCEPT STUDY

DRAWING TITLE
SITE PLAN - OPTION 3

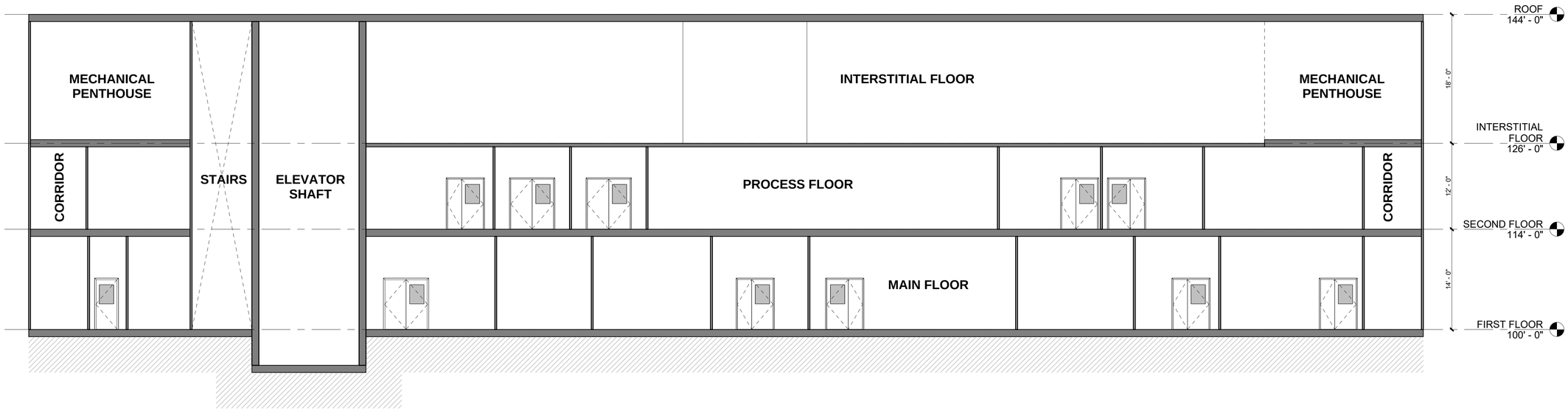
PROJ #: CND21090.01
DWG #: ASK-011
SCALE: 1" = 60'-0"
DATE: 21-APR-2021 REV: A
DRAWN BY: AAS CHECKED BY: DBL

CLIENT
National Research Council Canada
Conseil national de recherches Canada



1 BUILDING SECTION 1 - OPTION 1

ASK-012 1/8" = 1'-0"



2 BUILDING SECTION 1 - OPTION 2

ASK-012 1/8" = 1'-0"

PROJECT
Clinical Trial Manufacturing Facility (CTMF)

LOCATION
6100 Royalmount Ave, Montreal, Quebec, H4P 2R2 Canada

LEGEND
AREA CLASSIFICATIONS

REST OF WORLD	US FDA
UNCLASSIFIED	UNCLASSIFIED
CONTROLLED/ NON-CLASS	CONTROLLED/ NON-CLASS
GRADE D	-
GRADE C	ISO 8
GRADE A AIR SUPPLY	LOCAL PROTECTION
GRADE B	ISO 7
GRADE A	ISO 5

NEW CTMF CONCEPT STUDY

DRAWING TITLE
SCHEMATIC SECTIONS

PROJ #: CND21090.01

DWG #: ASK-012

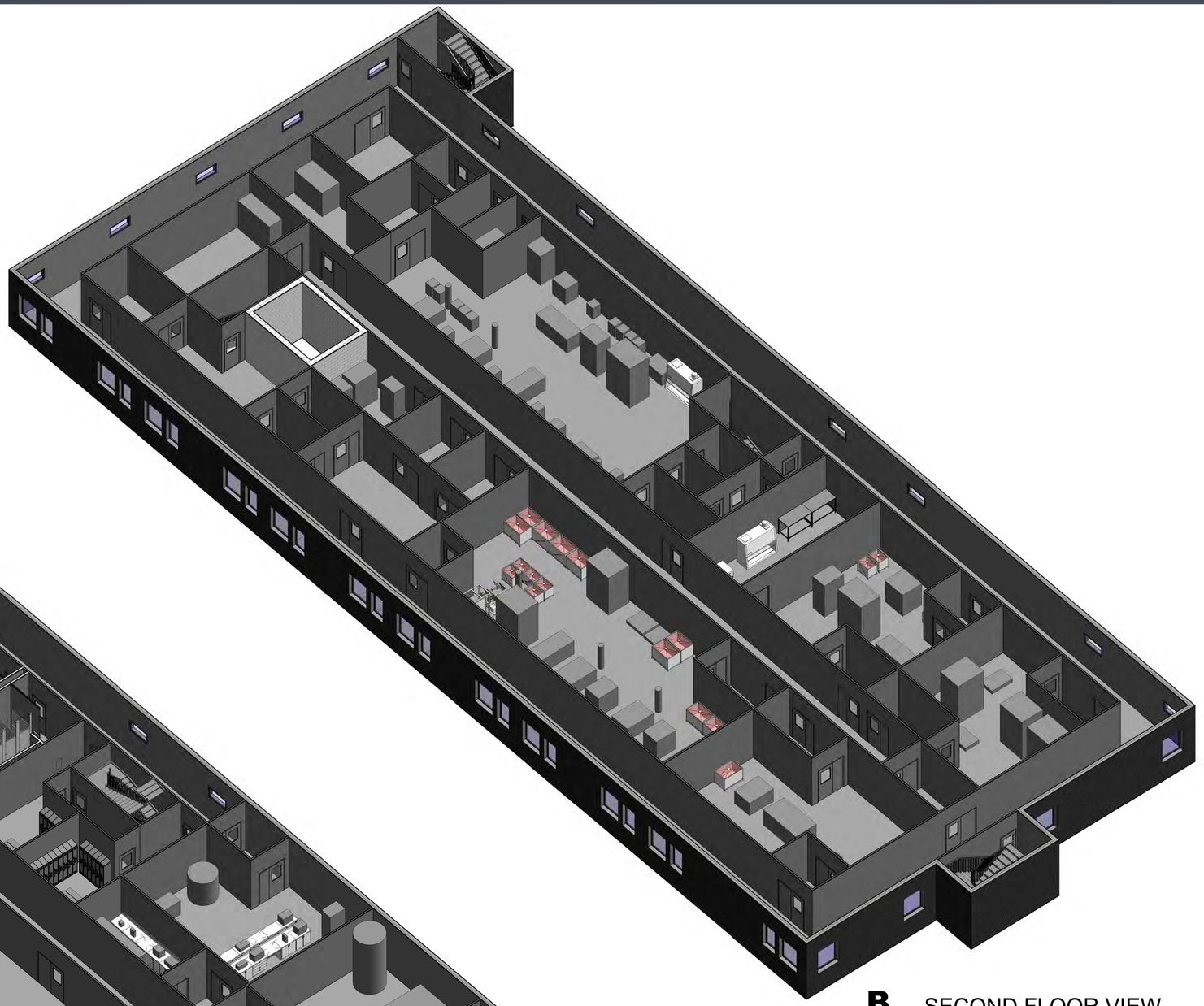
SCALE: 1/8" = 1'-0"

DATE: 21-APR-2021 REV: A

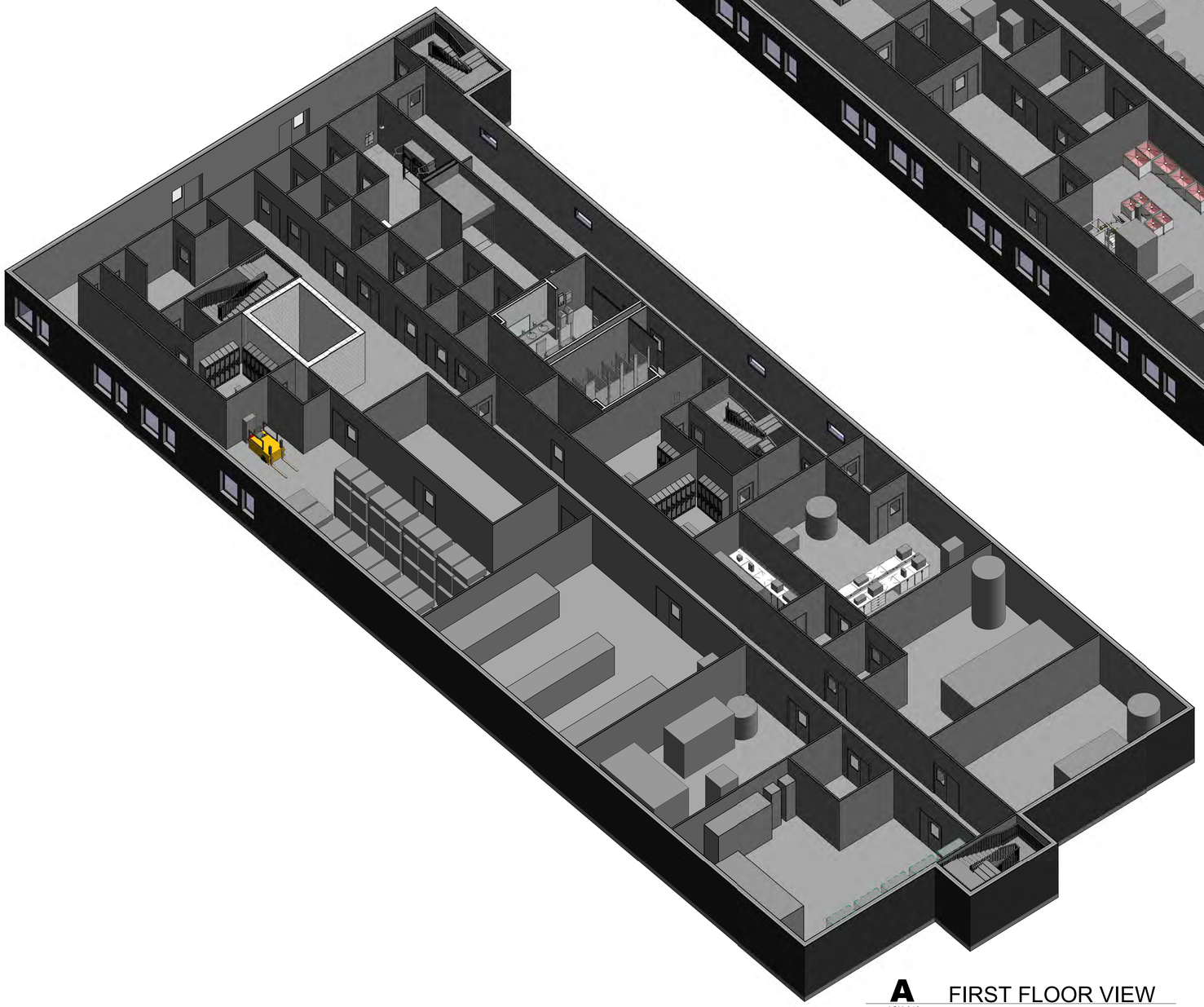
DRAWN BY: AG CHECKED BY: DBL

CLIENT

National Research Council Canada Conseil national de recherches Canada



B SECOND FLOOR VIEW
ASK-013



A FIRST FLOOR VIEW
ASK-013

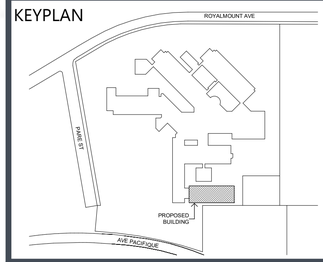
PROJECT
Clinical Trial Manufacturing Facility (CTMF)

LOCATION
6100 Royalmount Ave, Montreal, Quebec, H4P 2R2 Canada

LEGEND
AREA CLASSIFICATIONS

REST OF WORLD	US FDA
UNCLASSIFIED	UNCLASSIFIED
CONTROLLED/ NON-CLASS	CONTROLLED/ NON-CLASS
GRADE D	-
GRADE C	ISO 8
GRADE A AIR SUPPLY	LOCAL PROTECTION
GRADE B	ISO 7
GRADE A	ISO 5

KEYPLAN



NEW CTMF CONCEPT STUDY

DRAWING TITLE
AXONOMETRIC VIEWS - FIRST AND SECOND FLOOR

PROJ #: CND21090.01

DWG #: ASK-013

SCALE:

DATE: 21-APR-2021 | REV: A

DRAWN BY: AG | CHECKED BY: DBL

CLIENT

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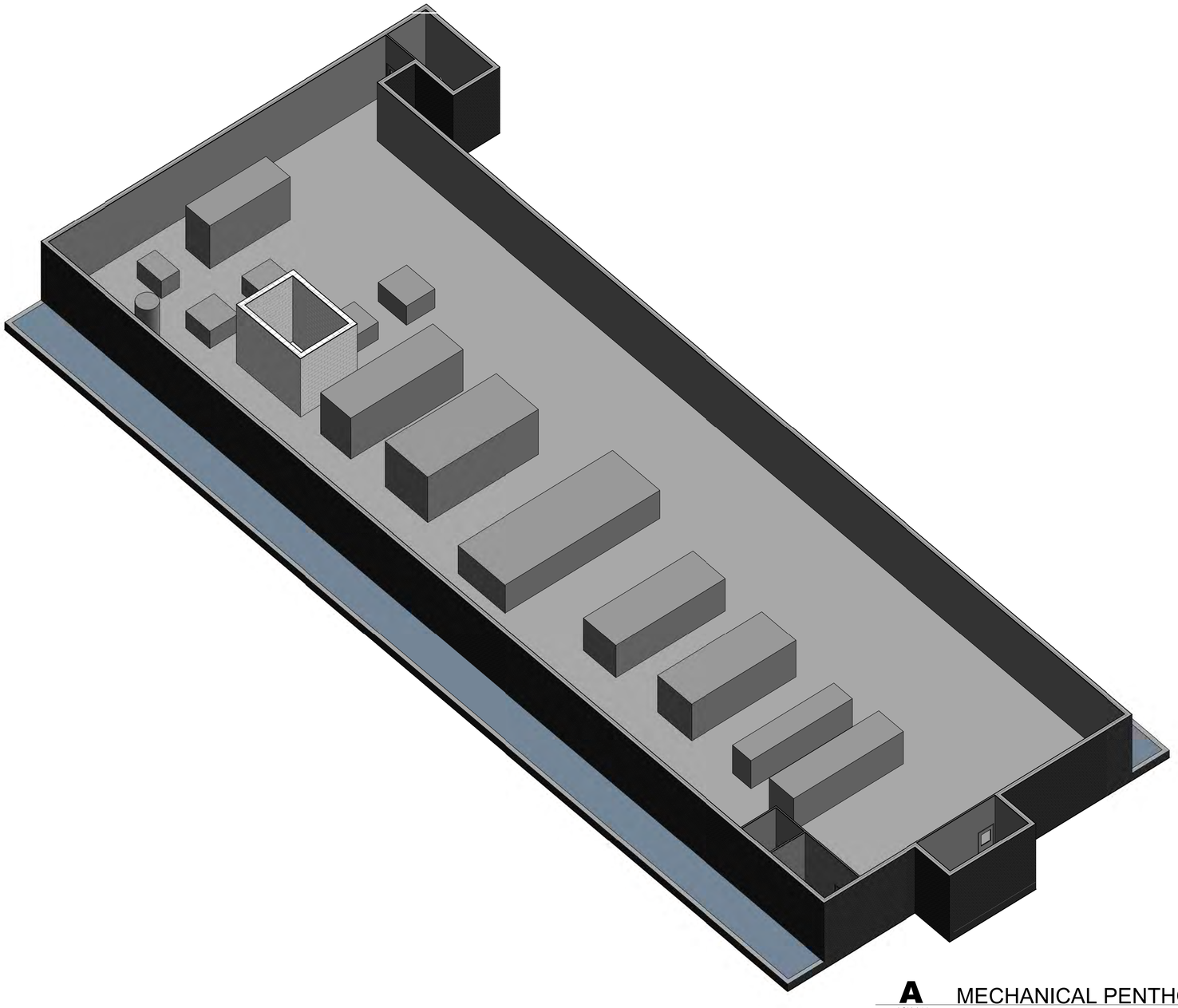


A ASK-014 MECHANICAL PENTHOUSE VIEW

PROJECT
Clinical Trial Manufacturing Facility (CTMF)

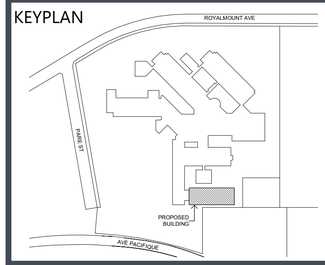
LOCATION
6100 Royalmount Ave, Montreal, Quebec, H4P 2R2 Canada

LEGEND

AREA CLASSIFICATIONS

REST OF WORLD	US FDA
UNCLASSIFIED	UNCLASSIFIED
CONTROLLED/ NON-CLASS	CONTROLLED/ NON-CLASS
GRADE D	-
GRADE C	ISO 8
GRADE A AIR SUPPLY	LOCAL PROTECTION
GRADE B	ISO 7
GRADE A	ISO 5

KEYPLAN



NEW CTMF CONCEPT STUDY

DRAWING TITLE
AXONOMETRIC VIEW - MECHANICAL PENTHOUSE

PROJ #: CND21090.01

DWG #: ASK-014

SCALE:

DATE: 21-APR-2021 | REV: A

DRAWN BY: AG | CHECKED BY: DBL

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National Research Council Canada | Conseil national de recherches Canada

NRC
CND21090

7-APR-2021
REVIEW

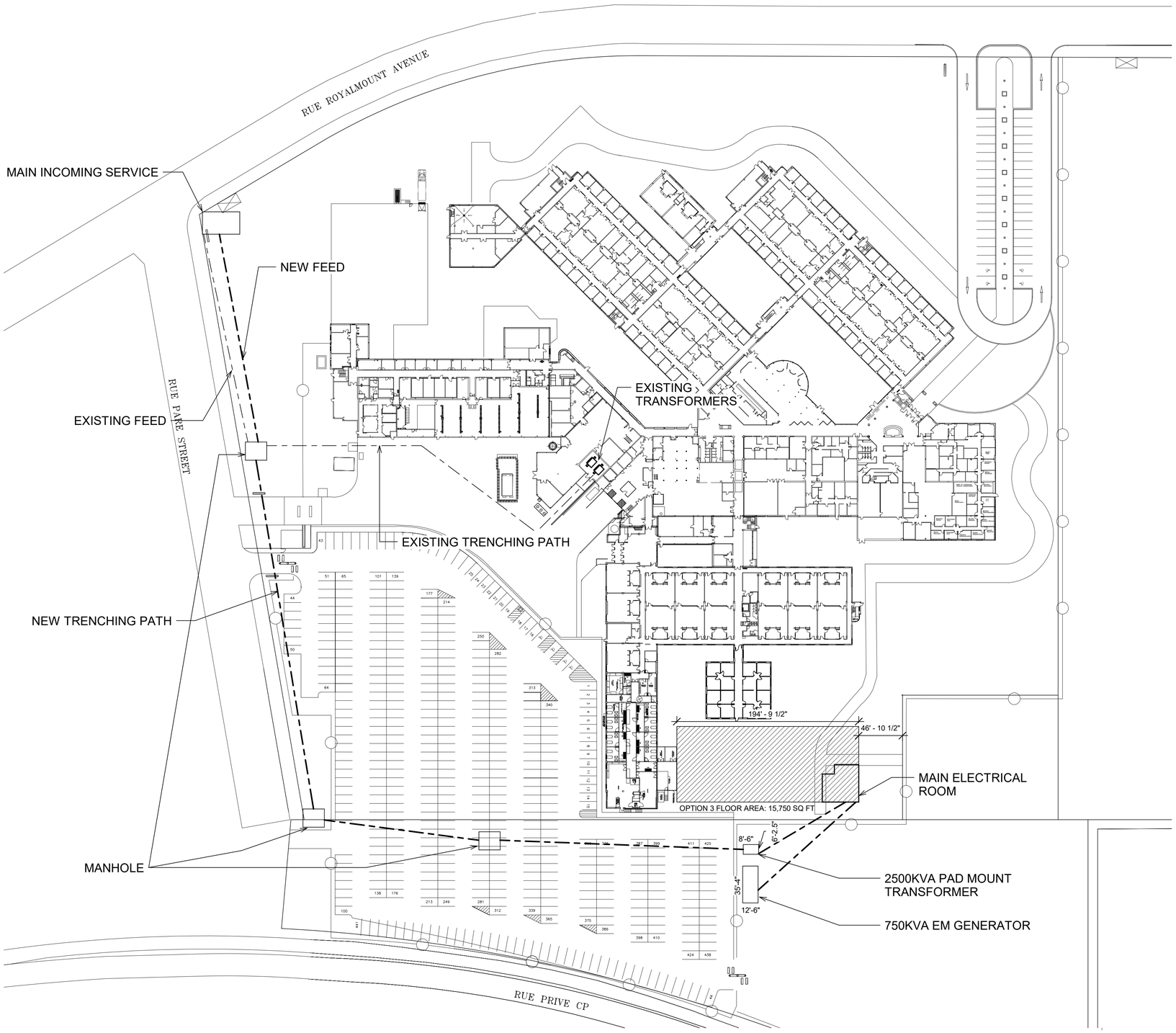
Electrical Load Estimate

Location	Area sq Feet	Estimated Loads																				Sub totals	Sub totals	Sub totals
		Ltg	Ltg	Rec	Rec	HVAC Chillers	HVAC Chillers	HVAC Pumps	HVAC Pumps	Process Pumps	Process Pumps	Fans	Fans	AHU	AHU	Steam Boiler	Steam Boiler	Process Equip	Process Equip	Misc	Misc	Total Area	Connected	Demand
		W/ ft2	KVA	W/ ft2	KVA	W/ ft2	KVA	W/ ft2	KVA	W/ ft2	KVA	W/ ft2	KVA	W/ ft2	KVA	W/ft2	KVA	W/ ft2	KVA	W/ ft2	KVA	W/ ft2	KVA	KVA
Process Rooms	7,172	2.2	17.2	1.5	11.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	20.5	160.0	1.5	253.0	42.3	441.9	330.0
Clean Corridors	5,380	1.6	9.4	0.5	2.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.9	12.3	11.4
Clean Storage	2,680	1.6	4.7	0.5	1.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	2.0	6.2	5.8
Air Locks	1,886	1.1	2.3	0.5	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.5	3.3	3.1
Corridors	2,336	1.0	2.5	1.0	2.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.7	5.0	4.2
Mechanical Room	1,339	0.7	1.0	0.5	0.7	0.0	0.0	47.4	69.0	41.9	61.0	0.0	0.0	0.0	0.0	4.3	6.3	0.0	0.0	1.0	100.0	119.9	238.0	174.5
Electrical Room	1,722	1.0	1.9	0.5	0.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.4	2.8	2.6
Locker Rooms	1,915	1.2	2.5	1.0	2.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.9	4.6	4.0
Warehouse	2,249	1.3	3.2	1.0	2.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	2.0	5.6	4.9
Other	1,939	1.0	2.1	0.5	1.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	100.0	34.6	103.2	72.9
Penthouse	11,424	0.7	8.7	0.5	6.2	0.0	0.0	0.0	0.0	0.0	0.0	16.5	205.0	26.3	326.0	0.0	0.0	0.0	0.0	1.0	100.0	40.9	645.9	507.6
Total (Connected)	28,618	1.5	46.8	0.9	26.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	123.8	6.3	5.1	160.0	8.1	253.0	**47.2**	**1,468.8**	
Demand Factor			100%		65%		80%		80%		70%		80%		80%		80%		80%		70%			
Total (Demand)	28,618	1.5	46.8	0.6	17.4	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	#DIV/0!	5.0	4.1	128.0	5.7	177.1	**36.0**		**1,121.0**

Note
1. Misc = equipment, elevators etc
2. Redunant equipment (Chillers, Fans, and Pumps) are not been included in totals.
3. Power Factor = 0.92
4. Chillers and HVAC loads are according to HVAC Equipment List
5. Process loads are based on Process equipment list

Total Diversity: **76%**

Peak Demand Load Summary	
Calculated Connected Load (kVA)	**1,468.8**
Calculated Demand Load (kVA)	**1,121.0**
Diversity	**76%**
Safety Factor	**25%**
Total Projected Demand (kVA)	**1,401.3**
Transformer Size Each(kVA)	**2,500**



A SITE POWER PLAN - OPTION 1

E1.02 SCALE: 1" = 60'-0"

PROJECT

Clinical Trial Manufacturing Facility (CTMF)

LOCATION

6100 Royalmount Ave, Montreal, Quebec, H4P 2R2 Canada

LEGEND

AREA CLASSIFICATIONS

REST OF WORLD	US FDA
UNCLASSIFIED	UNCLASSIFIED
CONTROLLED/ NON-CLASS	CONTROLLED/ NON-CLASS
GRADE D	-
GRADE C	ISO 8
GRADE A AIR SUPPLY	LOCAL PROTECTION
GRADE B	ISO 7
GRADE A	ISO 5

PLAN LEGEND

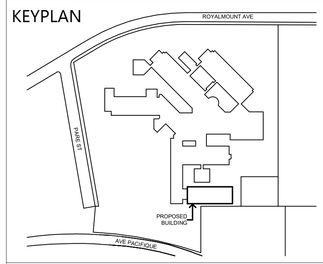
VIRAL BOUNDARY

FLOW DIAGRAMS LEGEND

MATERIAL FLOW

PERSONNEL FLOW

KEYPLAN



NEW CTMF CONCEPT STUDY

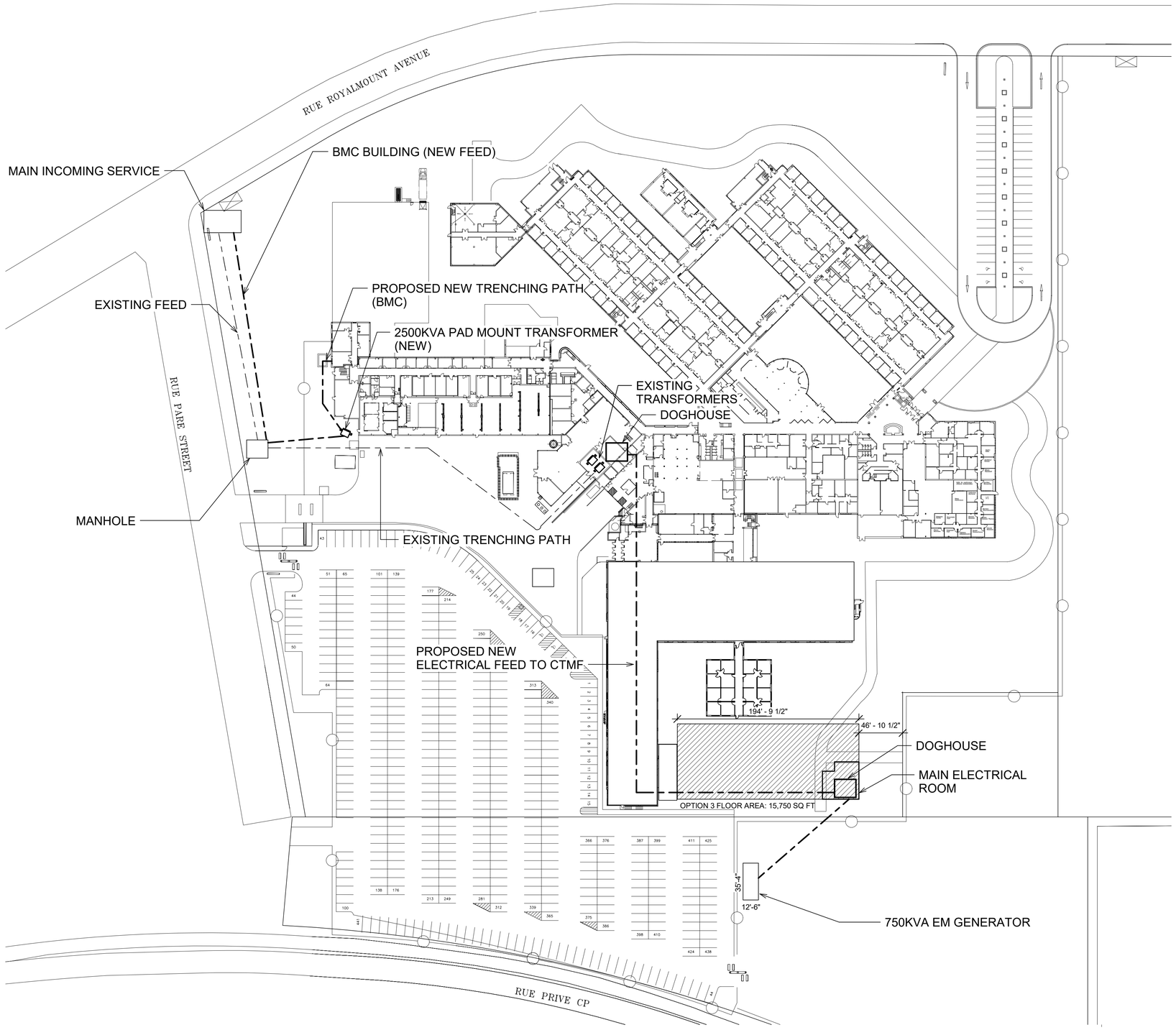
DRAWING TITLE

SITE POWER PLAN - OPTION 1

PROJ #:	CND21090.01
DWG #:	E1.02
SCALE:	1" = 60'-0"
DATE: 21/04/2021	REV: A
DRAWN BY: NK	CHECKED BY: UG

CLIENT

National Research Council Canada / Conseil national de recherches Canada



A SITE POWER PLAN - OPTION 2
E1.03 SCALE: 1" = 60'-0"

PROJECT
Clinical Trial Manufacturing Facility (CTMF)

LOCATION
6100 Royalmount Ave, Montreal, Quebec, H4P 2R2 Canada

LEGEND

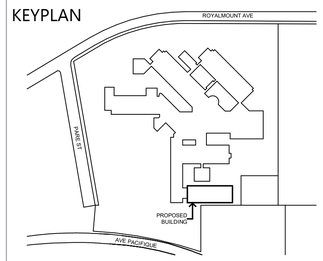
AREA CLASSIFICATIONS

REST OF WORLD	US FDA
UNCLASSIFIED	UNCLASSIFIED
CONTROLLED/ NON-CLASS	CONTROLLED/ NON-CLASS
GRADE D	-
GRADE C	ISO 8
GRADE A AIR SUPPLY	LOCAL PROTECTION
GRADE B	ISO 7
GRADE A	ISO 5

PLAN LEGEND
VIRAL BOUNDARY

FLOW DIAGRAMS LEGEND
MATERIAL FLOW
PERSONNEL FLOW

KEYPLAN

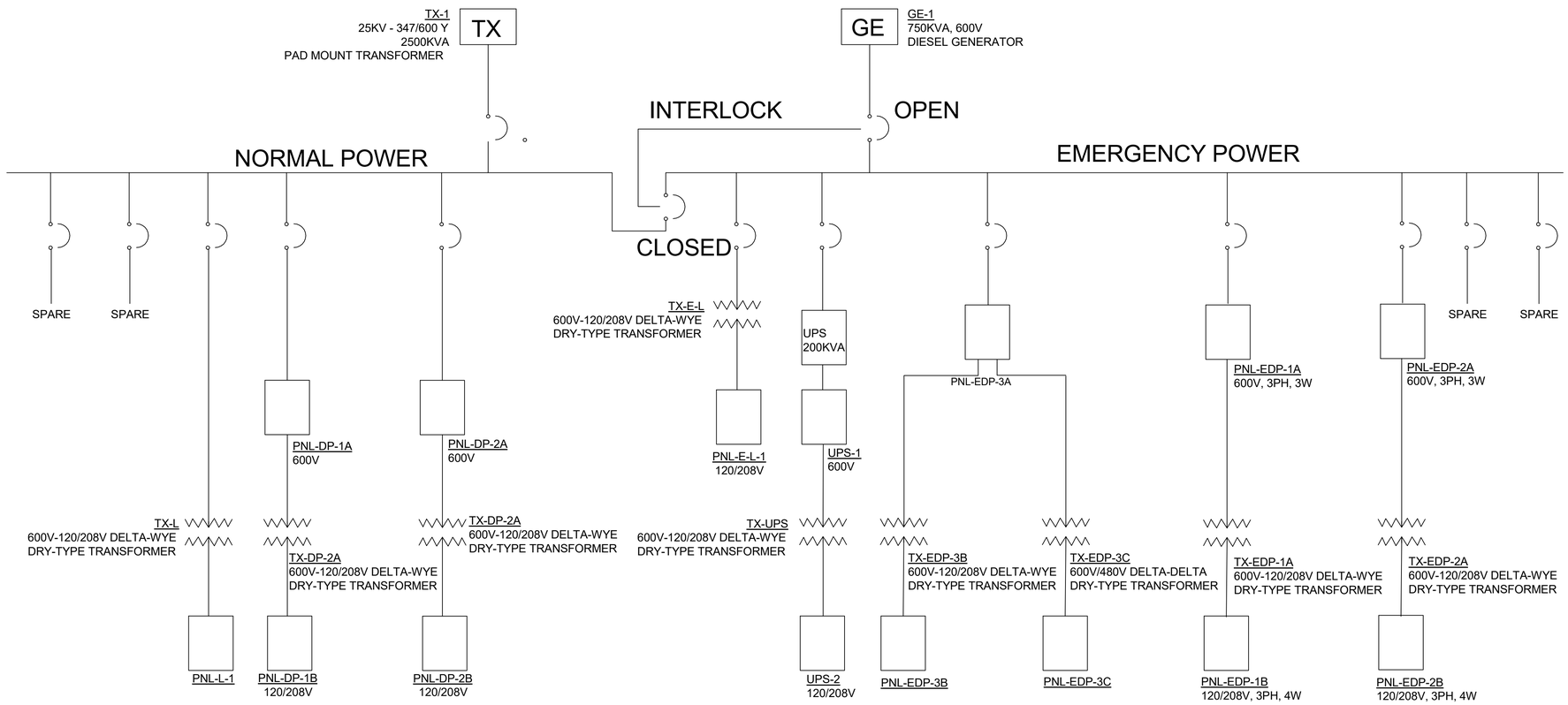


NEW CTMF CONCEPT STUDY

DRAWING TITLE
SITE POWER PLAN - OPTION 2

PROJ #:	CND21090.01
DWG #:	E1.03
SCALE:	1" = 60'-0"
DATE: 21/04/2021	REV: A
DRAWN BY: NK	CHECKED BY: UG

CLIENT
National Research Council Canada
Conseil national de recherches Canada



1 SINGLE LINE DIAGRAM

E5.01 SCALE: NONE

FEEDER SCHEDULE

FEEDER NUMBER	ALL FEEDER SIZES MAY NOT APPEAR ON THESE DWGS.		
#	NO. OF CONDUITS	SIZE OF CONDUITS	NO. AND SIZE OF CONDUCTORS IN EACH CONDUIT
3W20	1	3/4"	3#12 AWG & 1#12 GND
4W20	1	3/4"	4#12 AWG & 1#12 GND
2W30	1	3/4"	2#10 AWG & 1#10 GND
3W30	1	3/4"	3#10 AWG & 1#10 GND
4W30	1	3/4"	4#10 AWG & 1#10 GND
2W40	1	1"	2#8 AWG & 1#10 GND
3W40	1	1"	3#8 AWG & 1#10 GND
4W40	1	1"	4#8 AWG & 1#10 GND
3W50	1	1"	3#6 AWG & 1#10 GND
4W50	1	1"	4#6 AWG & 1#10 GND
3W70	1	1 1/2"	3#4 AWG & 1#8 GND
4W70	1	1 1/2"	4#4 AWG & 1#8 GND
3W90	1	1 1/2"	3#2 AWG & 1#8 GND
4W90	1	1 1/2"	4#2 AWG & 1#8 GND
3W110	1	2"	3#1 AWG & 1#6 GND
4W110	1	2"	4#1 AWG & 1#6 GND
3W150	1	2"	3#1/0 AWG & 1#6 GND
4W150	1	2"	4#1/0 AWG & 1#6 GND
3W175	1	2"	3#2/0 AWG & 1#6 GND
4W175	1	2"	4#2/0 AWG & 1#6 GND
3W200	1	2"	3#3/0 AWG & 1#6 GND
4W200	1	2"	4#3/0 AWG & 1#6 GND
3W225	1	2 1/2"	3#4/0 AWG & 1#4 GND
4W225	1	2 1/2"	4#4/0 AWG & 1#4 GND
3W250	1	3"	3#250 KCMIL & 1#4 GND
4W250	1	3"	4#250 KCMIL & 1#4 GND
3W300	1	3"	3#350 KCMIL & 1#4 GND
4W300	1	3"	4#350 KCMIL & 1#4 GND
3W350	1	4"	3#500 KCMIL & 1#2 GND
4W350	1	4"	4#500 KCMIL & 1#2 GND
3W400	1	4"	3#600 KCMIL & 1#2 GND
4W400	1	4"	4#600 KCMIL & 1#2 GND
3W450	2	2 1/2"	3#4/0 AWG & 1#2 GND
4W450	2	2 1/2"	4#4/0 AWG & 1#2 GND
3W500	2	2 1/2"	3#250 KCMIL & 1#2 GND
4W500	2	2 1/2"	4#250 KCMIL & 1#2 GND
3W600	2	3"	3#350 KCMIL & 1#1 GND
4W600	2	3"	4#350 KCMIL & 1#1 GND
3W800	2	4"	3#600 KCMIL & 1#1/0 GND
4W800	2	4"	4#600 KCMIL & 1#1/0 GND
3W1000	3	4"	3#500 KCMIL & 1#2/0 GND
4W1000	3	4"	4#500 KCMIL & 1#2/0 GND
3W1200	3	4"	3#600 KCMIL & 1#3/0 GND
4W1200	3	4"	4#600 KCMIL & 1#3/0 GND
3W1600	4	4"	3#600 KCMIL & 1#4/0 GND
4W1600	4	4"	4#600 KCMIL & 1#4/0 GND
3W2000	5	4"	3#600KCMIL & 1#250KCMIL GND
4W2000	5	4"	4#600KCMIL & 1#250KCMIL GND
3W3000	8	4"	3#600KCMIL & 1#600KCMIL GND
4W3000	8	4"	4#600KCMIL & 1#600KCMIL GND
3W4000	10	4"	3#600KCMIL & 1#750KCMIL GND
4W4000	10	4"	4#600KCMIL & 1#750KCMIL GND

TRANSFORMER FEEDER SCHEDULE

FEEDER NUMBER	ALL FEEDER SIZES MAY NOT APPEAR ON THESE DWGS.		
#	NO. OF CONDUITS	SIZE OF CONDUITS	NO. AND SIZE OF CONDUCTORS IN EACH CONDUIT
4W20T	1	3/4"	3#12 + 1#10 NEUTRAL + 1#8 GROUND
4W20T	1	3/4"	3#12 + 1#10 NEUTRAL + 1#8 GROUND
4W30T	1	3/4"	3#10 + 1#10 NEUTRAL + 1#8 GROUND
4W30TN	1	3/4"	3#10 + 1#6 NEUTRAL + 1#8 GROUND
4W50T	1	1"	3#6+ 1#6 NEUTRAL + 1#8 GROUND
4W50TN	1	1"	3#6 +1#2 NEUTRAL + 1#8 GROUND
4W100T	1	2"	3#1 + 1#1 NEUTRAL + 1#6 GROUND
4W100TN	1	2"	3#1 + 1#1/0 NEUTRAL + 1#6 GROUND
4W150T	1	2"	3#1/0 + 1#1/0 NEUTRAL + 1#6 GROUND
4W150TN	1	2"	3#1/0 + 1#4/0 NEUTRAL + 1#6 GROUND
4W250T	1	3"	3#250kCMIL + 1#250kCMIL NEUTRAL + 1#2 GROUND
4W250TN	1	3"	3#250kCMIL + 1#500kCMIL NEUTRAL + 1#2 GROUND
4W400T	1	3 1/2"	3#600kCMIL + 1#600kCMIL NEUTRAL + 1#1/0 GROUND
4W400TN	1	3 1/2"	3#600kCMIL + 2#350kCMIL NEUTRAL + 1#1/0 GROUND
4W600T	2	3"	3#350kCMIL + 1#350kCMIL NEUTRAL + 1#2/0 GROUND
4W600TN	2	3"	3#350kCMIL + 1#500kCMIL NEUTRAL + 1#2/0 GROUND
4W800T	2	3 1/2"	3#600kCMIL + 1#600KCMIL NEUTRAL + 1#3/0 GROUND
4W800TN	2	3 1/2"	3#600kCMIL + 2#350kCMIL NEUTRAL + 1#3/0 GROUND
4W1000T	3	3 1/2"	3#500kCMIL + 1#500kCMIL NEUTRAL + 1#3/0 GROUND
4W1000TN	3	3 1/2"	3#500kCMIL + 2#250kCMIL NEUTRAL + 1#3/0 GROUND
4W1600T	4	3 1/2"	3#600kCMIL + 1#600kCMIL NEUTRAL + 1#4/0 GROUND
4W1600TN	4	3 1/2"	3#600KCMIL + 2#350kCMIL NEUTRAL + 1#4/0 GROUND

PROJECT
Clinical Trial Manufacturing Facility (CTMF)

LOCATION
6100 Royalmount Ave, Montreal, Quebec, H4P 2R2 Canada

LEGEND

AREA CLASSIFICATIONS

REST OF WORLD	US FDA
UNCLASSIFIED	UNCLASSIFIED
CONTROLLED/ NON-CLASS	CONTROLLED/ NON-CLASS
GRADE D	-
GRADE C	ISO 8
GRADE A AIR SUPPLY	LOCAL PROTECTION
GRADE B	ISO 7
GRADE A	ISO 5

PLAN LEGEND

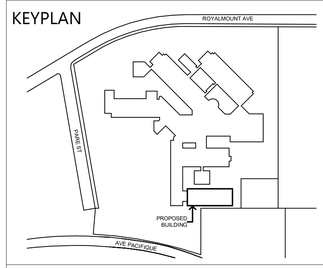
VIRAL BOUNDARY

FLOW DIAGRAMS LEGEND

MATERIAL FLOW

PERSONNEL FLOW

KEYPLAN



NEW CTMF CONCEPT STUDY

DRAWING TITLE
SINGLE LINE DIAGRAM

PROJ #: CND21090.01

DWG #: E5.01

SCALE: As indicated

DATE: 21/04/2021 REV: A

DRAWN BY: NK CHECKED BY: UG

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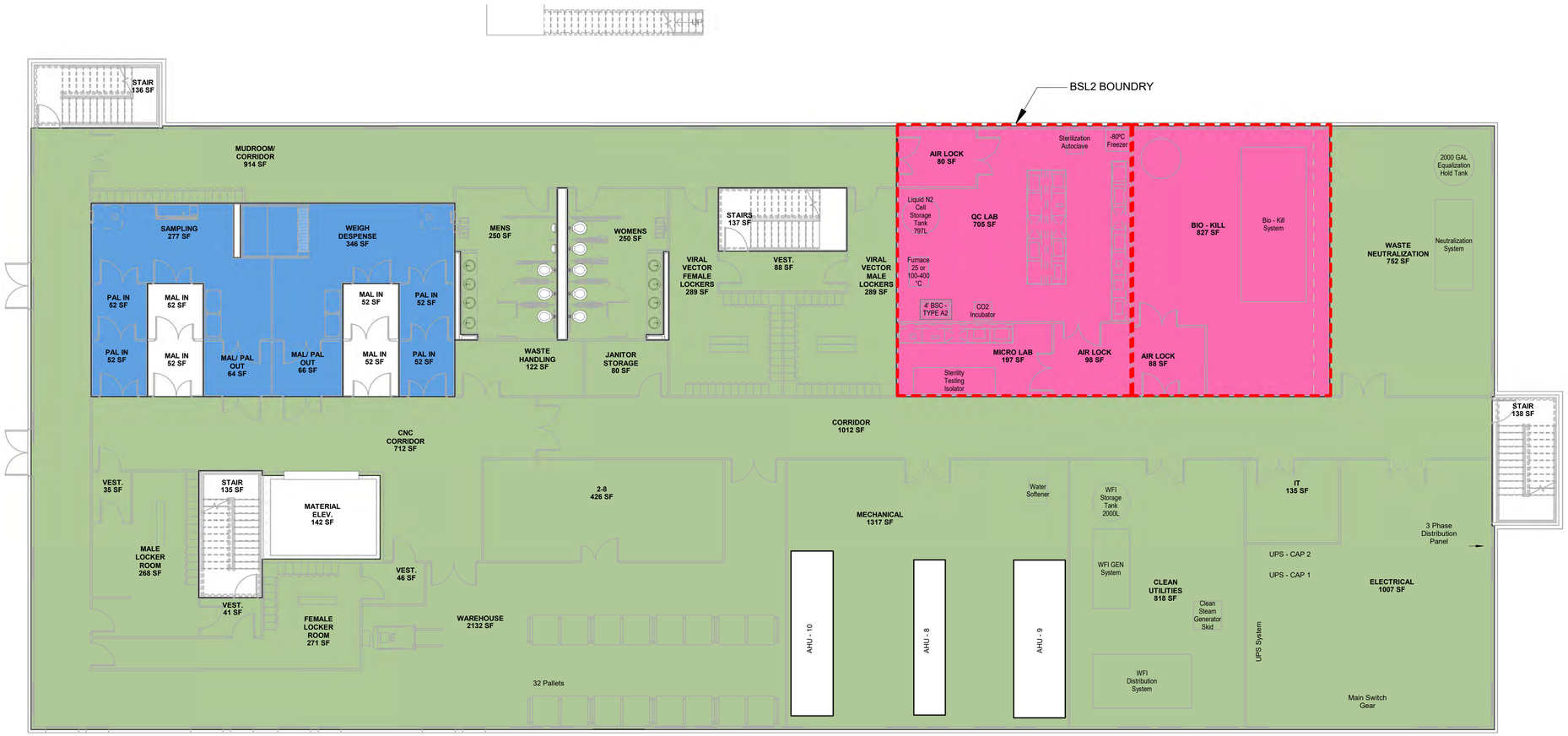


ZONING LEGEND

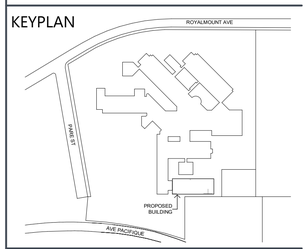
- HVAC 8
- HVAC 9
- HVAC 10

PROJECT
Clinical Trial Manufacturing Facility (CTMF)

LOCATION
6100 Royalmount Ave, Montreal, Quebec, H4P 2R2 Canada

LEGEND

KEYPLAN



NEW CTMF CONCEPT STUDY

DRAWING TITLE
HVAC ZONING PLAN - FIRST FLOOR

PROJ #:	ITD21090.01
DWG #:	M5.01
SCALE:	1/8" = 1'-0"
DATE: 21-APR-2021	REV: A
DRAWN BY: DF	CHECKED BY: MB

CLIENT

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ZONING LEGEND

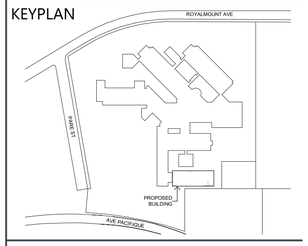
- HVAC 1
- HVAC 2
- HVAC 3
- HVAC 4
- HVAC 5
- HVAC 6
- HVAC 7

PROJECT
Clinical Trial Manufacturing Facility (CTMF)

LOCATION
6100 Royalmount Ave, Montreal, Quebec, H4P 2R2 Canada

LEGEND

KEYPLAN



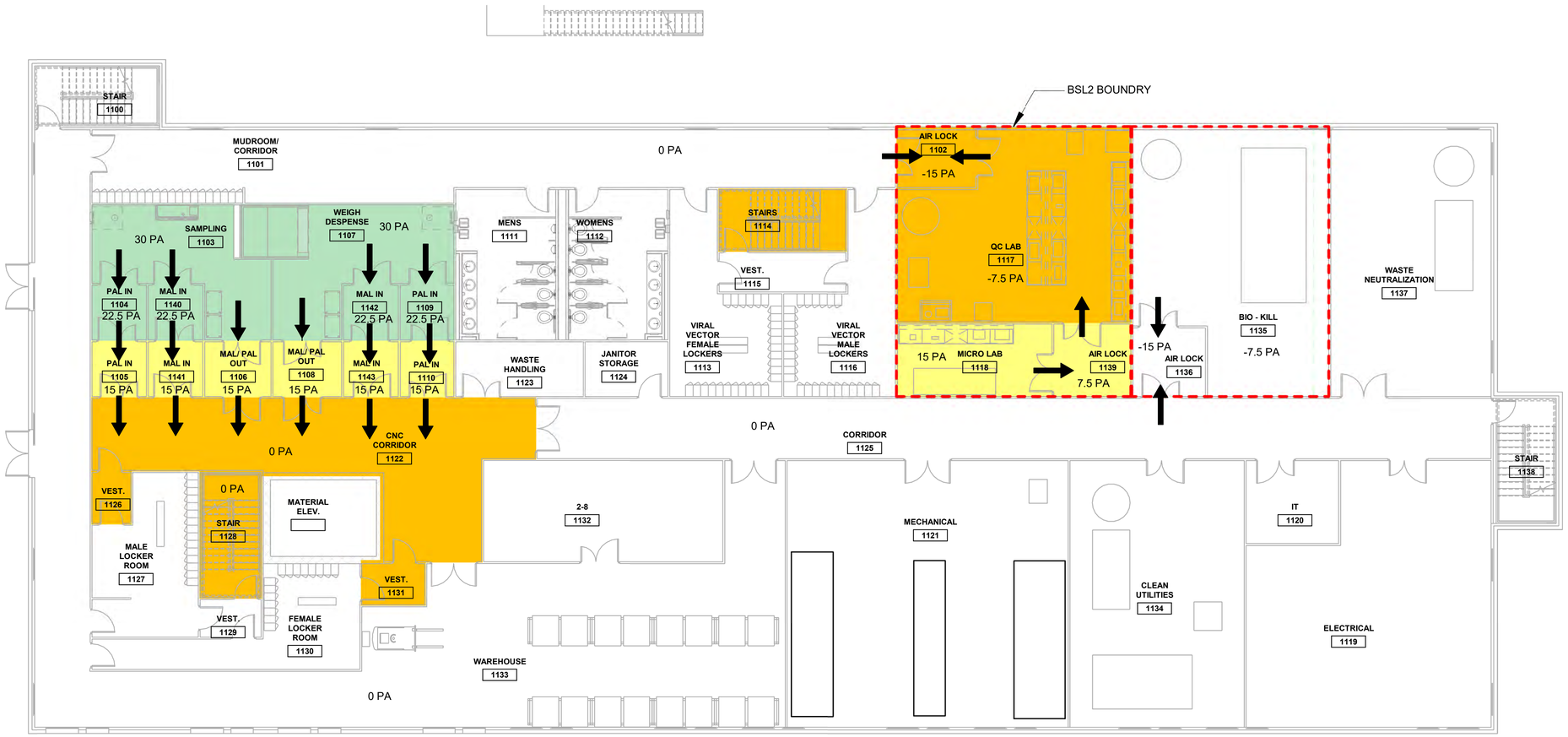
NEW CTMF CONCEPT STUDY

DRAWING TITLE
HVAC ZONING PLAN - SECOND FLOOR

PROJ #:	ITD21090.01
DWG #:	M5.02
SCALE:	1/8" = 1'-0"
DATE: 21-APR-2021	REV: A
DRAWN BY: DF	CHECKED BY: MB

CLIENT

National Research Council Canada
Conseil national de recherches Canada



PROJECT
Clinical Trial Manufacturing Facility (CTMF)

LOCATION
6100 Royalmount Ave, Montreal, Quebec, H4P 2R2 Canada

LEGEND
AREA CLASSIFICATIONS

REST OF WORLD	US FDA
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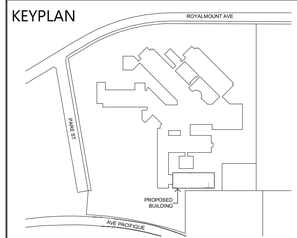
GRADE D	-
GRADE C	ISO 8
GRADE A AIR SUPPLY	LOCAL PROTECTION
GRADE B	ISO 7
GRADE A	ISO 5

KEYPLAN



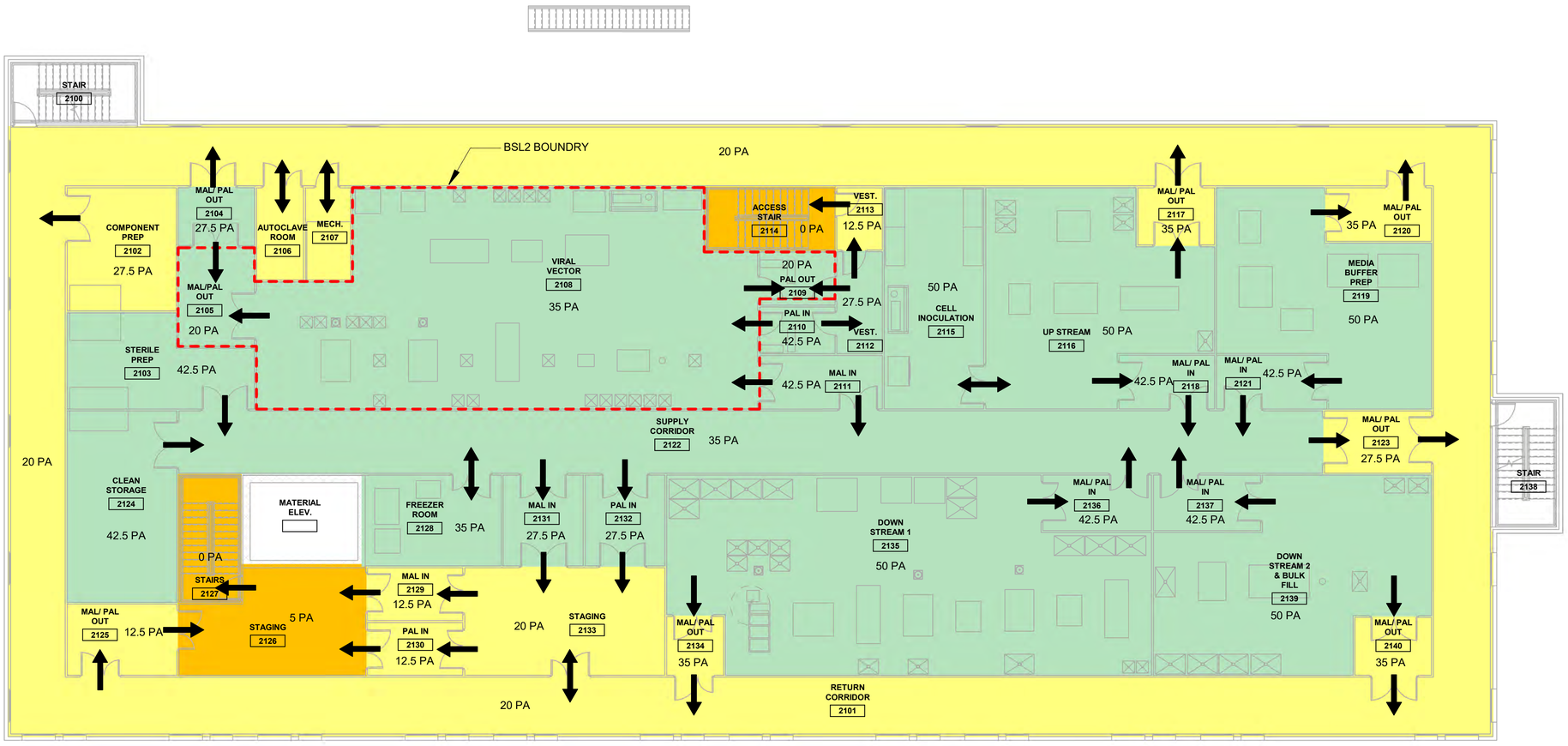
NEW CTMF CONCEPT STUDY

DRAWING TITLE
PRESSURIZATION PLAN - FIRST FLOOR

PROJ #:	ITD21090.01
DWG #:	M5.10
SCALE:	1/8" = 1'-0"
DATE: 21-APR-2021	REV: A
DRAWN BY: DF	CHECKED BY: MB

CLIENT

National Research Council Canada
Conseil national de recherches Canada



PROJECT
Clinical Trial Manufacturing Facility (CTMF)

LOCATION
6100 Royalmount Ave, Montreal, Quebec, H4P 2R2 Canada

LEGEND
AREA CLASSIFICATIONS

REST OF WORLD	US FDA
UNCLASSIFIED	UNCLASSIFIED
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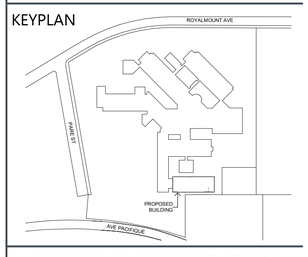
KEYPLAN



NEW CTMF CONCEPT STUDY

DRAWING TITLE
PRESSURIZATION PLAN - SECOND FLOOR

PROJ #:	ITD21090.01
DWG #:	M5.11
SCALE:	1/8" = 1'-0"
DATE: 21-APR-2021	REV: A
DRAWN BY: DF	CHECKED BY: MB

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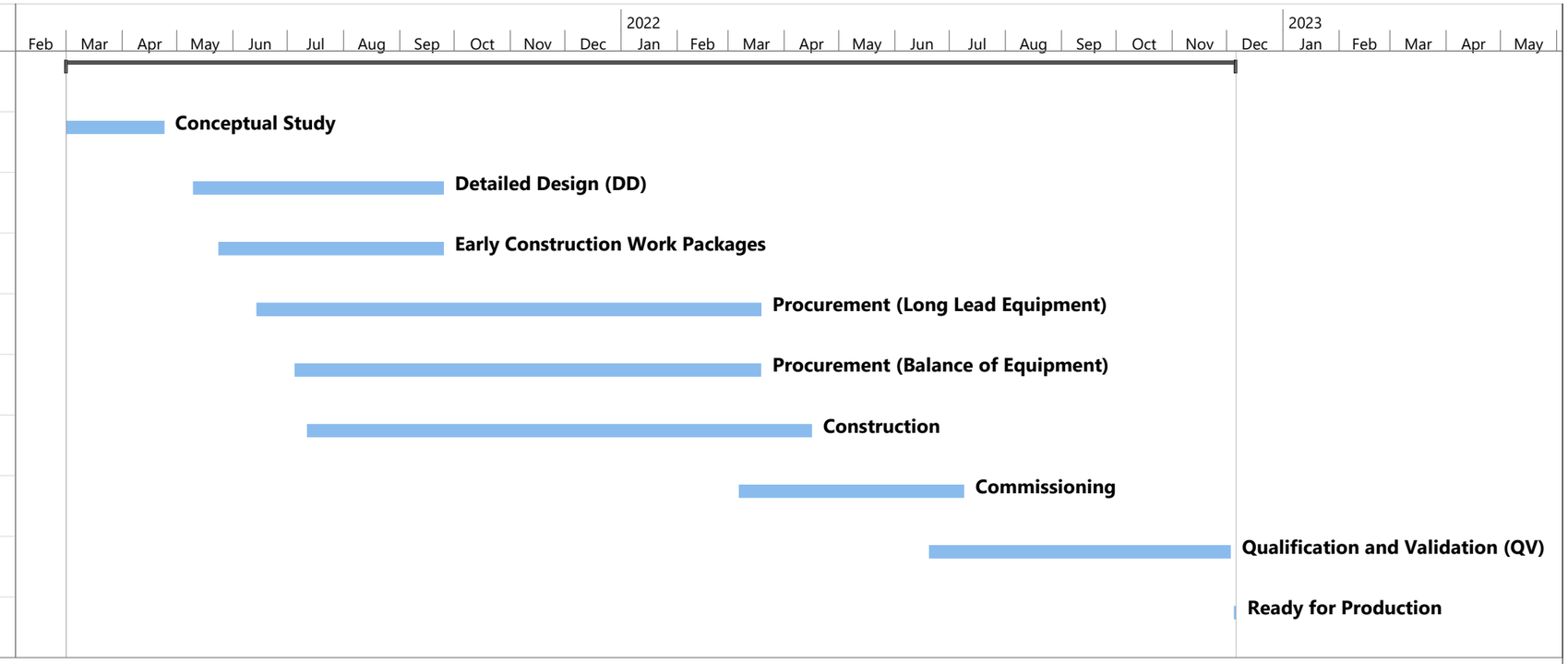
ID	Task Name	Duration	Start Month	Finish Month
1	**NRC CTMF Project Schedule**	**461 days**	**Mar 2021**	**Dec 2022**
2	Conceptual Study	40 days	Mar 2021	Apr 2021
3	Detailed Design (DD)	100 days	May 2021	Sept 2021
4	Early Construction Work Packages	90 days	May 2021	Sept 2021
5	Procurement (Long Lead Equipment)	200 days	June 2021	Mar 2022
6	Procurement (Balance of Equipment)	185 days	July 2021	Mar 2022
7	Construction	200 days	July 2021	Apr 2022
8	Commissioning	90 days	Mar 2022	July 2022
9	Qualification and Validation (QV)	120 days	June 2022	Dec 2022
10	Ready for Production	1 day	Dec 2022	Dec 2022



Assumptions:

1) DD shall begin right after Concept Study.
2) Permit will be applied for. However, construction shall proceed without a permit.