Advance Contract Award Notice (ACAN)

23-58188
AKTApure 150M system and AxiChrom columns 50-100 mm ID

1. Advance Contract Award Notice (ACAN)

An ACAN is a public notice indicating to the supplier community that a department or agency intends to award a contract for goods, services or construction to a pre-identified supplier, thereby allowing other suppliers to signal their interest in bidding, by submitting a statement of capabilities. If no supplier submits a statement of capabilities that meets the requirements set out in the ACAN, on or before the closing date stated in the ACAN, the contracting officer may then proceed with the award to the pre-identified supplier.

2. Definition of the requirement

The National Research Council (NRC) Human Health Therapeutics (HHT) has a requirement for the supply of three (3) AKTApure 150M system and four (4) new Chromatography columns: two (2) with 50mm and two (2) with 100mm internal dimeter.

AKTApure 150M system

The system was chosen for reason of interoperability with existing systems and software. NRC needs three additional units to increase its downstream purification capacity and to meet the increasing demand of Canadian biopharmaceutical industry for development of purification process of recombinant proteins, viruses, virus like particles expressed in various production platforms like Microbial expression systems, mammalian cell expression systems, insect cell expression system etc. These AKTA systems will integrate seamlessly into our production-like environment, thus allowing for repeatability of processes and commonality of the Operating System (O/S), parts and hardware configurations.

Chromatography columns:

The columns need to integrate with existing equipment. The hardware platforms use the same proprietary technology thus allowing for seamless integration and interchangeability of parts. HHT develops the purification process/technology and transfer them to Contract Manufacturing Organization (CMOs) for GMP productions. Biologics Manufacturing Center (BMC) and Clinical Trial Manufacturing Facility (CTMF) will act as future CMOs and they also have the capabilities to work with these columns which is essential for a seamless transfer.

The Chromatography system that NRC desire to acquire must have following specifications:

3. Criteria for assessment of the Statement of Capabilities (Minimum Essential Requirements)

Any interested supplier must demonstrate by way of a statement of capabilities that its its Chromatography system and/or Chromatography columns meets the following requirements:

Minimum essential Requirement for chromatography system;

3.1 Be of modular design and must ensures that functionality can be added or removed as per the user requirement changes.

3.2 Must have two metering type piston pumps for buffers (equilibration, wash, elution, strip, sanitization, column packing buffer etc.) with following flow rate capacity,

3.2.1 System pump: 0.01 to 150 ml/min (300 ml/min in column packing mode)

3.3 Must have one metering type piston pump for samples (Clarified cell culture fluid, cell lysate, periplasmic extract etc.) loading with following flow rate capacity,

3.3.1 Sample pump: 0.01 to 150 ml/min

3.4 Must have following pressure range.

3.4.1 System: 0 to 5 MPa

3.5 Must have two buffer valves and one sample valve with 3 to 7 inlets each and built-in air sensors to avoid air being pumped onto the column.

3.6 Must have a column valve with 3 to 5 column ports and integrated pre and post column pressure sensors to be able to monitor column pressures and able to calculate differential pressure across the column (delta P).

3.7 Must have multi-wavelength UV detector (190 to 700 nanometer), monitor three simultaneous wavelength and must use the Xenon flash lamp (does not generate heat).

3.8 Must have pH valve with integrated pH electrode with a reading range of 1-14.

3.9 Must have conductivity monitor with integrated temperature sensor to correct the variation in conductivity due to temperature variations with reading range of 0.01-999 mS/cm.

3.10 Must have fraction collector with no spill feature at high flow collection to prevent contamination or a possible loss of sample due to spill. It must have a closed design to protect fractions from dust and other free particles.

3.11 Include all required software to operate the systems and be fully compatible with Windows 10 or higher.

3.12 The software must have programmed phases that can be quickly dragged and dropped to create a purification method for automated runs in daily operations.

3.13 Include DoE module (Design of Experiment) with operating software to enable user design experiments for scouting parameters like flow velocity, sample/buffer pH, ionic strength, chromatography media etc., create methods and runs them. The module must analyze the DoE results to provide and able to generate graphical data representation.

3.14 Must be fully compatible and interchangeable with NRCs existing Cytiva AKApure 150M system and Cytiva Chromatography columns.

Minimum essential Requirement for chromatography columns;

3.15 The Chromatography columns must have Specification mentioned in the table below;

Column	1	2
Internal Diameter (mm)	50	100
Minimum Bed height (mm)	100	100
Maximum bed height (mm)	300	300
Minimum Bed Volume (L)	0.2	0.79
Maximum Bed Volume (L)	0.59	2.36
Packing Pressure (bar)	20	10
Operating Pressure (bar)	10	8

3.16 The column tubes must be made of Borosilicate glass.

3.17 The adapter movement must be by hydraulic pressure.

3.18 The columns must support automated packing methods of our existing chromatography systems. (Intelligent packing).

3.19 The columns must have mechanical lock to keep the adapter at set bed height.

3.20 The columns must have rotating pivot stand for easy emptying, safer operation, and convenient access to bed supports and O-rings

3.21 The columns must be able to operate with temperature range of 2 – 30 ºC

3.22 The columns must have 20µm stainless steel bed support.

4. Applicability of the trade agreement(s) to the procurement

This procurement is subject to the following trade agreement(s)

- *Canadian Free Trade Agreement* (CFTA)
- Revised *World Trade Organization - Agreement on Government Procurement* (WTO-AGP)
- *Canada-European Union Comprehensive Economic and Trade Agreement* (CETA)
- *Comprehensive and Progressive Agreement for Trans-Pacific Partnership* (CPTPP)
- *Canada-Chile Free Trade Agreement* (CCFTA)
- *Canada-Colombia Free Trade Agreement* (CCOFTA)
- *Canada-Honduras Free Trade Agreement* (CHFTA)
- *Canada-Korea Free Trade Agreement* (CKFTA)
- *Canada-Panama Free Trade Agreement* (CPAFTA)
- *Canada-Peru Free Trade Agreement* (CPFTA)
- *Canada-United Kingdom Trade Continuity Agreement* (Canada-UK TCA)
- *Canada-Ukraine Free Trade Agreement* (CUFTA)

7. Justification for the Pre-Identified Supplier

Due to commonality and compatibility with existing equipment, the preidentified supplier, Global Life Sciences Solutions Canada ULC, is the only one able to distribute Cytiva equipment in Canada.

- HHT develops the purification process/technology and transfer them to CMOs for GMP productions. Biologics Manufacturing Center (BMC) and Clinical Trial Manufacturing Facility (CTMF) will act as future CMOs and they also have the capabilities to work with these columns which is essential for a seamless transfer.
- These AKTApure 150M systems will fully integrate into our production-like environment, thus allowing for repeatability of processes and commonality of the O/S, parts and hardware configurations.

- The nomenclature, phase programing, process pictures and sensor technologies in this small-scale chromatography equipment are similar with AKTA system at production scale like CTMF which simplifies process transfer and operation.
- NRC will need to use the equipment in both teams to make a seamless purification process transfers from NRC R&D team to NRC manufacturing team, reducing the risk of process failure at the manufacturing scale.
- These are the only system capable of performing an automated unattended purification process using an enclosed fraction collector with an accumulator granting a fraction collection without splash thus eliminating cross-contamination risks among samples.

8. Government Contracts Regulations Exception(s)

The following exception(s) to the *Government Contracts Regulations* is *(are)* invoked for this procurement under subsection (d) - "only one person is capable of performing the work".

9. Exclusions and/or Limited Tendering Reasons

The following exclusion(s) and/or limited tendering reasons are invoked under the:

a. Canadian Free Trade Agreement (CFTA) – Article 513 (1) (b) (iii): due to an absence of competition for technical reasons;
b. World Trade Organization - Agreement on Government Procurement (WTO-AGP) – Article XIII (b) (iii): due to an absence of competition for technical reasons;
c. Canada-European Union Comprehensive Economic and Trade Agreement (CETA) – Article 19.12 (b) (iii): due to an absence of competition for technical reasons;
d. Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) – Article 15.10 (2) (b) (iii): due to an absence of competition for technical reasons;
e. Canada-Chile Free Trade Agreement (CCFTA) – Article Kbis-16 (2) (c): necessary to protect intellectual property;
f. Canada-Colombia Free Trade Agreement – Article 1409 (1) (b) (iii): due to an absence of competition for technical reasons;
g. Canada-Honduras Free Trade Agreement – Article 17.11 (2) (b) (iii): due to an absence of competition for technical reasons;
h. Canada-Korea Free Trade Agreement – referencing the WTO Protocol Amending the GPA, Article XIII (1) (b) (iii): due to an absence of competition for technical reasons;
i. Canada-Panama Free Trade Agreement – Article 16.10 (1) (b) (iii): because of the absence of competition for technical reasons;
j. Canada-Peru Free Trade Agreement (CPFTA) –Article 1409 (1) (b) (iii): due to an absence of competition for technical reasons;
k. Canada-Ukraine Free Trade Agreement (CUFTA) – Annex 10-6 (2) (a): any form of preference, including set asides, to benefit micro, small and medium enterprises; and

l. Canada-United Kingdom Trade Continuity Agreement: refer to CETA as the provisions of CETA are incorporated by reference into and made part of this Agreement. (CETA) Article 19.12 (b) (iii).

10. Ownership of Intellectual Property

Not Applicable

11. Period of the proposed contract or delivery date

NRC is expecting the equipment to be delivered within the month of March 2024, based on the date of the contract.

12. Name and address of the pre-identified supplier

Global Life Sciences Solutions Canada ULC
250 Howe Street, Suite 1400-C
Vancouver, BC
V6C 3S7

13. Suppliers' right to submit a statement of capabilities

Suppliers who consider themselves fully qualified and available to provide the goods, services or construction services described in the ACAN may submit a statement of capabilities in writing to the contact person identified in this notice on or before the closing date of this notice. The statement of capabilities must clearly demonstrate how the supplier meets the advertised requirements.

14. Closing date for a submission of a statement of capabilities

The closing date and time for accepting statements of capabilities is January 17th, 2024 at 2:00PM EST.

15. Inquiries and submission of statements of capabilities

Name: Roberta Ranaldi
Title: Procurement Officer
Organization: National Research Council Canada

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