ERP/LIMS/CMMS/MES Consultation services for the new Biologic Manufacturing Centre

1.0 Background

On August 31st 2020, the Government of Canada announced an investment of $126 million over two years to establish a new biomanufacturing facility at the NRC Royalmount site. The new Bilogics Manufacturing Centre (BMC) will house the process and equipment for the production and the quality control of vaccines intended for human use.

The production of the vaccines, will be regulated by Health Canada under the authority of the Food and Drugs Act. The facility will require being compliant with Canadian Good Manufacturing Practices (GMP).

Given the urgency of the pandemic situation, the complexity and the variability of the potential vaccines to manufacture, the stringent production regulations applied to vaccine and biologic products and the flexibility needed to manage a variety of key GMP and non-GMP functions; the BMC requires the support of an expert-consultant to guide the NRC in the identification, selection, implementation and integration of suited Enterprise Resource Planning Enterprise Resource Planning (ERP), a Laboratory Information Management System (LIMS), a Computerized Maintenance Management System (CMMS) and a Manufacturing Execution Systems (MES) platforms resulting in the integration and automation of the BMC operations.

To that end, the NRC is looking for the support and guidance of an experienced consultant who deliver within the project timeline by following a proven methodology, establishing the BMC needs and guiding the full implementation stream, from User Requirements Specifications (URS) to Integration and operationalization of the ERP/LIMS/CMMS/MES platforms, while mitigating project risks, and handling tight delivery schedules.

2.0 Statement of Work

General Requirements:

The service provider must be able to recognize and avoid pitfalls, to address scopes creep of the project, and inadequate capability of integration of the ERP/LIMS/CMMS/MES platforms with the key functions, software and/or hardware of the BMC.

The consultant will possess expertise and sound experience with ERP/LIMS/CMMS/MES platforms generally used in the GMP compliant manufacturing industry.

The ideal consultant must have:

- good listening, analytical skills and experience applied to the assessment of the client needs in order to guide the full implementation stream of the best adapted ERP/LIMS/CMMS/MES platforms;
- a sound experience in User Requirement Specifications (URS) drafting of ERP/LIMS/CMMS/MES used in a GMP compliant industry and the applicable ISO/TEC/IEEE 15288 standards related to the ‘’stakeholder needs and requirements definition process’’;

- experience with request for proposals (RFP) and procurement process applied to the supply of ERP/LIMS/CMMS/MES platforms with medium size and large organizations (with government organization would be an asset);

- a proven experience in selection and recommendation process applied to ERP/LIMS/CMMS/MES platforms used in a GMP compliant industry; a track record of expertise deployed in support to the integration, automation and operationalization of ERP/LIMS/CMMS/MES platforms in GMP compliant manufacturing facilities.

- The ability to offer bilingual (French/English) services to the stakeholders involved at all levels of the implementation of the Scope of Work of this mandate.

Deliverables:

The selected Consultant will provide the following services:

1. Assessment of client needs: The consultant shall explore prospective client needs and the fit with potential ERP solution available with regards to the implementation of an ERP platform interacting with LIMS and other systems (CMMS/MES and others as required) needed to manage a variety of key GMP and non-GMP functions of its new GMP compliant BMC. To achieve this, the consultant may be required to undertake interviews with professionals and other consultants of the BMC, mapping, tapping networks of IT and automation professional support and vendors to leverage the complete analysis of the client needs, systems available and the establishment of the relevant User Requirement Specifications (URS).

2. Drafting User Requirement Specifications (URS): Establish normative and clear URS on ERP/LIMS/CMMS/MES systems in preparation to a RFP process with vendors. The URS will include details associated with defining the functional and technical ERP/LIMS/CMMS/MES requirements (e.g. premise solution and/or clouds and bandwidth), including server requirements, operating systems, client computing integration to software and hardware, as well as manufacturing, Quality control, distribution, financial, HR, CRM, reporting requirements… suited for a GMP compliant manufacturing facility.

3. Supporting the BMC team in the ERP/LIMS/CMMS/MES, selection process: Support the Request for Proposals (RFP) process and vendors quotation with the BMC team. The consultant will provide the BMC team with recommendations regarding vendor selection according to the most suitable ERP/LIMS/CMMS/MES solution available for the BMC operation, with an emphasis on:

- GMP compliance management of diversified regulated biological products (vaccines, therapeutics…);
- Real time bi-directional material traceability;
- Effective management of Batch Manufacturing Records (BMR) and batch processing records (BPC);
- Quality management (in-process IPQC);
- Extended capacity to manage outsourced lab-testing;
- Adaptive to GMP and non-GMP business processes.

4. Supporting the acquisition process: Consultant will support the acquisition process with the selected vendors for a well-structured and efficient deployment of the ERP/LIMS/CMMS/MES platforms.

5. Providing support to integration: The consultant will coordinate the support needed for the integration, customization, fine tuning (if needed) and testing of the ERP/LIMS/CMMS/MES in interaction with other systems and equipment to insure their full functionality and the operationalization of the BMC activities.

3.0 Evaluation Criteria and Basis of Selection

Responses to this RFP will be evaluated according to Appendix B – Evaluation Criteria and Basis of Selection.

4.0 Work Location

1. All work will be primarily done remotely;
2. Meetings will be conducted primarily through Microsoft Teams or equivalent medium;
3. The BMC is located at the following address: 6100 Royalmount, Montréal, QC.

5.0 Schedule

All work under this mandate must be completed by August 31, 2021. Bidders are required to provide a high level and detailed schedule on how they intend to meet the requirements under the SoW.

6.0 Project Management

NRC will appoint a project manager, to liaise with designated key personnel from the consultant.

The bidders are required to identify the key personnel that will be assigned to complete the tasks under the Statement of Work.

7.0 Turnaround time for requested services

Given the current pandemic situation, the consultant must be readily available for remote work within 2 hours of notification. On-site presence may be required during the execution of qualification protocols. Consultant must be readily available for on-site work under a 4 hour notification period. Where such is deemed necessary and ensuring that all COVID-19 health and safety measures are followed.

8.0 Work Language

The team members should be able to write and speak French and English (intermediate level). The consultant project manager should have advanced level of French to participate in meetings which are conducted only in French.

https://www.tpsgc-pwgsc.gc.ca/app-acq/sat-ths/clients/competences-proficiency-eng.html
https://www.tpsgc-pwgsc.gc.ca/app-acq/sat-ths/clients/competences-proficiency-fra.html

9.0 Technical Proposal

Technical proposals must be presented in 5 sections as followed:

Section A: Contractors' relevant experience in delivering similar work. Proposals shall describe how the Contractor meets the general requirements described in section 2.0.

Section B: Contractors' proposed approach and methodology for the activities identified in Deliverables under section 2.0 Statement of Work.

Section C: Proposals shall indicate the estimated length of time required to implement each of the services identified in section 2.0, Statement of Work.

Section D: A brief outline of the Consultant/firm/agency and services offered, including:

- Full legal name, jurisdiction of incorporation and address of the company
- Year business was established.

Section E: Qualifications of key staff (CVs) who will be assigned to this project along with a high level summary of qualification.

10.0 Financial Proposal

The consultant must submit a detailed price for his service offer by completing Appendix C- Pricing Form and as per section 2.0 under Deliverables. Pricing Proposal must be a separate document from the technical proposal.

11.0 Timelines

The consultant must present his strategy how he intends to carry out the mandate within the time frame indicated in the section ''Schedule''.