

RFP 23-58010 – Engineering Services

Phase 2: Feasibility Study of supplemental area Clinical Trial Manufacturing Facility (CTMF)

Statement of Work (SOW)

As part of the Government of Canada's policy to develop vaccine expertise in Canada, the NRC is mandated to build a manufacturing plant for clinical batches of vaccines of different types. A first phase was completed in 2023 and consisted of the construction of a vaccine manufacturing facility (see attached drawings). The second phase consists of adding a viral vector ball room on the first floor, an mRNA vaccine production suite and a Quality Control Laboratory on the second floor of an existing building, the project includes all necessary utilities needed for the scope of work:

- Complete the viral vector manufacturing ball room, room 157 with an area of 112 m²,
- Add a mRNA vaccine production suite using part of room 210 with an area of 278,5 m²,
- Add a Quality Control Laboratory (Chemistry and Microbiology) in room 210 if possible or in a building extension,
- Add necessary services and utilities needed to produce the vaccines in the new production areas,
- Production rooms and utilities required will follow the following standards:
 - Health Canada Good Manufacturing Practices (GMP)
 - FDA Current Good Manufacturing Practices (cGMP)
 - Eudralex GMP standards
- The following drawings describe the state of the existing plant and will serve as the basis for the new feasibility study:
 - Annex 1 - A-201 : First floor - Construction
 - Annex 2 -A-202 : Interstitial floor - Construction
 - Annex 3 -A-203 : Second floor - Construction

List of Deliverables:

- Preliminary and final versions of the Feasibility Study (Report in English)
 - Working assumptions by section
 - Regulatory context
 - Design criteria
 - Applicable codes

- Preliminary project budget:
 - Construction budget – itemized with assumptions as per attached (example) see Appendix D Budget-example of details , to include at a minimum– separate costs between the two production suites
 - Engineering and Architecture budget
 - Process Equipment budget
 - IT improvement budget
 - Validation budget
 - Contingencies
- Process flow diagram
- Preliminary architectural layouts
- One-liner (schematics) of utilities – non-exhaustive list : (HVAC, Electrical, Chilled water, Water for injectable (WFI), Purified water (PW), clean compressed air, process gas)
- Validation – hypotheses and potential scope of work
- All minutes of meetings (within 48 hours)

Project Management:

This Project includes a number of questions and hypotheses that will be answered during the duration of the project, so it will be necessary to schedule a series of workshops with participants from the NRC team and McGill University. These ~~statutory~~ meetings will be scheduled on a weekly basis and for each, meeting minutes will be prepared and submitted to the participants no later than 48 hours after the meeting. The administrative work to support this methodology is part of the tender.

The majority of meetings can be held using a videoconference system but the start-up meeting, the presentation of the preliminary report and the final report must be done face-to-face with videoconference support for certain speakers (majority of participants to be in person/on site) who cannot be on site.

Note concerning the architecture: the chosen team must include an architectural firm whose mandate will be included in the service offer of the engineering firm.

The service offer must, at a minimum, have the following elements which will be used in the analysis grid:

- Brief description of the business
- Knowledge of the pharmaceutical and biotechnology industry
- Relevant experience (projects carried out after 2017) with project fact sheets attached
- Project team with organizational chart and curriculum vitae attached
- Understanding of the project and potential issues
- Scope of services
- List of deliverables including a table of contents of the final report

RFP 23-58010 - Annexe A – Statement Of Work

- Project stages
- Timeline of the study
- Price to carry out the work according to the price table provided in fixed price
- Hourly rate for additional work
- Exclusions

Schedule:

Estimated contract award date is 13 June-2023

Steps	Start	End
Estimated Kick-off meeting	2023-06-16	S/O
Estimated Preliminary report meeting	2023-08-11	S/O
Final report meeting	S/O	2023-09-01

See Appendix B for RFQ Evaluation Criteria and Basis of Selection