

Evaluation Criteria and Basis of Selection

RFP: Professional Validation Services for GMP Clinical Trial Manufacturing Facility

Bid Evaluation Process: The proposal will be evaluated and scored in accordance with the specific criteria as detailed herein. It is imperative that these criteria be addressed in sufficient depth in the proposal to fully describe the bidder’s response. The evaluation will be conducted by LOTs as identified in **Appendix F - Equipment List & Utility System Qualification**. Each LOT will be ranked according to the Rated Requirements as presented in Table 2. NRC reserves the right to award each LOT separately to different vendors or group 1 LOT or more and assess the LOTs in groups, at its sole discretion, to select the most beneficial combination of LOTs, according to its needs. NRC may also assess all the LOTs as one group for evaluation purposes, at its sole discretion.

Basis of Selection: Highest combined technical score (90%) and price (10%) with a minimum consensus score of 70%.

To be declared responsive, a bid must:

- (a) comply with all the requirements of the bid solicitation.
- (b) meet the mandatory evaluation criteria;
- (c) obtain the required minimum consensus score of 70% of the points for the technical evaluation criteria (*Rated Requirements*); and

Bids not meeting (a) or (b) or (c) will be declared non-responsive. Neither the responsive bid obtaining the highest number of points nor the one with the lowest evaluated price will necessarily be accepted.

The responsive bid(s) with the highest combined technical score (90%) and price (10%) according to the evaluation process as described above will be recommended for award of a contract (s). NRC

NRC may accept minor non-compliances at its sole discretion. Minor non-compliances may be defined according to NRC’s own interpretation only.

Mandatory Requirements

Proposals must address the mandatory requirement described below. This will be evaluated as either “Yes” or “No”. Failure by bidders to meet the mandatory requirement will render the bidder’s proposal non-responsive and it will not be considered further.

Proposals should clearly identify the firm’s ability to meet the mandatory requirement (e.g., provide relevant proposal page numbers against the mandatory requirement). NRC reserves the right to seek further validation of any mandatory compliances.

Table 1: Mandatory Requirements

Mandatory Requirements		
Requirement	Mandatory Criteria	Yes/No
M-1 on-site test validation services within a 4 hour notification period	Consulting services are required daily and on-site at the existing facility located at 6100 Royalmount Ave, Montréal, QC. The validation team members should be readily available to perform the test protocol validations on-site within a 4 hours notification period.	
M-2 Work Language	At least half of the validation team members (on-site) must be able to write and speak French and English (intermediate level). The consultant project manager should have advanced level of French to participate in construction coordination meetings which are conducted only in French.	

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

Bidders must receive a minimum consensus score of 70 points in the Rated Requirements to be considered responsive and considered further.

Table 2: Rated Requirements

Rated Requirements			
Requirement	Evaluation Criteria	Maximum Score	Bidder to Reference Section / Page in Proposal
R-1 Canadian Good Manufacturing Practices (GMP)	<p>The project team must have deep knowledge of, and demonstrated experience with, the Canadian Good Manufacturing Practices (GMP).</p> <p>The consultant company must have at least 5 years' experience in biomanufacturing mabs and viral vectors. (5 pts)</p> <p>The project manager must have at least 15 years in GMP & biopharmaceutical environment. (12.5 pts)</p> <p>50 % of the team members must have at least 7 years in GMP & biopharmaceutical environment and 50% of the team members must have at least 2 years in GMP and biopharmaceutical environment. (12.5 pts)</p>	30 points	
R-2 Instruments	<p>The selected consultant must provide all the necessary measuring instruments for the qualifications. The consultant must indicate in his bid the instruments (type, manufacturer & model) that will be used for the validation exercise.</p> <p>The list should include:</p> <ul style="list-style-type: none"> all the necessary instruments to perform the validations (data logger, kaye validator, etc.) all instruments are NIST calibrated or equivalent <p>(10 pts)</p>	10 points	

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<p>R-3 Demonstrated understanding of the work and its execution</p>	<p>The proposal should demonstrate a clear understanding of the work and the problems that might be encountered. Repeating the statements contained in the Statement of Work alone is not sufficient to demonstrate understanding of this requirement. This demonstrated understanding of the work should include:</p> <ul style="list-style-type: none"> • overview of the issues involved (5 pts) • description of the methodology/approach being proposed (8 pts) • details on how the proposed methodology/approach will be carried out to ensure the results are valid and reliable (7 pts) • a discussion of challenges and risks associated with the proposed undertaking, including any impact on project quality, costs or timing, and demonstrating the capacity to propose solutions and strategies to addressing these challenges (10 pts). 	<p>30 points</p>	
<p>R-4 Project work plan and level of effort</p>	<p>The proposal should include:</p> <ul style="list-style-type: none"> • an outline of the proposed work strategy, plan and schedule, including the proposed method of project management coordination and liaison with the NRC (10 pts); • a project plan, including phases, milestones etc. Indicate the steps that will be taken to ensure that the project is completed within the required time (10 pts). 	<p>20 points</p>	
<p>R-5 General impression</p>	<p>Overall comprehensiveness and rigour of the proposal. (clarity, conciseness, structure, methodology, consistency) (2 pts each)</p>	<p>10 points</p>	
<p>Total</p>		<p>100 points</p>	

1.3 Financial Requirements

Bids must meet the mandatory financial criteria specified in the table inserted below. Bids which fail to meet the mandatory financial criteria will be declared non-responsive.

Financial proposal must be submitted using Pricing Table provided below.

Bidders must submit their financial bid in Canadian funds and in accordance with the pricing table provided. The Bidder must complete this pricing schedule and include it as a separate attachment in the electronic bid submission.

The Bidder's all-inclusive per diem rates in response to the RFP and resulting contract will apply to where the Work is to be performed in Canada as may be specified in the RFP and the resulting contract.

All-inclusive per diem rates and other expenses included in the pricing below must include the total estimated cost of all additional expenses need to be incurred for Work described in the Statement of Work.

Project Team (Please list Project Lead and staff)	QUOTED ALL-INCLUSIVE PER DIEM RATE/Hour* (in Can \$) (A)	Estimated Level of Effort (B)	Total Estimated Cost (in Cdn \$) [A x B]
Total Estimated Cost (A x B for all proposed resources):			\$
Other Expenses such as travel, supplies, communications etc.			\$
Total Bid Price (Total Estimated Cost + Other Expenses):			\$

*a normal work day is 8 hours per day.