National Research Council Canada | Conseil national de recherches Canada

RETURN BIDS TO:

RETOURNER LES SOUMISSIONS À :

NRC.BidReceiving-ReceptiondesSoumissions.CNRC@nrc-cnrc.gc.ca

REQUEST FOR PROPOSAL
DEMANDE DE PROPOSITIONS

Proposal To: National Research Council Canada

We hereby offer to sell to His Majesty the King in right of Canada, in accordance with the terms and conditions set out herein, referred to herein or attached hereto, the goods, services, and construction listed herein and on any attached sheets at the price(s) set out thereof.

Proposition au : Conseil national de recherches Canada

Nous offrons par la présente de vendre à Sa Majesté le Roi du chef du Canada, aux conditions énoncées ou incluses par référence dans la présente et aux annexes ci-jointes, les biens, services et construction énumérés ici sur toute feuille ci-annexées, au(x) prix indiqué(s).

Instructions : See Herein

Instructions: Voir aux présentes
Comments - Commentaires

Vendor/Firm Name and address
Raison sociale et adresse du fournisseur/de l'entrepreneur

Issuing Office – Bureau de distribution
National Research Council Canada
Conseil national de recherches Canada

Title – Sujet CTMF External Laboratory Services to monitor the environment	
Solicitation No. – N° de l'invitation **23-58226**	**Date** 27 February -2024
Solicitation Closes – L'invitation prend fin **at – à 02 :00 PM** **on – le 22 March - 2024**	**Time Zone** **Fuseau horaire** EST
F.O.B. - F.A.B. **Plant-Usine:** ☐ **Destination:** ☒ **Other-Autre:** ☐	
Address Inquiries to : - Adresser toutes questions à: **Cindy Romain**	
Email address – l'addresse courriel : Cindy.Romain@nrc-cnrc.gc.ca	
Destination – of Goods, Services, and Construction: **Destination – des biens, services et construction :**	
National Research Council Canada **Clinical Trial Material Centre (CTMF)** **6100 Royalmount Ave Gate 10** **Montreal, Qc** **H4P 2R2**	

Vendor/firm Name and address **Raison sociale et adresse du fournisseur/de l'entrepreneur** **Facsimile No. – N° de télécopieur** **Telephone No. – N° de téléphone**
Name and title of person authorized to sign on behalf of Vendor/firm (type or print)- **Nom et titre de la personne autorisée à signer au nom du fournisseur/de l'entrepreneur (taper ou écrire en caractères d'imprimerie)** **Signature** **Date**

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PART 1 - GENERAL INFORMATION

1.1 Security Requirements

There is no security requirement associated with the requirement.

1.2 Statement of Work

To provide External Laboratory Services to monitor the environment for the Clinical Trial Manufacturing Facility (CTMF) in accordance with the detailed Statement of Work attached as **Appendix "A".**

1.3 Debriefings

Bidders may request a debriefing on the results of the bid solicitation process. Bidders should make the request to the Contracting Authority within 15 working days from receipt of the results of the bid solicitation process. The debriefing may be in writing, by telephone or in person.

PART 2 - BIDDER INSTRUCTIONS

2.1 Standard Instructions, Clauses and Conditions

You are invited to submit one electronic Technical Proposal and one electronic Financial Proposal in two separate attachments to fulfil the following requirement forming part of this Request for Proposal. One attachment must be clearly marked 'Technical Proposal' and the other attachment must be marked 'Financial Proposal'. All financial information must be fully contained in the Financial Proposal, and only in the Financial Proposal. Vendors who provide financial information in the technical proposal will be disqualified. All proposals should include the front page of this RFP duly completed.

2010B 2022-12-01, General Conditions - Professional Services (Medium Complexity) apply to and form part of the Contract.

Bidders who submit a bid agree to be bound by the instructions, clauses and conditions of the bid solicitation and accept the clauses and conditions of the resulting contract.

Proposals submitted must be valid for not less than sixty (60) calendar days from the closing date of the RFP.

2.1.1 It is the Bidder's responsibility to:

(a) return a signed copy of the bid solicitation, duly completed, IN THE FORMAT REQUESTED;

(b) direct its bid ONLY to the Bid Receiving address specified;

(c) ensure that the Bidder's name, the bid solicitation reference number, and bid solicitation closing date and time are clearly visible;

(d) provide a comprehensive and sufficiently detailed bid, including all requested pricing details, that will permit a complete evaluation in accordance with the criteria set out in the bid solicitation.

Timely and correct delivery of bids to the specified bid delivery address is the sole responsibility of the Bidder. The National Research Council Canada (NRC) will not assume or have transferred to it those responsibilities. All risks and consequences of incorrect delivery of bids are the responsibility of the Bidder.

2.1.2 Bids may be accepted in whole or in part. The lowest or any bid will not necessarily be accepted. In the case of error in the extension of prices, the unit price will govern. NRC may enter into contract without negotiation.

2.1.3 Bidders who submit a bid agree to be bound by the instructions, clauses and conditions of the bid solicitation and accept the terms and conditions of the resulting contract.

2.1.4 Bids will remain open for acceptance for a period of not less than sixty (60) days from the closing date of the bid solicitation, unless otherwise indicated by NRC in such bid solicitation.

2.1.5 While NRC may enter into contract without negotiation, Canada reserves the right to negotiate with bidders on any procurement.

2.1.6 Notwithstanding the bid validity period stipulated in this solicitation, Canada reserves the right to seek an extension from all responsive bidders, within a minimum of three (3) days prior to the end of such period. Bidders shall have the option to either accept or reject the extension.

2.1.7 If the extension referred to above is accepted, in writing, by all those who submitted responsive bids, then Canada shall continue immediately with the evaluation of the bids and its approval processes.

2.1.8 If the extension referred to above is not accepted, in writing, by all those who submitted responsive bids then Canada shall, at its sole discretion: either continue to evaluate the responsive bids of those who have accepted the extension and seek the necessary approvals; or cancel the solicitation; or cancel and reissue the solicitation.

2.2 Late Bids

All risks and consequences of incorrect delivery of electronic bids are the responsibility of the Bidder. The National Research Council Canada will not be responsible for late bids received at destination after the closing date and time, even if it was submitted before. Electronic bids received after the indicated closing time based on NRC servers' received time will be irrevocably rejected. Bidders are urged to send their proposal in sufficient time, in advance of the closing time to reduce any technical issues. The National Research Council Canada will not be held responsible for bids sent before closing time but received by the NRC servers after the closing time.

2.3 Submission of Bids

Technical and Financial Proposals must be **received electronically** no later than **02 :00 PM on 22 March - 2024** 14:00 EST, to the following NRC email address:

NRC.BidReceiving-ReceptiondesSoumissions.CNRC@nrc-cnrc.gc.ca

The NRC has restrictions on incoming e-mail messages. **The maximum e-mail message size including all file attachments must not exceed 10MB.** Zip files or links to bid documents will not be accepted. Incoming e-mail messages exceeding the maximum file size and/or containing zip file attachments will be blocked from entering the NRC e-mail system. A bid transmitted by e-mail that gets blocked by the NRC e-mail system will be considered not received.

Proposals must not be sent directly to the Contracting Authority or the Project Authority.
All submitted proposals become the property NRC.

2.4 Former Public Servant

Contracts awarded to former public servants (FPS) in receipt of a pension or of a lump sum payment must bear the closest public scrutiny, and reflect fairness in the spending of public funds. In order to comply with Treasury Board policies and directives on contracts awarded to FPSs, bidders must provide the information required below before contract award. If the answer to the questions and, as applicable the information required have not been received by the time the evaluation of bids is completed, Canada will inform the Bidder of a time frame within which to provide the information. Failure to comply with Canada's request and meet the requirement within the prescribed time frame will render the bid non-responsive.

Definitions
For the purposes of this clause, "former public servant" is any former member of a department as defined in the *Financial Administration Act*, R.S., 1985, c. F-11, a former member of the Canadian Armed Forces or a former member of the Royal Canadian Mounted Police. A former public servant may be:

a. an individual;
b. an individual who has incorporated;
c. a partnership made of former public servants; or
d. a sole proprietorship or entity where the affected individual has a controlling or major interest in the entity.

"lump sum payment period" means the period measured in weeks of salary, for which payment has been made to facilitate the transition to retirement or to other employment as a result of the implementation of various programs to reduce the size of the Public Service. The lump sum payment period does not include the period of severance pay, which is measured in a like manner.

"pension" means a pension or annual allowance paid under the *Public Service Superannuation Act* (PSSA), R.S., 1985, c. P-36, and any increases paid pursuant to the *Supplementary Retirement Benefits Act*, R.S., 1985, c. S-24 as it affects the PSSA. It does not include pensions payable pursuant to the *Canadian Forces Superannuation Act*, R.S., 1985, c. C-17, the *Defence Services Pension Continuation Act*, 1970, c. D-3, the *Royal Canadian Mounted Police Pension Continuation Act* , 1970, c. R-10, and the *Royal Canadian Mounted Police Superannuation Act*, R.S., 1985, c. R-11, the *Members of Parliament Retiring Allowances Act*, R.S. 1985, c. M-5, and that portion of pension payable to the *Canada Pension Plan Act*, R.S., 1985, c. C-8.

Former Public Servant in Receipt of a Pension

As per the above definitions, is the Bidder a FPS in receipt of a pension? **Yes** ( ) **No** ( )

If so, the Bidder must provide the following information, for all FPSs in receipt of a pension, as applicable:

a. name of former public servant;
b. date of termination of employment or retirement from the Public Service.

By providing this information, Bidders agree that the successful Bidder's status, with respect to being a former public servant in receipt of a pension, will be reported on departmental websites as part of the published proactive disclosure reports in accordance with Contracting Policy Notice: 2019-01 and the Guidelines on the Proactive Disclosure of Contracts.

Work Force Adjustment Directive

Is the Bidder a FPS who received a lump sum payment pursuant to the terms of the Work Force Adjustment Directive? **Yes** ( ) **No** ( )

If so, the Bidder must provide the following information:

a. name of former public servant;
b. conditions of the lump sum payment incentive;
c. date of termination of employment;
d. amount of lump sum payment;
e. rate of pay on which lump sum payment is based;
f. period of lump sum payment including start date, end date and number of weeks;
g. number and amount (professional fees) of other contracts subject to the restrictions of a work force adjustment program.

2.5 Enquiries - Bid Solicitation

All enquiries must be submitted in writing to the Contracting Authority no later than 5 calendar days before the bid closing date. Enquiries received after that time may not be answered.

Contracting Authority, Procurement Services
National Research Council Canada
Cindy.Romain@nrc-crc.gc.ca (Cindy Romain – Senior Contracting Officer)
Phone: 613-299-2748

2.6 For invited RFPs

To ensure the equality of information among Bidders, responses to general enquiries will be sent simultaneously to all bidders without identifying the source. All formal questions and answers will be distributed to all competing bidders unless such publication would reveal proprietary information. The bidder who initiates the question will not be identified.

Bidders should reference, as accurately as possible, the numbered item of the bid solicitation to which the enquiry relates. Care should be taken by Bidders to explain each question in sufficient detail in order to enable Canada to provide an accurate answer. Technical enquiries that are of a proprietary nature must be clearly marked "proprietary" at each relevant item. Items identified as "proprietary" will be treated as such except where Canada determines that the enquiry is not of a proprietary nature. Canada may edit the question(s) or may request that the Bidder do so, so that the proprietary nature of the question(s) is eliminated, and the enquiry can be answered to all Bidders. If NRC does not consider the question proprietary, the bidder submitting it will be allowed to withdraw the question, or have the question and answer distributed to all bidders. Enquiries not submitted in a form that can be distributed to all Bidders may not be answered by Canada.

2.7 Applicable Laws

Any resulting contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in Quebec.

Bidders may, at their discretion, substitute the applicable laws of a Canadian province or territory of their choice without affecting the validity of their bid, by deleting the name of the Canadian province or territory specified and inserting the name of the Canadian province or territory of their choice. If no change is made, it acknowledges that the applicable laws specified are acceptable to the Bidders.

2.8 Bid Challenge and Recourse Mechanisms

If you have any concerns relating to the procurement process, please refer to the Recourse Mechanisms page on the Buyandsell.gc.ca website. Please note that there are strict deadlines for filing complaints with the Canadian International Trade Tribunal (CITT) or the Office of the Procurement Ombudsman (OPO). Suppliers should therefore act quickly when they want to challenge any aspect of the procurement process.

https://buyandsell.gc.ca/for-businesses/selling-to-the-government-of-canada/bid-follow-up/bid-challenge-and-recourse-mechanisms

https://opo-boa.gc.ca/plaintesurvol-complaintoverview-eng.html

PART 3 - BID PREPARATION INSTRUCTIONS

3.1 Bid Preparation Instructions

Canada requests that the Bidder submits its bid in separate attachment sections (when applicable) as follows:

Section I: Technical Bid
Section II: Financial Bid
Section III: Additional Information

There shall be no payment by the National Research Council for costs incurred in the preparation and submission of proposals in response to this request. No payment shall be made for costs incurred for clarification(s) and/or demonstration(s) that may be required by NRC. The National Research Council reserves the right to reject any or all proposals submitted, or to accept any proposal in whole or in part without negotiation. A contract will not necessarily be issued as a result of this competition. NRC reserves the right to amend, cancel or reissue this requirement at any time.

In April 2006, Canada issued a policy directing federal departments and agencies to take the necessary teps to incorporate environmental considerations into the procurement process Policy on Green Procurement (https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=32573). To assist Canada in reaching its objectives, bidders should:

1) Include all environmental certification(s) relevant to your organization (e.g., ISO 14001, Leadership in Energy and Environmental Design (LEED), Carbon Disclosure Project, etc.)
2) Include all environmental certification(s) or Environmental Product Declaration(s) (EPD) specific to your product/service (e.g., Forest Stewardship Council (FSC), ENERGYSTAR, etc.)

Canada is committed to greening its supply chain. Environmentally preferable goods and services are those that have a lesser or reduced impact on the environment over the life cycle of the good or service, when compared with competing goods or services serving the same purpose. Environmental performance considerations include, among other things: the reduction of greenhouse gas emissions and air contaminants; improved energy and water efficiency; reduced waste and support reuse and recycling; the use of renewable resources; reduced hazardous waste; and reduced toxic and hazardous substances. In accordance with the Policy on Green Procurement (https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=32573), for this solicitation:

- Bidders are encouraged to offer or suggest green solutions whenever possible.

- Bidders are requested to provide all correspondence including (but not limited to) documents, reports and invoices in electronic format unless otherwise specified by the Contracting Authority or Project Authority, thereby reducing printed material.
- Bidders should recycle (shred) unneeded copies of non-classified/secure documents (taking into consideration the Security Requirements).
- Product components used in performing the services should be recyclable and/or reusable, whenever possible.
- Bidders are encouraged to offer goods and/or services certified to a reputable eco-label.
- Bidders should use equipment that has high energy efficiency or produces low air emissions.
- Bidders are encouraged to offer environmentally preferred products which supports a sustainable environment for nature and wildlife.
- Bidders are encouraged to offer environmentally preferred products which ensure the comfort and air quality of building occupants.

Bidders are encouraged to consult the following websites:
https://www.tpsgc-pwgsc.gc.ca/app-acq/ae-gp/index-eng.html
https://www.tpsgc-pwgsc.gc.ca/app-acq/ae-gp/rle-glr-eng.html

Section I: Technical Bid
In their technical bid, Bidders should explain and demonstrate how they propose to meet the requirements and how they will carry out the Work.

Section II: Financial Bid
Bidders must submit their financial bid in accordance with the Basis of Payment.

3.2.1 Electronic Payment of Invoices – Bid

Payments from the National Research Council Canada (NRC) are made by electronic payment. Direct deposit payments will be made in Canadian dollars and can only be deposited into Canadian bank accounts.

Only bank accounts outside of Canada are eligible to enroll as a Wire transfer payment method.

3.2.2 Exchange Rate Fluctuation

Bids will be evaluated in Canadian currency, therefore, for evaluation purposes, the exchange rate quoted by the Bank of Canada as being in effect on date of bid closing, shall be applied as the conversion factor for foreign currency. Prices quoted shall not be subject to, or conditional upon, fluctuations in commercial or other interest rates during either the evaluation or contract period.

PART 4 - EVALUATION PROCEDURES AND BASIS OF SELECTION

4.1 Evaluation Procedures

(a) Bids will be assessed in accordance with the entire requirement of the bid solicitation including the "technical", and "financial", evaluation criteria.

(b) An evaluation team composed of representatives of Canada will evaluate the bids.

4.1.1 Technical Evaluation

Proposals will be assessed in accordance with the mandatory and rated evaluation attached as ***Appendix B Evaluation Criteria and Basis* of Selection** and ***Appendix D Table of Years of Analyst Laboratory Experience***. Bidders shall provide a detailed response to each criterion. NRC reserves the right to verify any and all information provided by the bidder in their proposal.

4.1.2 Financial Evaluation

The Contractor must complete the pricing schedule provided in accordance with ***Annex B Evaluation Criteria and Basis of Selection*** *Pricing Table 1 - Air analysis and microbial identification* – ***Option 1*** *(minimal plates) and Table 2- Air analysis and microbial identification* ***– Option 2*** (maximal plates) *to* include as a separate attachment in the electronic bid submission.

The cost proposal must have sufficient structure to show how the total proposed cost was calculated. It should contain the following elements:

a) The amount and explanation for other miscellaneous expenses that could be incurred.

Canada will not accept travel and living expenses that may need to be incurred by the Contractor for any relocation of resources required to satisfy its contractual obligations

Applicable Sales Tax: The GST, PST, QST or HST, whichever is applicable, shall be considered an applicable tax for the purposes of this RFP and extra to the price herein. The amount of applicable sales tax shall be disclosed and shown as a separate item.

4.2 Basis of Selection

2010C 2022-12-01, General Conditions - Services (Medium Complexity) apply to and form part of the Contract.

A0031T 2010-08-16 Basis of Selection Mandatory Technical Criteria and, *A0069T* 2007-05-25 Instructions to Bidders/Contractors

4.2.1 Minimum Point Rating

To be declared responsive, a bid must:

a. comply with all the requirements of the bid solicitation; and
b. meet all mandatory technical evaluation criteria; and
c. "obtain the required minimum of 50% percent overall of the points for the technical evaluation criteria which are subject to point rating. The rating is performed on a scale of 90 points."

A bid must comply with the requirements of the bid solicitation and meet all mandatory technical evaluation criteria to be declared responsive. The responsive bid with the highest combined technical score (70%) and price (30%) will be recommended for award of a contract.

4.2.2 Financial Evaluation

4.2.2.1 For bid evaluation and Contractor selection purposes, the evaluated price of a bid will be determined in accordance with the initial contract period of the Basis of Payment detailed in Appendix B.

4.2.2.2 In their financial bids, Bidders must provide a breakdown for the firm **testing price quoted in response to the pricing schedule detailed in Appendix B- Basis of Payment.**

4.2.2.3 NRC reserves the right to choose OPTION 1 or OPTION 2 and the responsive bid in the chosen option with the highest combined technical score (70%) and price (30%) will be recommended for award of a contract.

PART 5 – CERTIFICATIONS AND ADDITIONAL INFORMATION

Bidders must provide the required certifications and additional information to be awarded a contract.

The certifications provided by Bidders to Canada are subject to verification by Canada at all times. Unless specified otherwise, Canada will declare a bid non-responsive, or will declare a contractor in default if any certification made by the Bidder is found to be untrue whether made knowingly or unknowingly, during the bid evaluation period or during the contract period.

The Contracting Authority will have the right to ask for additional information to verify the Bidder's certifications. Failure to comply and to cooperate with any request or requirement imposed by the Contracting Authority will render the bid non-responsive or constitute a default under the Contract.

5.1 Integrity Provisions - Declaration of Convicted Offences

In accordance with the Integrity Provisions of the Standard Instructions, all bidders must provide with their bid, **if applicable**, the declaration form available on the Forms for the Integrity Regime website (http://www.tpsgc-pwgsc.gc.ca/ci-if/declaration-eng.html), to be given further consideration in the procurement process.

5.2 Certifications Precedent to Contract Award and Additional Information

The certifications and additional information listed below should be submitted with the bid but may be submitted afterwards. If any of these required certifications or additional information is not completed and submitted as requested, the Contracting Authority will inform the Bidder of a time frame within which to provide the information. Failure to provide the certifications or the additional information listed below within the time frame provided will render the bid non-responsive.

5.2.1 Integrity Provisions – Required Documentation

In accordance with the section titled Information to be provided when bidding, contracting or entering into a real property agreement of the Ineligibility and Suspension Policy (http://www.tpsgc-pwgsc.gc.ca/ci-if/politique-policy-eng.html), the Bidder must provide the required documentation, as applicable, to be given further consideration in the procurement process.

In addition to all other information required in the procurement process, the Bidder **must** provide the following:

- Bidders who are incorporated, including those bidding as a joint venture, must provide a complete list of names of all individuals who are currently directors of the Bidder or, in the case of a private company, the owners of the company.

- Bidders bidding as sole proprietorship, as well as those bidding as a joint venture, must provide the name of the owner(s).

SURNAME	GIVEN NAME(S)	TITLE

PART 6 - RESULTING CONTRACT CLAUSES

The following clauses and conditions apply to and form part of any contract resulting from the bid solicitation.

6.1 Security Requirements

6.1.1 There is no security requirement applicable to the Contract.

6.2 Statement of Work

B4007C 2014-06-26 Statement of Work - Contract

6.3 General Conditions

2010C 2022-12-01, General Conditions - Services (Medium Complexity) apply to and form part of the Contract.

6.4 Term of Contract

6.4.1 Period of the Contract

A9022C 2007-05-25 Period of the Contract

The Work is to be performed during the period of 01 April 2024 to 31 March 2025.

6.4.2 Option to Extend the Contract

The Contractor grants to Canada the irrevocable option to extend the term of the Contract by one (1) additional year under the same conditions. The Contractor agrees that, during the extended period of the Contract, it will be paid in accordance with the applicable provisions as set out in the Basis of Payment.

Optional period will be calculated based on a 2% increase or the Statistics Canada Consumer Price Index (CPI), whichever is the higher percentage.

The Contracting Authority may exercise the option at any time before the expiry of the Contract by sending a written notice to the Contractor.

6.4.3 Delivery Date

All the deliverables must be received on or before 31 March, 2025.

6.4.4 Delivery Points

Delivery of the requirement will be made to delivery point specified at **Appendix A – Statement of Work** of the Contract.

As part of NRC's commitment to Greening Government Operations, the Contractor is encouraged to minimize, include recycled content, re-use, or reduce/eliminate toxics in packaging, when possible.

6.4.5 Packaging

The methods used for preservation and packaging must be in conformity with the requirements for shipping the laboratory testing in **Appendix A – Statement of Work** of the Contract.

6.5 Authorities

6.5.1 Contracting Authority

The Contracting Authority for the Contract is:

Name: Cindy Romain
Title: Senior Contracting Officer
National Research Council Canada
Directorate: NRC CTMF Project
Address: 6100 Royalmount Ave, Montreal, Qc, H4P 2R2

E-mail address: Cindy.Romain@nrc-cnrc.gc.ca

The Contracting Authority is responsible for the management of the Contract and any changes to the Contract must be authorized in writing by the Contracting Authority. The Contractor must not perform work in excess of or outside the scope of the Contract based on verbal or written requests or instructions from anybody other than the Contracting Authority.

6.5.2 Technical Authority

The Technical Authority for the Contract is: [to be inserted at contract award]

Name: _____
Title: _____
Organization: _____
Telephone: ___ ___ _____
E-mail address: _____

The Technical Authority is the representative of the department or agency for whom the Work is being carried out under the Contract and is responsible for all matters concerning the technical content of the Work under the Contract. Technical matters may be discussed with the Technical Authority; however, the Tehcnical Authority has no authority to authorize changes to the scope of the Work. Changes to the scope of the Work can only be made through a contract amendment issued by the Contracting Authority.

6.5.3 Contractor's Representative [to be inserted at contract award]

Name: _____
Title: _____
Address: _____
Telephone: ___ ___ _____
E-mail address: _____

6.6 Proactive Disclosure of Contracts with Former Public Servants

By providing information on its status, with respect to being a former public servant in receipt of a Public Service Superannuation Act (PSSA) pension, the Contractor has agreed that this information will be reported on departmental websites as part of the published proactive disclosure reports, in accordance with Contracting Policy Notice: 2012-2 of the Treasury Board Secretariat of Canada.

6.7 Payment

6.7.1 Basis of Payment

4.70.20.1. (2010-01-11) *Firm Price – Basis of payment*

The Contractor will be paid for costs reasonably and properly incurred in the performance of the work under this Contract in accordance with the following:

For the Work described in the *Statement of Work* in Annex A:

In consideration of the Contractor satisfactorily completing its obligations under the Contract, the Contractor will be paid a firm price for a cost of $_____ (*insert the amount at contract award*). Customs duties are excluded and Applicable Taxes are extra.

The contractor will provide monthly billing in accordance with the submitted laboratory testing.

For the firm price portion of the Work only, Canada will not pay the Contractor for any design changes, modifications or interpretations of the Work unless they have been approved, in writing, by the Contracting Authority before their incorporation into the Work.

6.7.3 Method of Payment

H1001C (2008-05-12**), Multiple Payment**

Canada will pay the Contractor upon completion and delivery of units in accordance with the payment provisions of the Contract if:

a. an accurate and complete invoice and any other documents (laboratory reports) required by the Contract have been submitted in accordance with the invoicing instructions provided in the Contract;
b. all such documents have been verified by Canada;
c. the Work delivered has been accepted by Canada.

6.6.5 Electronic Payment of Invoices – Contract

The Contractor accepts to be paid using any of the following Electronic Payment Instrument(s):

a. Direct Deposit (Domestic Only);
b. Wire Transfer (International Only);

6.8 Inspection and Acceptance

The Technical Authority is the Inspection Authority. All reports, deliverable items, documents, good and all services rendered under the Contract are subject to inspection by the Inspection Authority or representative. Should any report, document, good or service not be in accordance with the Statement of Requirement and to the satisfaction of the Inspection Authority, as submitted, the Inspection Authority will have the right to reject it or require its correction at the sole expense of the Contractor before recommending payment.

6.9 Invoicing Instructions

The Contractor must submit invoices in accordance with the section entitled "Invoice Submission" of the general conditions. Invoices cannot be submitted until all work identified in the invoice is completed.

Invoices **must** be sent to: nrc.invoice-facture.cnrc@nrc-cnrc.gc.ca

PLEASE QUOTE CONTRACT NO. *[to be inserted at contract award]* **ON ALL DOCUMENTATION AND INVOICES.**

6.10 Certifications and Additional Information

6.10.1 Compliance

Unless specified otherwise, the continuous compliance with the certifications provided by the Contractor in its bid or precedent to contract award, and the ongoing cooperation in providing additional information are conditions of the Contract and failure to comply will constitute the Contractor in default. Certifications are subject to verification by Canada during the entire period of the Contract.

6.11 Applicable Laws

The Contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in Quebec.

6.12 Priority of Documents

If there is a discrepancy between the wording of any documents that appear on the list, the wording of the document that first appears on the list has priority over the wording of any document that subsequently appears on the list.

(a) the Contract;
(b) the general conditions - 2010C 2022-12-01, General Conditions - Services (Medium Complexity);
(d) ANNEX A, Statement of Work External Laboratory Services to monitor the environment
(e) ANNEX B, Basis of Payment
(f) the Contractors technical Proposal _____ (insert date of bid) ;

6.13 *SACC Manual* Clauses

G1005C (2016-01-28) Insurance – No Specific Requirements

6.14 Dispute Resolution

The Parties agree to make every reasonable effort, in good faith, to settle amicably all disputes or claims relating to the Contract, through negotiations between the Parties' representatives authorized to settle. If the Parties do not reach a settlement within 25 working days after the dispute was initially raised to the other party in writing, either Party may contact the Office of the Procurement Ombudsman (OPO) to request dispute resolution/mediation services. OPO may be contacted by e-mail at boa.opo@boa-opo.gc.ca, by telephone at 1-866-734-5169, or by web at www.opo-boa.gc.ca. For more information on OPO's services, please see the Procurement Ombudsman Regulations or visit the OPO website.

6.15 Non-Permanent Resident (Canadian Company)

The Contractor is responsible for compliance with the immigration requirements applicable to non-permanent residents entering Canada to work on a temporary basis in fulfilment of the Contract. In some instances, the employment authorization necessary to enter Canada cannot be issued without prior approval of Human Resources Centre Canada (HRCC). HRCC should always be contacted as soon as the decision to bring in a non-permanent resident is made. The Contractor will be responsible for all costs incurred as a result of non-compliance with immigration requirements.

6.16 Withholding of 15 percent on Service Contracts with Non-residents

Pursuant to the Income Tax Act, 1985, c. 1 (5th Supp.) and the Income Tax Regulations, Canada must withhold 15 percent of the amount to be paid to the Contractor in respect of services provided in Canada if the Contractor is not a resident of Canada, unless the Contractor obtains a valid waiver from the Canada Revenue Agency (CRA). The amount withheld will be held on account for the Contractor in respect to any tax liability which may be owed to Canada.

Although most tax treaties between Canada and other countries provide for some relief from Canadian tax, Canada does not normally relinquish its right to withhold tax pursuant to the provisions of section 153 of the *Income Tax Act* and subsection 105(1) of the *Income Tax Regulations*. If the non-resident contractor can adequately demonstrate, based on treaty protection, that the withholding normally required is in excess of the ultimate tax liability, or that the withholding creates undue hardship to the contractor, then the CRA may issue permission to the payer authorizing a reduction of the subsection 105(1) withholdings. The procedure to apply for a reduction of withholding is detailed in Income Tax Information Circular IC75-6R2 Appendices A and B, as well as in CRA's T4061, Non resident

Tax Withholding, Remitting, and Reporting. Requests for a waiver or a reduction of the withholding will not be entertained unless deductions at source are remitted to CRA.

6.17 Government Smoking Policy

Where the performance of the work requires the presence of the Contractor's personnel on government premises, the Contractor shall ensure that its personnel shall comply with the policy of the Government of Canada which prohibits smoking on any government premises.

6.18 Access to Government Facilities/Equipment

Access to the facilities and equipment necessary to the performance of the work shall be provided through arrangements to be made by the Technical Authority named herein. There will be however, no day-to-day supervision of the Contractor's activities, nor control of the Contractor's hours of work by the Technical Authority.

The Contractor undertakes and agrees to comply with all Standing Orders and Regulations in force on the site where the work is to be performed, relating to the safety of persons on the site or the protection of property against loss or damage from any and all causes including fires.

External Laboratory Services to monitor the environment for the Clinical Trial Manufacturing Facility

Background

The National Research Council of Canada is building a new Clinical Trial Material Facility (CTMF) that will house the process and equipment for the production and the quality control of protein, viral vector or virus-like particle vaccines or biologics.

The facility will require being compliant with Canadian Good Manufacturing Practices (GMP) as well as FDA current GMP (cGMP) and Eudralex requirements.

Detailed Statement of Work

The environment must be monitored.

To do so, a certain number of samples (active, passive and surfaces) needs to be tested in order to meet the regulation expectations for grade C and D rooms.

Requirements

The testing must be carried out in accordance with Canadian GMP standards as well as FDA current GMP (cGMP) and Eudralex requirements. A quality agreement is required prior to the testing samples see Appendix C – Quality Assurance Agreement Template of the requirements to be approved by quality assurance.

As part of this mandate, the external laboratory must:

1. A daily pick-up must be in place for the plates, at controlled temperature, to ensure that plates are incubated within 24-36 hours of sampling.
2. Immediately after reception, incubate the environmental plates as per following scheme: incubation of plate in reverse position at 32.5 ± 2.5 °C for 48 -72 hours then at 22.5 ± 2.5 °C for 72- 96 hours. After incubation, the plates are read and if there is growth, a morphology description must be provided within 24h to determine if an identification is required.
3. Identify each micro-organism when required, and establish a documented flora bank
4. Provide a CoA by email

Plate Qualification

- Growth promotion and sterility testing
- CoA to be provided by email within 1 month

Sample Pick-Up

- Pickup-up sampling location is NRC- CTMF site at 6100 Royalmount Ave. Gate 10, Montreal, Quebec H4P 2R2 Will be daily at approximately 1:30 to 3:30 pm as requested by NRC.
- Vendor is to provide courier service and fee in pricing.

Vendor must be able to meet the sampling time schedule detailed above REQUIREMENTS (1,2,3, 4).

Note: Vendor is to provide pick-up method/information in technical submission

Weekend/Holidays Pick-Up and Laboratory Testing

- In exceptional circumstances pick up and testing may be required weekends or holidays
- Arrangements to be requested at a minimum of 24 hours
- Costing to be included in Table 1, Table 2 and Table 3 -**Appendix B** Evaluation Criteria and Basis of Selection

Deliverables

A pick-up method must be in place daily between 1:30 to 3:30 pm.

A CoA summarizing testing results for each sample within one month via email.

If Out-Of-Specifications (OOS) occurs, a notification within 24 hours must be obtained, and OOS investigation and report must be completed within 30 days of discovery.

Identification of the micro-organism report when required.

Schedule

Environmental air analysis
Expected start: March - 2024 for a duration of (1) one year plus (1) Optional year.
Expected end: March - 2025 (this contract can be stopped anytime for one or all tests as per operational requirements of NRC)

Number of samples planned and frequency

Laboratory Minimum requirement for testing	
	Number of samples
Plates	750 samples / month
Microbial identification (on demand)	Estimated 10 / month
Plate Qualification	Estimated 3 lots / month

Optional Additional Testing	
Plates	530 samples / month
Microbial identification (on demand)	Estimated 15 / month
Plate Qualification	Estimated 3 lots / month

Additional information

The laboratory must be approved by quality assurance and a quality agreement and audit is mandatory. All additional potential fees must be estimated and documented (OOS investigation, rush fees, raw data copies, etc..) in order to have a realistic price. The table below must be filled. If some items are included in testing, please put N/A

Description	Cost (specify unit in comments)	Comment
RUSH analysis		
OOS investigation report		
Raw data copy		
Others:		
Others:		

Appendix B - Evaluation Criteria and Basis of Selection

RFP 23-58226: External Laboratory Services to monitor the environment for the CTMF (*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.

Basis of Selection: Highest combined technical score (70%) and price (30%) with a minimum consensus score of 50%.

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 45/ 90 points or 50% 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 (70%) and price (30%) according to the evaluation process as described above will be recommended for award of a contract (s).

NRC reserves the right to accept at its sole discretion the lowest price for Option 1 (minimal plates) or lowest price for Option 2 (maximal plates) in order to meet NRC's operational needs.

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	The vendor needs to provide proof that they conform to Canadian GMP regulations (audit within the last three years by a regulatory agency without critical observations, e.g., health Canada, FDA, ..). **Demonstrate by providing documented proof i.e. redacted audit report from a regulatory agency less then 3 years old.	
M-2	The vendor must be able to meet the pick-up conditions – in Appendix A Statement of Work at NRC- CTMF site at 6100 Royalmount Ave. Gate 10, Montreal, Quebec H4P 2R2 between business hours 1:30 pm to 3:30 pm.	

M-3	The vendor must demonstrate* that they meet the requirements to be approved by quality assurance – in **Appendix C- Technical Quality Agreement Template example**. *Demonstrate by providing an intention letter stating that they understand and agree to the information that was provided (**Appendix C- Technical Quality Agreement Template example**) and will approve/sign the Technical Quality Agreement with NRC.	

See: Appendix C - Quality Assurance Agreement Template for example of requirements to be approved by quality assurance.

Rated Requirements

Bidders must receive a minimum consensus score of 45 points or 50 % 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 Good Manufacturing Practices (GMP)	The Quality Assurance and Microbiology Quality Control departments must have deep knowledge of, and demonstrated experience with, the Good Manufacturing Practices (GMP). • The supervisors of the Quality Assurance and Quality Control departments must have a minimum of 5 years experience in GMP standards **(10 pts)** • The manager of the Quality Assurance and Quality Control departments must have a minimum of 10 years experience in GMP standards **(10 pts)** • 50 % of the Quality Control team members implicated in the scope of project must have at least 3 years in GMP & microbiological testing **(10 pts)** * Demonstrated by providing documented proof as follows: 1. An Organizational chart, 2. Resumes of Quality Assurance and Quality Control (must include all resumes for Managers and Supervisors) implicated in the scope of the SOW and ** Demonstrated by completing **Appendix D – Table Years of Analyst Laboratory Experience** 3. A table summarizing the experience of the laboratory analysts implicated in the scope of the project - see Appendix D Table of Years Analyst Laboratory Experience.	**30 points**	

R-2 Compliance to regulation: -Canada -US FDA	The vendor must have a Laboratory License. Points as follows: -Canada **(5 Points)** -US FDA **(5 points)** ** Demonstrated by providing documented proof as follows: license number or license report. If the vendor has only one license, a gap analysis comparing the quality systems and quality control procedures to the missing regulations can be submitted to evaluate if points towards the second licence can be assigned.	**10 points**	
R-3 Compliance to regulation: Regulatory inspection	For the last 10 years*, provide for each Health Agency: Health Canada, FDA, European Union: Number of inspections for the laboratory, number of minor, major and critical observations *Demonstrated by including information in Technical submission : summary of audits in a table containing: 1. Number of observations 2. Criticality 3. Detailed Description 4. Remediation measures and status (completed, on going, not started Or the audits reports If all available audit reports are not provided, there will be 0 points attributed. Rating: Points will be calculated as follows: **Inspections: Max 20 points** • Zero (0) inspections with critical observations or 3 or less than 3 major observations: **(20 points)** • One (1) inspection with critical observations or between 3 and 6 major observations: **(10 points)** • Two (2) or more inspections with critical observations or 7 or more critical observations: (**0 Points)** **Observations: Max 10 points** • Zero (0) Critical observations in the last audit of each agency, or 1 or less major observations **(10 points)** • One (1) Critical observations in the last audit of each agency, or 2 to 3 major observations (**5 points)** • Two (2) or more Critical observations in the last audit of each agency, or more than 4 major observations **(0 Points)** **Repeated Observations (last 10 years): Max 10 points** • Zero (0) repeated observations per subject **(10 point)** • One (1) repeated observation per subject **(5 points)** • Two (2) or more repeated observations per subject **(0 points)**	**40 points**	

R-4 Presentation of the documents	Overall comprehensiveness and rigour of the proposal. (Clarity, conciseness, structure, methodology, consistency) **(2 points each)**	**10 Points**	
Total		**90 points**	

1.2 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.

1) Financial proposal must be submitted using the Pricing Tables provided below - *Table 1* –Option 1, Table 2- Option 2 & Table 3 – Additional Fees.

2) Bidders must submit their financial bid in Canadian $. **The Bidder must complete this pricing schedule and include it as a separate attachment in the electronic bid submission**.

3) The Bidder's all-inclusive per unit 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.

4) Optional period of (1) one year will be calculated based on a 2% increase or the Statistics Canada Consumer Price Index (CPI), whichever is the higher percentage.

All-inclusive per unit rates and other expenses included in the pricing below must include the total estimated cost of all additional expenses for **Table 1- Air Analysis and Microbial Identification (Option 1) & Table 2** - **Air Analysis and Microbial Identification (Option 2)** and **Table 3 -Additional Laboratory Fees** needed to be incurred for Work described in the Statement of Work.

Pricing Table 1 – Air analysis and microbial identification – Option 1 (minimal plates)

SUPPLY Laboratory Services to monitor air FOR CTMF		**Estimated # of tests Quantity monthly**	**Unit Costs per Laboratory test** **(Must include all fees regarding analysis, including pick-up fees, CoA, sample discard, etc..)** **UNIT**	**Monthly cost**	**Total / Yearly cost (12 x the estimated monthly costs)** **$ CAD**	
		Quantity	**$ CAD/Per Unit**	**Estimated monthly $**	**$ CAD/year**	
1a	Incubation and plate reading as per SOW	750 / month	$	$	**A**	$
1b	Microbial identification	10 per month	$	$	**B**	$
1c	Plate lot qualification (growth promotion / sterility check)	3 lot / month	$	$	**C**	$

Total Estimated Cost (A+B +C for all proposed services):		$
Other Expenses Optional items, supplies, etc.	**D**	$
(Total Estimated service Costs (A+B +C + D):		$

Pricing Table 2 – Air analysis and microbial identification – Option 2 (maximal plates)

SUPPLY Laboratory Services to monitor air FOR CTMF		**Estimated # of tests Quantity monthly**	**Unit Costs per Laboratory test (Must include all fees regarding analysis, including pick-up fees, CoA, sample discard, etc..) UNIT**	**Monthly cost**	**Total / Yearly cost (12 x the estimated monthly costs) $ CAD**	
		Quantity	**$ CAD/Per Unit**	**Estimated monthly $**	**$ CAD/year**	
1a	Incubation and plate reading as per SOW	1900 / month	$	$	**A**	$
1b	Microbial identification	50 per month	$	$	**B**	$
1c	Plate lot qualification (growth promotion / sterility check)	6 lot / month	$	$	**C**	$
Total Estimated Cost- (A+B +C for all proposed services):						$
Other Expenses Optional items, supplies, etc.					**D**	$
Total Estimated service Costs (A+B +C + D):						$

Note: Pricing for Table 1 and Table 2 are unit prices per laboratory test including pick-up fees, CoA, sample discard and all fees required

Pricing Table 3 – Detail of Extra Laboratory Fees

All additional extra potential fees (not included in *Table 1 or Table 2*) that could happen during the project but that are not part of regular testing must be estimated and documented (rush/ after hours/ holidays pick-up fees, OOS investigation, rush fees, raw data copies etc..) in order to have a firm price.

The table below must be completed including others field if applicable.

Description	Cost/ unit	Comment
Rush/ afterhours/ holidays pick-up fees		

RUSH testing specify the delay: _____		
OOS investigation and report		
Raw data copy		
Others :		
Others :		
	Total Unit Costs	

Note 2: if “Others” are included, please specify “what” the additional items is as well as pricing per unit lab test.

Note 3: Table 3 will not be part of the financial evaluation.

NRC·CNRC

Human Health Therapeutics (HHT)

Good Manufacturing Practices (GMP)

Quality Agreement between NRC HHT and XXXXX	Page 1 of 20
NRC Business Confidential (Protected B) Once approved	Version: 01

CONTRACT LABORATORY

QUALITY AGREEMENT

By and between

National Research Council Canada (NRC)

Human Health Therapeutics (HHT)

Clinical Trial Manufacturing Facility (CTMF)

6100 Royalmount

Montreal (Quebec), H4P 2R2

(Hereinafter called **CLIENT**)

And

XXXXX

XXXXXX

XXXXXX

(Hereinafter called **SUPPLIER**)

1.0 GENERAL INFORMATION

1.1 Introduction

This Quality Agreement defines the expectations and responsibilities between XXXXX as Contract Laboratory and the HHT CTMF as service requestor (THE CLIENT).

THE SUPPLIER holds a license issued by {to be added} {and is registered with Health Canada / FDA}.

1.2 Scope of the Quality Agreement

THE CLIENT desires to entrust THE SUPPLIER to perform certain activities related to the services listed in Appendix B.

This quality agreement defines the roles and allocates responsibilities between THE CLIENT and THE SUPPLIER in accordance with all applicable rules and regulations including without limitation the requirements in relation to quality assurance for the activities listed in Appendix B.

It is the responsibility of THE SUPPLIER quality unit to ensure that the requirements of this quality agreement are fulfilled.

This Quality Agreement is primarily a technical agreement and does not purport to be exhaustive with respect to legal and commercial issues, which are set forth in the “Service Agreement”. In the event of a conflict between this Quality Agreement and the Service Agreement, this Quality Agreement shall prevail for matters of quality and the Service Agreement, including supporting documentation shall control for all business, legal, and financial issues. In the event that a dispute or breach arises between THE CLIENT and THE SUPPLIER regarding quality matters described in this document, the resolution shall proceed as per the Service Agreement.

1.3 Structure of the Quality Agreement

The quality agreement comprises the core document and Appendices. The Appendices to this quality agreement are an integral part of the quality agreement and are incorporated into this quality agreement by reference.
This document is effective from the date of the last signature of the Core document.

1.4 Amendment of the Quality Agreement

Changes to this quality agreement, core document or appendix, can only be made by mutual consent in writing. The appendix shall be updated as needed according to the progress of development without the necessity to update the core document. Amendments to the quality agreement and appendix shall be recorded in APPENDIX E, with each subsequent revision.

2.0 GENERAL PROVISIONS (QUALITY ASSURANCE), DIRECTIVES AND GUIDELINES

If not otherwise defined in this quality agreement, the provisions of THE SUPPLIER quality management system and standard operating procedures shall be applied to THE SUPPLIER operations.

The following general guidelines, in their current effective version, (see table 1) are considered as standards for quality assurance.

THE SUPPLIER shall maintain an establishment license (the "Establishment License") in compliance with the Regulations at all times during the term of this Agreement (the "Term"). THE SUPPLIER shall provide a current copy of the Establishment License to THE CLIENT upon written request. THE SUPPLIER shall immediately notify THE CLIENT if the Establishment License is amended, suspended or revoked.

Upon receipt of a newly issued GMP certificate from the authorities, THE SUPPLIER shall send THE CLIENT a copy of the current version. If three years have elapsed since the last date of inspection by the local health authority issuing the GMP-certificate, THE SUPPLIER should provide THE CLIENT with the confirmed inspection date or written documentation from the health authority extending the validity of the certificate.

THE SUPPLIER shall provide information about the regulatory status (e.g. health authority inspections and outcome, GMP certificate of CEP licence withdrawal). THE SUPPLIER shall promptly notify THE CLIENT if the regulatory inspection is directly associated with THE CLIENT samples and/or THE CLIENT test results. In case of any major deficiencies directly associated with THE CLIENT samples and/or THE CLIENT test results, THE CLIENT and THE SUPPLIER shall establish a corrective and preventive action plan.

Table 1: Guidelines to Good Manufacturing Practice for Contract laboratory testing

Organization	**Guideline**
Health Canada	Division 1A, Part C of the Food and Drug Regulations Good manufacturing practices guide for drug products (GUI-0001) Guidance Document - Annex 13 to the Current Edition of the Good Manufacturing Practices Guidelines Drugs Used in Clinical Trials (GUI-0036) Applicable for biologics: Annex 2 to the Current Edition of the Good Manufacturing Practices Guidelines Schedule D Drugs (Biological Drugs) (GUI-0027)
FDA	21 CFR 210 and 211 SUBCHAPTER F - BIOLOGICS
ICH	Q1 Stability Q2 Analytical Validation Q3 Impurities Q4 Pharmacopoeias Q5 Qualityof biotechnoligical producs
USP, Pharm. EU, JP	Pharmacopoeias
PIC/S	Annex 11: Computerised Systems

3.0 INSPECTIONS AND AUDITS

THE SUPPLIER agrees that its facilities, operations and quality systems may be audited by THE CLIENT or on behalf of THE CLIENT in order to ensure compliance with this quality agreement, GMP guidelines. THE CLIENT is entitled to perform audits for cause (e.g. undesirable events, launch of products) and at reasonable intervals to ensure the compliance with the registration of products.

The audit report should be available within thirty (30) calendar days. THE SUPPLIER must provide the proposed corrective actions within thirty (30) calendar days. Audits having unsatisfactory outcomes or critical observations require a CAPA plan addressing the critical deficiencies within fifteen (15) calendar days of audit report distribution. THE SUPPLIER shall correct audit observations in a timely manner.

THE CLIENT has the right to stop any operation for THE CLIENT if activities should be observed, violating agreed upon standards and regulations. THE SUPPLIER has to implement corrective actions before continuation of the operations.

In case of a documental inspection at THE CLIENT facilities from foreign and local governmental authorities, THE SUPPLIER shall support and provide the authority or THE CLIENT all the documentation (e.g. reports, SOPs, flow charts, SMF, organization charts, testing methods etc.), necessary to facilitate, obtain or maintain the registration in the countries where THE CLIENT or its affiliates, licensees or distributors, as the case may be, desire to sell the products.

THE SUPPLIER shall allow foreign and local governmental authorities to inspect THE SUPPLIER facilities, operations and quality systems, as it is necessary to facilitate, obtain or maintain the registration in the countries where THE CLIENT or its affiliates, licensees or distributors, as the case may be, desire to sell the products. A representative of THE CLIENT may participate in such inspections. THE SUPPLIER has to notify THE CLIENT within two (2) business days after the announcement of such an inspection.

THE SUPPLIER must notify THE CLIENT about major and/or critical issues encountered during authority inspections that might adversely affect the quality of the service for THE CLIENT within one (1) business day and must provide an excerpt and the proposed corrective actions within ten (10) business days for THE CLIENT approval.
If not otherwise agreed the audit rights shall survive five (5) years upon the termination of this quality agreement.

4.0 OUTSOURCED ACTIVITIES

THE SUPPLIER may only use sub-contractors listed in Appendix D. SUPPLIER shall not subcontract or delegate its obligations (in whole or part) hereunder to any third party or affiliate

without prior written approval of THE CLIENT in accordance with Section 7.0, Change Control. THE SUPPLIER shall remain solely and fully responsible for the performance of its sub-contractors.

THE SUPPLIER shall perform regular sub-contractor audits and provide copies of audit reports on request during an audit performed by THE CLIENT.

5.0 QUALIFICATION AND VALIDATION

Qualification and validation should be carried out according to THE SUPPLIER validation master plan.

5.1 Qualification and training of personnel

THE SUPPLIER shall ensure that there is at all times an adequate number of personnel with the appropriate level of qualification, training and experience to perform operations related to testing and to operate the facility in full compliance with the terms of this quality agreement, cGMP and any applicable laws, regulations, procedures (including safety) and guidelines. THE SUPPLIER shall keep a record of personnel trainings and make such records available during audits. Written procedures (SOPs) must define all GMP activities as appropriate.

5.2 Qualification of equipment and computer systems

THE SUPPLIER shall ensure that its processes, testing methods, equipment, and Information Technology (IT) systems are validated (or equivalent).
THE SUPPLIER shall provide, upon request evidence that key quality parameters can be met by the manufacturing and testing facilities. THE SUPPLIER shall also make available to THE CLIENT any associated control procedures (including cleaning procedures, where applicable).

THE SUPPLIER shall ensure that quality-critical measuring and test equipment used in THE SUPPLIER's facilities, computerized systems and laboratories are calibrated and maintained according to its internal procedures.

6.0 FACILITY

THE SUPPLIER shall adequately manage its operations, facilities and equipment to prevent any type of contamination and to ensure the cleanness and quality of the service supplied. THE SUPPLIER shall maintain a pest control procedure to keep buildings free from infestation by rodents, birds, insects and other vermin.

THE SUPPLIER shall keep a preventive maintenance and calibration program for its equipment and utilities. THE SUPPLIER shall ensure that its computer systems are adequate to prevent unauthorized access or changes to software, hardware or data.

7.0 CHANGE CONTROL

7.1 General

When a need for a change is identified at either THE CLIENT or THE SUPPLIER, the change initiating party shall inform the other in written form of planned changes for the services provided that have the potential to impact THE CLIENT test results.
In this document the following items shall be defined:

- a comparative description of the change (current versus intended status)
- the rationale for the change
- an impact assessment

THE SUPPLIER shall communicate any such MAJOR changes which may have an impact on the testing result of a Material to THE CLIENT, as defined in section18.0, at least ninety (90) calendar days prior to such change. The change can only be implemented following authorization from the relevant functions. All actions defined as part of the change require completion before the change can be closed.

7.2 Changes to the Quality Agreement

Changes to this quality agreement and its relevant Appendix shall only be made by mutual agreement between the parties and must be in writing.

7.3 Changes to site registration

In case of changes related to the facility with a potential impact on the valid GMP Certificate (e.g. location, company name, key contact) THE CLIENT must be informed in a timely manner.

7.4 Changes to analytical testing methods/specifications

For changes (that have the potential to impact THE CLIENT test results) to analytical testing methods or specifications and equipment initiated by THE SUPPLIER or a subcontractor of THE SUPPLIER, THE SUPPLIER shall provide THE CLIENT a comparative description of the change (current versus intended status), rationale for the change, and GMP assessment as described in the general section 7.
If required THE CLIENT shall address a formal change control in order to perform the required evaluation of impact on safety, integrity, strength, purity and quality of the product.

7.5 Changes from health authorities

Change requests induced by health authority activities shall not be refused without good reason.

8.0 DEVIATIONS

Deviations must be handled according to the SUPPLIER standard operation procedure (SOP).

THE SUPPLIER shall notify THE CLIENT of any Critical or Major deviation which is affecting the testing results to THE CLIENT. Notification shall occur within maximum two (2) business days of discovery of the deviation or non-conformance, to the generic email address (see Appendix A).

THE SUPPLIER shall initiate corrective and preventive actions for every product related deviation according to its own SOP to determine an assignable cause.

THE SUPPLIER shall send THE CLIENT the investigation report (Major/Critical deviation) for review together with the final documentation of analysis, when requested by THE CLIENT. Corrective and preventive actions shall be sent by THE SUPPLIER to THE CLIENT for information.

All documentation regarding deviations shall be available for THE CLIENT inspections.

9.0 OUT OF SPECIFICATION (OOS) RESULTS

OOS is every valid result that does not meet a specification or an acceptance criterion i.e. outside a specified limit or range. Any non-conformity to defined specifications is considered as an OOS according to THE CLIENT definition.
OOS results must be handled according to THE SUPPLIER corresponding standard operation procedure. If the investigation reveals no identifiable laboratory error, THE SUPPLIER shall notify THE CLIENT within two (2) business days.

Confirmed OOS results shall be referenced in the Certificate of Analysis (CoA), and a copy of the failure investigation report shall be provided to THE CLIENT. THE SUPPLIER shall send THE CLIENT the investigation report approved by THE SUPPLIER and accordant corrective and preventive actions, when requested by THE CLIENT.

All documentation regarding an out-of-specification event or unexpected result shall be part of the analytical file, including all the analysis raw data. The documentation package shall be sent to THE CLIENT within 2 business days. Additional delay shall be considered if documents need to be unarchived.

If the investigation reveals laboratory error, THE SUPPLIER shall re-test the sample without any additional fees.

10.0 COMPLAINTS

THE CLIENT is responsible for handling customer complaints and shall reply to inquiries as promptly as possible.
THE SUPPLIER shall notify THE CLIENT of any complaint received from other clients, which might impact THE CLIENT's results. Notification shall occur within maximum 2 business days of discovery, to the generic email address (see Appendix A).
THE SUPPLIER shall investigate all complaints addressed by THE CLIENT and sent a preliminary report investigation within fifteen (15) calendar days and a complete report within seven (7) calendar days of investigation closure. In case of delay (more than 30 calendar days after initiation), THE SUPPLIER shall advise THE CLIENT.

11.0 DATA INTEGRITY

THE SUPPLIER and THE CLIENT shall ensure that all data relevant for activities conducted pursuant to this quality assurance agreement is attributable, legible (permanent), contemporaneous, original, accurate, complete, available, consistent and endurable (ALCOA^{+}). Data must be kept safe from intentional or unintentional manipulation or loss.

THE SUPPLIER procedures, automation systems and management controls must ensure data integrity, and must be assessed regularly to ensure all data generated by such systems is valid.
THE SUPPLIER shall ensure that its documentation practices and data handling processes (paper and electronic) are well defined and that they are understood and implemented by all personnel.

THE SUPPLIER shall ensure that any breach of data integrity concerning THE CLIENT testing is investigated and shall immediately be reported in writing to THE CLIENT if there is any potential impact on the quality of product or services provided. This includes data integrity issues arising from outsourced activities (see also Appendix D) if documentation / product / testing result from THE CLIENT is concerned.

12.0 TESTING OF SAMPLES

12.1 Specifications (if applicable)

THE CLIENT is responsible for providing to THE SUPPLIER instructions on product testing, approved specifications, and method of analysis.

12.2 Method transfer and validation (if applicable)

12.2.1 Method transfer and validation between THE CLIENT and THE SUPPLIER

If validated test methods have to be transferred from THE CLIENT to THE SUPPLIER, THE CLIENT shall conduct a formal method transfer (method transfer package shall include validation as applicable) according to THE CLIENT procedure. THE SUPPLIER has to provide results according to the requirements defined in the transfer protocol. Transfer protocols and reports have to be reviewed and approved by THE SUPPLIER and THE CLIENT.

If test methods have to be transferred from THE SUPPLIER to THE CLIENT, the formal method transfer shall be carried out according to either THE SUPPLIER or THE CLIENT procedure, as agreed by both parties in writing. Transfer protocol / report shall be reviewed and approved by THE CLIENT and THE SUPPLIER to assure compliance to procedures at both parties.

If there are stricter requirements according to THE SUPPLIER standard operation procedure, this must be agreed by both parties in the transfer/validation protocol.

12.2.2 Method transfer and validation between THE SUPPLIER and third parties under THE CLIENT responsibility

In the case of transfers between THE SUPPLIER and third parties under THE CLIENT responsibility, the leadership for the method transfer is at THE CLIENT. The transfer protocol and report shall be prepared by THE SUPPLIER and reviewed and approved by THE CLIENT and the third party.

If there are stricter requirements according to THE SUPPLIER standard operation procedure, this must be agreed by both parties in the transfer/validation protocol.

12.3 Reference standards

Non-commercial reference standards for testing of products are supplied by THE SUPPLIER or THE CLIENT, as agreed upon.

If not stored at room temperature, standards have to be stored in qualified and monitored storage chambers. Large amounts of reference standards have to be aliquoted in a suitable way in order to avoid multiple freeze / thaw cycles.

12.4 Testing of samples

THE SUPPLIER shall use only the most current edition of official monographs, unless otherwise requested by THE CLIENT.

In the event that THE CLIENT uses its own methods based on official monographs, such as European Pharmacopoeia, Pharmacopée française, Pharmacopoeia Internationalis, The British Pharmacopoeia, The Canadian Formulary, The National Formulary, The Pharmaceutical Codex and The United States Pharmacopoeia ("Official Monographs"), THE CLIENT is responsible to provide the most current copies to THE SUPPLIER.

If the methods are not from Official Monographs, then THE CLIENT shall provide THE SUPPLIER with its own validated methods.
Complex methods (e.g. HPLC) that are from Official Monographs are recommended to be verified. Client is responsible for the verification of such methods.

THE SUPPLIER shall carry out testing according to the assays listed in Appendix B that have to be applied according to the analysis request form / testing instruction. All raw data acquired by THE SUPPLIER and the subsequent calculation of results shall be reviewed, dated and initialed by a second qualified person. All individual results shall be assessed for conformity.

The final report shall be reviewed and approved by THE SUPPLIER qualified personal and responsible scientist / responsible staff member of THE SUPPLIER testing laboratory.

If any standard, reagent, analytical column or other material required for analysis of THE CLIENT's samples is not routinely used by THE SUPPLIER, THE CLIENT shall be required to provide such item to THE SUPPLIER or, alternatively, THE SUPPLIER shall purchase the item and invoice THE CLIENT for its cost with THE CLIENT's approval. In this event, the item so purchased shall be used only for testing THE CLIENT's sample and not for any other purpose and shall be returned to THE CLIENT upon the termination of this Agreement.

Whenever possible, each testing shall be completed within two weeks from reception of sample and THE CLIENT's complete and unambiguous instructions (exception shall be communicated to each party), unless the test itself requires more time. THE SUPPLIER shall contact THE CLIENT as soon as possible, in case of delay.

12.5 Reporting of results

THE SUPPLIER prepares and provides to THE CLIENT for each delivery of service, the final documentation of analyses in the form of a Certificate of Analysis (CoA). Documentation has to be performed according to the good documentation practice guidelines.
CoA must include:

- THE CLIENT sample Name,
- Batch specific information, if applicable
- Test method,
- Test results,
- Specification, if applicable
- Date of testing (optional),
- Review and approval by responsible persons (responsible scientist/responsible staff member and if applicable, THE SUPPLIER quality assurance),
- List of Major/Critical deviation/OOS.

The CoA/final report shall be sent as hard copy and as a PDF-file by e-mail.

Note: On request, THE SUPPLIER shall provide to THE CLIENT preliminary results, but those results must not be considered as official.

12.6 Stability OOS (if applicable)

THE SUPPLIER shall notify THE CLIENT of any OOS related to stability results which is affecting the quality of the Material tested. Notification shall occur within one (1) business day of discovery to the generic email address (see Appendix A).

12.7 Stability Performed at THE SUPPLIER (if applicable)

THE CLIENT is responsible to provide approved stability protocol with all relevant instructions.

THE CLIENT has the responsibility to send enough samples to perform the stability study.

THE CLIENT has the responsibility to advise THE SUPPLIER for special handling of samples.

THE SUPPLIER is responsible to pull out sample from the chambers with max +3 days of the due date for ongoing stability studies.

THE SUPPLIER is responsible to send sample to THE CLIENT or any identified and authorized Contract lab as defined in Appendix D.

THE CLIENT is responsible to provide data loggers to THE SUPPLIER for all transfer of stability samples to third party testing site.

THE SUPPLIER is responsible to advise THE CLIENT of significant OOS excursions of stability chambers where THE CLIENT products are stored and provide a copy of the deviation.

THE SUPPLIER is responsible to advise in writing THE SUPPLIER if study needs to be ended, or extra sample need to be sent/tested.

12.8 Stability performed by THE CLIENT, stability sample send to THE SUPPLIER (if applicable)

Whenever possible, each testing shall be initiated within one (1) week of sample reception.

THE SUPPLIER shall contact THE CLIENT in case of delay.

12.9 Shipping of samples

THE CLIENT shall ship to THE SUPPLIER sufficient samples for the purpose of the testing, accompanied with a request of analysis. THE CLIENT shall ensure that samples are properly packaged and labeled and that transportation conditions are suitable.
THE CLIENT shall clearly identify every sample and its storage condition requirements on a label affixed to the product's container.
If applicable, when both chemistry and microbiology testing are requested, whenever possible separate samples clearly identified must be provided.
THE CLIENT shall complete a request of analysis with the following information:

- Name of THE CLIENT's contact persons for the request of analysis, the mailing address, telephone and facsimile number;
- Information that would identify the product and batch/lot number of the sample and number of bottles (if more than one bottle);
- Test(s) required, with corresponding specifications and method analysis plus their corresponding version number, if applicable; and
- Analysis delay, special storage conditions, quotation and purchase order number, if any.

THE CLIENT must inform THE SUPPLIER of any relevant information that may affect the analysis of the sample.
THE CLIENT must inform THE SUPPLIER of any potential risk to affect employee's health and any hazardous material.

12.10 Receiving of samples and storage

On receipt of samples, THE SUPPLIER shall complete an internal receiving form or THE CLIENT sample tracking form to document the reception of sample and send it to THE

CLIENT within one (1) business day. THE SUPPLIER must immediately advise THE CLIENT of any physical damage to the samples, identification problem and missing documentation.
On receipt of samples, THE SUPPLIER has the responsibility to keep samples within required storage conditions.
QC Analytical testing sheet shall be created within one (1) business day of receipt unless there is discrepancy between request and sample received and/or missing information.
After analysis, THE SUPPLIER agrees to keep remaining samples for thirty (30) days within required storage conditions, or longer if so directed by THE CLIENT unless the testing renders the samples useless for further testing (i.e. Sterility testing) or if testing is time sensitive (i.e. water testing).
THE SUPPLIER shall maintain a system to assure proper identification and traceability of samples.

13.0 ARCHIVING OF DOCUMENTATION

THE SUPPLIER shall generate and maintain analysis reports, all records (electronic and/or paper) related to testing, instruments, reference standards and solutions used in testing THE CLIENT's samples, and personnel training records on file for a period of at least five (5) years.
Records shall be archived in an appropriate secure and protected environment in accordance with THE SUPPLIER procedures.

THE SUPPLIER shall ensure that these records are available to THE CLIENT upon request within one week of such request or within two (2) business days for critical issues.

Following the end of the archiving period for documents specific to the services covered in this quality agreement, THE SUPPLIER shall contact THE CLIENT in writing in order to agree on the further procedure.

If no instructions are received within 30 days of the receipt of this notification, THE SUPPLIER reserves the right to perform destruction without further notice.

14.0 SAMPLE SECURITY

14.1 Waste material

Waste material shall be disposed of in a secure, environmentally friendly and legal manner preventing unauthorized use. Any sample, packaging and/or labels bearing THE CLIENT name must be defaced and/or incinerated. THE SUPPLIER shall provide appropriate documentation concerning disposal to THE CLIENT on request.

15.0 CONFIDENTIALITY (Applicable only if no formal CDA in place)

Except if required by law, regulation or court order, including, in the case of the THE CLIENT, if required by the Canadian Access to Information Act, all information exchanged between THE CLIENT and THE SUPPLIER, including, without limitation, specifications, procedures, test methods, testing data and CoA relating to THE CLIENT's test products or THE SUPPLIER's services and activities, is confidential and considered to be a trade secret of THE CLIENT or THE SUPPLIER. Neither party shall, under any circumstances, disclose this information to any other party, or use this information in any manner other than for the purposes of this Agreement, without THE CLIENT's or THE SUPPLIER's (as the case may be) prior written approval.

16.0 TERM AND EXPIRATION OF THE QUALITY AGREEMENT

This agreement shall come into force and effect once signed by the parties hereto. This quality agreement may not be amended or modified except by written agreement executed by both parties. Appendices shall be updated as needed according to the progress of development without the necessity to update this quality agreement.

This quality agreement needs to be reviewed and updated as necessary. However, it shall be reviewed at least every five (5) years. It shall remain in effect for any period during which THE SUPPLIER tests products for THE CLIENT and retains samples and related thereto. This Quality Agreement shall remain in effect until termination, expiration or cancellation of the Service Agreement unless an updated agreement is put in place in the interim.

17.0 MISCELLANEOUS

a) Notices. All notices, requests, instructions, consents and other communications to be given under this Agreement shall be in writing, addressed to each party at the address first set forth above, delivered by reputable overnight courier, and shall be deemed given upon actual delivery or first attempted delivery if delivery is refused by the intended recipient. Any party may change it address for notice by giving written notice to the other parties under this Section.

b) Assignment. No party may assign any of its rights or benefits under this Agreement, or delegate any of its duties or obligations, except with the prior written consent of the other parties.

c) Counterparts. This Agreement and all documents contemplated by or delivered under or in connection with this Agreement may be executed and delivered in any number of counterparts, with the same effect as if all parties had signed and delivered the same document, and all counterparts shall be construed together to be an original and shall constitute one and the same agreement.

d) Further Assurances. Each of the parties hereto shall, from time to time hereafter and upon any reasonable request of the other, promptly do, execute, deliver or cause to be done, executed and delivered, all further acts, documents and things as may be required or necessary for the purposes of giving effect to this Agreement.

e) Language of the Agreement. It is the express wish of the parties to this Agreement that this Agreement and all related documents be drafted in English. Les parties aux présentes conviennent et exigent que cette convention ainsi que tous les documents qui s'y rattachent soient rédigés en langue anglaise.

f) Construction. Unless the context of this Agreement otherwise requires, (i) words of any gender include each other gender; (ii) words using the singular or plural number also include the plural or singular number, respectively; (iii) the terms "hereof," "herein," "hereby" and similar or derivative words refer to this entire Agreement; (iv) the term "paragraph" refers to the specified paragraph of this Agreement; (v) the word "or" shall be deemed to include both its disjunctive and its conjunctive meaning; and (vi) the term "including" and similar or derivative words shall be deemed to be followed by the words "without limitation." Whenever this Agreement refers to a number of days, that number shall refer to calendar days unless business days are specified. As used herein, "business day" means any day other than Saturday, Sunday or any day on which banks located in Canada are authorized or obligated to close.

18.0 DEFINITIONS

- **Applicable Standards** – is defined in Section 2.0 of this Quality Agreement
- **BSE** – Bovine Spongiform Encephalopathy
- **Critical Deviation**
  - (a) The deviation has a moderate to high severity or potential to adversely affect the safety, identity, strength, quality, purity, efficacy, performance, reliability or durability of a product which has been released **or** was detected by chance and no systematic detection point is in place (with quality or compliance impact);
  - (b) Deviation represents a significant failure of a quality system;
  - (c); The deviation represents a deviation from the license or regulatory requirements impacting the product which has been released;
  - (d) Fraud or critical / systemic issue that compromises the validity, reliability and integrity of data, which may impact batches which has been released.

- **Data Integrity** - the degree to which data (paper or electronic) is complete, consistent, available and enduring throughout the data lifecycle as the data is created, reviewed, modified, maintained, retrieved, processed, transferred, etc. The data should be attributable, legible, contemporaneously recorded, original and accurate.
- **Deviation** - any unplanned occurrence, problem, non-conformance or undesirable event or incident that represents a departure from this Quality Agreement, from approved instructions, processes or procedures, from applicable regulatory standards, or that result in an unexpected observation. Deviations are categorized as Critical Deviations, Major Deviations or Minor Deviations.
- **Effective Date** – the Date of last signature of this QA Agreement
- **GMO** – Genetically Modified Organisms
- **Major Change control**
    - Replacement or addition of a new testing site
    - Change to the specifications or analytical procedures
    - Change to the test parameters or acceptance criteria of the Material specifications
    - Change to the analytical procedures used to control the Material
    - Change in stability plan

  For guidance: **Change control** to be Notified: (Health Canada *Guidance Document: Post-Notice of Compliance (NOC) Changes: Quality Document* and Appendix 1 (Human Pharmaceuticals), Appendix 3 (Biologics))

    - Level I – Reporting category: Supplements (major quality changes)
    - Level II – Reporting category: Notifiable Changes (moderate quality changes)
    - Out-of-scope: Level III - Annual Notification (minor quality changes) and Level IV Changes - record of changes
    -
- **Major Deviation**
    - (a) The deviation has a moderate to high severity or potential to adversely affect the safety, identity, strength, quality, purity, efficacy, performance, reliability or durability of a product in our control **and** is detected during a routine check.
    - (b) The deviation has low severity or potential to adversely affect the safety, identity, strength, quality, purity, efficacy, performance, reliability or durability of a product which has been released **and** is detected during a routine check.

- (c) The deviation has low severity or potential to adversely affect the safety, identity, strength, quality, purity, efficacy, performance, reliability or durability of a product in our control **and** was detected by chance and no systematic detection point is in place (with quality or compliance impact).
- (d) The deviation represents a deviation from the license or regulatory requirements without impacting the product.
- (e) Critical, systemic or intentional issue of data integrity without impact on batches.

- **Minor Deviation**
  - (a) A deviation that is neither critical nor major.
  - (b) The deviation has a low severity or potential to adversely affect the safety, identity, strength, quality, purity, efficacy, performance, reliability or durability of a product in our control **and** is detected during a routine check.
  - (c) One-off data integrity issue without impact on batches.
- **OOS** – Out of Specification
- **Products** –the pharmaceutical products manufactured, distributed and/or sold by THE CLIENT
- **Service** – the Service supplied by SUPPLIER listed in Appendix B
- **Specifications** –the Specifications for the Materials agreed between THE SUPPLIER and THE CLIENT and referenced in Appendix B
- **Supply Agreement** – the relevant commercial supply agreement between any SUPPLIER entity and THE CLIENT in relation to any service
- **TSE** – Transmissible Spongiform Encephalopathy

19.0 LIST OF APPENDICES

APPENDIX A	List of Contacts
APPENDIX B	List of Services
APPENDIX C	List of Responsibilities
APPENDIX D	List of approved SUPPLIERs (Outsourced activities)
APPENDIX E	History of Changes

20.0 SIGNATURES

The parties have agreed with the foregoing terms and conditions and, in testimony whereof, the parties have signed

SUPPLIER: XXXXXX

Name	Title	Signature and Date

CLIENT: National Research Council Canada

Name	Title	Signature and Date
Helene Mauboussin	Team Leader, Quality Assurance, HHT	
Stephanie Hetzel	Team Leader, Quality Control, HHT	
Nadia Mameri	Section Head, Quality Unit, HHT	
Susan Twine, PhD	Director General, HHT	

Quality Agreement between NRC HHT and XXXXX **NRC Business Confidential (Protected B) Once approved**	**Page** 1 **of** 5
APPENDIX A: LIST OF QA/QC LIAISONS	**Version:** 01

THE CLIENT Contacts

Name	**Function**	**Address**
Helene Mauboussin	Quality Assurance	6100 Royalmount Montreal (Quebec) H4P 2R2 Canada
Telephone	**e-mail**	
438-364-6052	Helene.Mauboussin@nrc-cnrc.gc.ca	
QA Generic Email address	NRC.HHTQualityAssurance-AssuranceQualitePTSH.CNRC@nrc-cnrc.gc.ca	

Name	**Function**	**Address**
Stephanie Hetzel	Quality Control	6100 Royalmount Montreal (Quebec) H4P 2R2 Canada
Telephone	**e-mail**	
514-207-6483	Stephanie.Hetzel@nrc-cnrc.gc.ca	
QC Generic Email address	NRC.GMPExtTest-TestExtBPF.CNRC@nrc-cnrc.gc.ca	

Name	**Function**	**Address**
Nadia Mameri	Section Head Quality	6100 Royalmount Montreal (Quebec) H4P 2R2 Canada
Telephone	**e-mail**	
438-993-3704	Nadia.Mameri@cnrc-nrc.gc.ca	

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APPENDIX A: LIST OF QA/QC LIAISONS	**Version:** 01

Delivery Address

Name	**Function**	**Address**
Catalin Rusu	Material Coordinator	Clinical Trial Manufacturing Facility (CTMF) 6100 Royalmount Montreal (Quebec) H4P 2R2, Canada
Telephone	**e-mail**	
438-340-7436	Catalin.Rusu@cnrc-nrc.gc.ca	

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APPENDIX A: LIST OF QA/QC LIAISONS	Version: 01

THE SUPPLIER Contacts

Name	Function	Address
Telephone	e-mail	

Name	Function	Address
Telephone	e-mail	

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APPENDIX A: LIST OF QA/QC LIAISONS	Version: 01

SIGNATURES:

SUPPLIER: XXXXXX

Name	Title	Signature and Date

CLIENT: National Research Council Canada

Name	Title	Signature and Date
Helene Mauboussin	Team Leader, Quality Assurance, HHT	
Stephanie Hetzel	Team Leader, Quality Control, HHT	
Nadia Mameri	Section Head, Quality Unit, HHT	
Susan Twine, PhD	Director General, HHT	

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APPENDIX A: LIST OF QA/QC LIAISONS	Version: 01

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APPENDIX B: LIST OF SERVICE	Version: 01

Testing Type	Chemistry	Biological	Microbiological
Validation			
Stability storage			
Stability testing			
Raw material testing			
Semi-finished / Finished product testing			

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APPENDIX B: LIST OF SERVICE	**Version:** 01

SIGNATURES:

SUPPLIER: XXXXXX

Name	Title	Signature and Date

CLIENT: National Research Council Canada

Name	Title	Signature and Date
Helene Mauboussin	Team Leader, Quality Assurance, HHT	
Stephanie Hetzel	Team Leader, Quality Control, HHT	
Nadia Mameri	Section Head, Quality Unit, HHT	
Susan Twine, PhD	Director General, HHT	

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APPENDIX B: LIST OF SERVICE	Version: 01

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APPENDIX C: TABLE OF RESPONSIBILITIES	**Version:** 01

C = THE CLIENT
S = THE SUPPLIER

Directives and Guidelines	
Comply with Health Canada *(or applicable)* code/s of cGMP / GLP and quality systems	C/S
Upon receipt of a newly issued GMP certificate from the authorities provide a copy to the client	S

Inspections and Audits	
Facilities, operations and quality systems may be audited by the client or on behalf of the client in order to ensure compliance with this quality agreement, GMP guidelines	C/S
Write audit report within thirty (30) calendar days	C
Propose corrective actions within thirty (30) calendar days	S
Correct audit observations in a timely manner	S
Inform the client within two (2) business days after the announcement of a foreign or local governmental authority inspection directly related to THE CLIENT's Samples and/or THE CLIENT's test results	S

Outsourced Activities	
Use only approved supplier for the delegation of any portions of obligations under this Quality Agreement	S
Request written approval from the client before outsourcing any of the work described in the Quality Agreement to a third party	S
Establish Quality Agreements with approved suppliers and monitor them	S

Quality Agreement between NRC HHT and XXXXX **NRC Business Confidential (Protected B) Once approved**	**Page** 2 **of** 6
APPENDIX C: TABLE OF RESPONSIBILITIES	**Version:** 01

Facility	
Manage its operations, facilities and equipment to prevent any type of contamination	S
Ensure the cleanness and quality of the Materials supplied	S

Change Control	
Prepare change controls and communicate change controls which may have an impact on the testing results of a Material at least ninety (90) calendar days prior to such change	S
Evaluate the supplier change request	C
Approve change controls	C
Propose changes to the Quality Agreement in writing	C/S
Inform the client in case of changes to facility with a potential impact on the valid GMP Certificate	S
Inform the client about changes to the client analytical methods or specifications	C
Inform the client about changes to the supplier or subcontractor analytical methods or specifications (include draft SOP with change described in version history)	S
Approval of the supplier change including SOP regarding analytical testing methods or specifications	C
Implementation of change at the supplier following the client approval	S
Inform the client within ten (10) days of the implementation of changes in specifications of material or methods resulting from the update of compendia and pharmacopoeia	S

Deviations / OOS / OOT results

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APPENDIX C: TABLE OF RESPONSIBILITIES	**Version:** 01

Inform the client within one (1) business days of any Critical or Major deviation or OOS / OOT which is affecting the testing results.	S
Investigate Deviations / OOS / OOT results	S
Provide the client with copy of investigation report at the client's request	S

Complaints	
Management of complaints	C
Investigate all complaints addressed by the client and sent a preliminary report investigation within fifteen (15) calendar days client and send a final report of investigation within thirty (30) business days	S

Data Integrity	
Ensure all data relevant for activities conducted pursuant to this quality assurance agreement is accurate, controlled and safe from intentional or unintentional manipulation	S
Investigate any breach of data integrity (DI) concerning the client testing	S
Inform the client if potential impact on the quality of product or services provided (including DI issues arising from outsourced activities)	S

Testing of Products	
Perform tests according to testing instructions (Appendix B)	S
Review all records and analytical results for compliance	S
Submit approved results to the client	S

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APPENDIX C: TABLE OF RESPONSIBILITIES	**Version:** 01

Testing of Products	
Validate testing method	S
Establishment of Reference Standards	S
Retention of Reference Standard documents	S
Prepare, approve and provide Certificate of Analysis	S
OOS results referenced in the Certificate of Analysis (CoA)	S
Perform stability studies as per agreed stability protocol	S

Archiving Of Documentation	
Archive raw data for agreed periods of time	S

Qualification and Validation	
Ensure adequate number of personnel with appropriate qualification, training and experience to perform operations	S
Use calibrated and qualified equipment	S
Validate computer systems used for testing	S
Facilities well maintained with access control to limited to required personnel.	S

Sample Security	
Dispose of waste material in a secure, environmentally friendly and legal manner preventing unauthorized use	S

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APPENDIX C: TABLE OF RESPONSIBILITIES	**Version:** 01

Monitoring	
Monitoring of the supplier capabilities	C
Compilation of data required for monitoring	S
Review and update the core document and appendices at least every 3 years	C/S

Confidentiality	
Confidentiality shall be set forth in the applicable section of the Service Agreement or specific Confidential Disclosure Agreement (CDA).	S

Term and Expiration of the Quality agreement	
Update of Appendices or Core Agreement	C/S

Quality Agreement between NRC HHT and XXXXX NRC Business Confidential (Protected B) Once approved	**Page** 6 **of** 6
APPENDIX C: TABLE OF RESPONSIBILITIES	**Version:** 01

SIGNATURES:

SUPPLIER: XXXXXX

Name	Title	Signature and Date

CLIENT: National Research Council Canada

Name	Title	Signature and Date
Helene Mauboussin	Team Leader, Quality Assurance, HHT	
Stephanie Hetzel	Team Leader, Quality Control, HHT	
Nadia Mameri	Section Head, Quality Unit, HHT	
Susan Twine, PhD	Director General, HHT	

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APPENDIX D: LIST OF APPROVED SUPPLIERS	Version: 01

Name of outsourced supplier/service provider	Outsourced Activity (describe in detail)	List outsourced analyses (if THE CLIENT samples are outsourced, detailed test description)	Other Info	Date
SUPPLIER			QA Agreement	
			Last Audit	
			GMP certificate	

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APPENDIX D: LIST OF APPROVED SUPPLIERS	Version: 01

SIGNATURES:

SUPPLIER: XXXXXX

Name	Title	Signature and Date

CLIENT: National Research Council Canada

Name	Title	Signature and Date
Helene Mauboussin	Team Leader, Quality Assurance, HHT	
Stephanie Hetzel	Team Leader, Quality Control, HHT	
Nadia Mameri	Section Head, Quality Unit, HHT	
Susan Twine, PhD	Director General, HHT	

Quality Agreement between NRC HHT and XXXXX **NRC Business Confidential (Protected B) Once approved**	**Page** 1 **of** 2
APPENDIX E: HISTORY OF CHANGES	**Version:** 01

Document Part	Version	Date	Reason for change
Core document			
Appendix A			
Appendix B			
Appendix C			
Appendix D			
Appendix E			

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APPENDIX E: HISTORY OF CHANGES	Version: 01

SIGNATURES:

SUPPLIER: XXXXXX

Name	Title	Signature and Date

CLIENT: National Research Council Canada

Name	Title	Signature and Date
Helene Mauboussin	Team Leader, Quality Assurance, HHT	
Stephanie Hetzel	Team Leader, Quality Control, HHT	
Nadia Mameri	Section Head, Quality Unit, HHT	
Susan Twine, PhD	Director General, HHT	

RFP 23-58226 Appendix D - Table of Years of Analyst Laboratory Experience

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External Laboratory Services to monitor the environment Clinical Trial Manufacturing Facility

Appendix D - Table of Years of Analyst Laboratory Experience

Function*	Number of years of experience in GMP	Number of years of experience in water testing	
Supervisor Quality Assurance 1			
Supervisor Quality Assurance 2			
Supervisor Quality Control 1			
Supervisor Quality Control 2			
Manager Quality Assurance 1			
Manager and Quality Control 1			
Analyst 1			
Analyst 2			
Analyst 3			
Analyst 4			
Analyst 5			

* Add additional row for supervisor, manager and analyst when required if they are involved in the scope of the SOW.