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REQUEST FOR PROPOSAL (RFP)

Reference Number: 1000175432

CLOSING DATE: **November 30, 2015** **CLOSING TIME: 2:00 PM EDT**

PROJECT TITLE: In Vitro Pharmacokinetics for High Throughput Data Interpretation

Branch/ Directorate: Healthy Environments and Consumer Safety Branch
Environmental and Radiation Health Sciences Directorate
Environmental Health Science and Research Bureau
Health Canada

FOR ADDITIONAL INFORMATION PLEASE CONTACT:

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(Departmental Representative)

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RFP Issue Date: October 20, 2015

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PART I STATEMENT of WORK

1. Scope

1.1 Title

In Vitro Pharmacokinetics for High Throughput Data Interpretation

1.2 Introduction

As one component of a project under the Chemicals Management Plan (CMP), Health Canada researchers and regulatory scientists, in collaboration, are investigating the utility of integrating *in vitro* toxicity high-throughput screening (HTS) data for human health risk assessment. The interpretation of HTS data can be provided using pharmacokinetic tools to determine the relevance of these data into estimated levels of human exposure that will provide a better basis for informed decisions on a chemicals potential for toxicity. The generation of pharmacokinetic parameters is crucial to the interpretation of the HTS data.

The service required by the Contractor is to generate the required pharmacokinetic *in vitro* data on identified chemicals (Table 1 below) in fiscal year 2015-16, and on additional chemicals to be identified before the start of fiscal year 2016-17.

1.3 Estimated Value

The overall value of the requirement, including the cost of the professional services, equipment, miscellaneous costs, and any other costs which will be associated with the requirement is estimated at $85,000 in fiscal year 2015-16, with an option estimated at $55,000 in fiscal year 2016-17). The total estimated value of the requirement over 2 fiscal years is $140,000.

1.4 Objectives of the Requirement

The aim of this project is to conduct *in vitro* experiments to generate the pharmacokinetic parameters (microsomal metabolic stability and blood protein binding) for a series of chemicals identified by the Existing Substances Risk Assessment Bureau (ESRAB). Table 1 presents the first batch of chemical to be analyzed and a second batch of chemicals will be identified before the end of fiscal year 2015-2016. The resulting data will subsequently support the needed computational *in vitro*-to-*in vivo* extrapolation (IVIVE) methods which will then be used to estimate human equivalent doses. The data obtained from these pharmacokinetic evaluations will be used to facilitate the addition of a risk context to the high-throughput *in vitro* screening data.

1.5 Background and Specific Scope of the Requirement

As part of a project funded by Canada's Chemicals Management Plan (CMP) research fund, Health Canada research and regulatory scientists are developing tools and approaches to facilitate the use of *in vitro* studies and dosimetry to establish points of departure for risk assessment. The data generated through this contract will be used to assist in developing predictive tools and informing the utility of non-traditional toxicity data for regulatory use. Specifically, the development of tools to interpret and evaluate high-priority compounds that will assist evaluation programs within Health Canada in assessing the results of the high throughput data and contribute to informed screening and risk assessment of CMP chemicals.

The list of CMP cycle 3 substances included in the first experimental batch (Table 1) represent substances that the Existing Substances Risk Assessment Bureau has identified as early data needs to support methods development and

risk assessment activities. The pharmacokinetic parameters generated through this work fulfill a data-need priority for advancing our understanding for the integration of high throughput screening data into CMP. Specifically, the ethyl glycol ethers and hindered-substance groupings are currently being considered as an early assessment grouping under the upcoming phase of CMP cycle 3 assessment. Assessment-specific timelines will become available in winter 2015-16.

Table 1: First Batch of CMP3 Chemicals to be Investigated

CAS RN	DSL Name	Group
110714	Ethane, 1,2-dimethoxy-	Ethylene glycol ethers
111466	Ethanol, 2,2'-oxybis-	Ethylene glycol ethers
111900	Ethanol, 2-(2-ethoxyethoxy)-	Ethylene glycol ethers
111966	Ethane, 1,1'-oxybis[2-methoxy-	Ethylene glycol ethers
112072	Ethanol, 2-butoxy-, acetate	Ethylene glycol ethers
112276	Ethanol, 2,2'-[1,2-ethanediylbis(oxy)]bis-	Ethylene glycol ethers
112345	Ethanol, 2-(2-butoxyethoxy)-	Ethylene glycol ethers
112492	2,5,8,11-Tetraoxadodecane	Ethylene glycol ethers
112607	Ethanol, 2,2'-[oxybis(2,1-ethanediyloxy)]bis-	Ethylene glycol ethers
79743	1,4-Benzenediol, 2,5-bis(1,1-dimethylpropyl)-	Hindered phenols
88584	1,4-Benzenediol, 2,5-bis(1,1-dimethylethyl)-	Hindered phenols
96764	Phenol, 2,4-bis(1,1-dimethylethyl)-	Hindered phenols
98544	Phenol, 4-(1,1-dimethylethyl)-	Hindered phenols
118821	Phenol, 4,4'-methylenebis[2,6-bis(1,1-dimethylethyl)-	Hindered phenols
128370	Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-	Hindered phenols
128392	Phenol, 2,6-bis(1,1-dimethylethyl)-	Hindered phenols
6683198	Benzenepropanoic acid, 3,5-bis(1,1-dimethylethyl)-4-hydroxy-, 2,2-bis[[3-[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]-1-oxopropoxy]methyl]-1,3-propanediyl ester	Hindered phenols
35958306	Phenol, 2,2'-ethylidenebis[4,6-bis(1,1-dimethylethyl)-	Hindered phenols
36443682	Benzenepropanoic acid, 3-(1,1-dimethylethyl)-4-hydroxy-5-methyl-, 1,2-ethanediylbis(oxy-2,1-ethanediyl) ester	Hindered phenols
41484359	Benzenepropanoic acid, 3,5-bis(1,1-dimethylethyl)-4-hydroxy-, thiodi-2,1-ethanediyl ester	Hindered phenols

In addition to assessment activities, the substances are part of a larger research collaboration between the Environmental Health Science Research Bureau, Existing Substances Risk Assessment Bureau, and the US EPA National Center of Computational Toxicology. The *in vitro* pharmacokinetic parameters will be used to develop *in vitro*-to-*in vivo* extrapolation methods using pharmacokinetic models, high throughput data, chemo-informatics approaches, and available published health endpoints. An important deliverable of this collaboration is the development of a case study that will address several key elements, including uncovering the considerations of using high throughput data to develop categories and to evaluate the advantages and uncertainties associated with read-across.

Further substances comprising a second list will continue to be added for data generation as they are prioritized for assessment and/or are identified as being ideal candidates to support the development of predictive tools.

2. Requirements

2.1 Tasks, Activities, Deliverables and Milestones

Tasks and Activities

The following are the tasks and activities to be performed by the Contractor to generate pharmacokinetic *in vitro* data on identified chemicals in fiscal year 2015-16, and on additional chemicals in fiscal year 2016-17 (these chemicals are to be identified by Health Canada before the start of 2016-17):

A) Metabolic Stability

The Contractor shall conduct experiments to determine the loss of the specific chemical due to metabolism. The experiments will measure the loss of parent compound from rat or human microsomes due to metabolism over time. A few examples of this type of experiment have been published by Obach et al. (1999), Nartomi et al. (2001), and Zanelli et al. (2012). It is assumed that metabolism of the chemical is mainly by microsomes in the liver where most of the target chemical is processed or eliminated from the body. The pharmacokinetic parameters are needed to determine steady-state kinetics of each targeted chemical, and the intrinsic clearance of the parent substance in this experimental system is sufficient for the models in this work.

B) Blood Protein Binding

The Contractor shall conduct experiments to determine the chemical partition difference between blood serum and proteins. The Contractor shall use blood-binding assays such as the RED plates (Waters et al., 2008) or HTD-96 (Banker et al., 2003) as a surrogate estimate for blood partitioning of the chemical. As the modeling work is intended to estimate blood concentration, it is expected that these experiments will provide insight in regard to any observed differences between the estimated blood concentrations and the different protein components from the HTS platform. While human tissues would be ideal, the Contractor can use rat tissues as a surrogate for estimation purposes.

Milestones and Deliverables:

Milestones and Deliverables	Timeline by Fiscal Year
Milestone 1 & Deliverable 1: Report on results of pharmacokinetic parameters for the 1st batch of chemicals (Table 1 list of 20 chemicals)	2015-16: Before or on March 24, 2016
Milestone 2 & Deliverable 2 (Option Year): Report on final results of pharmacokinetic parameters (last 10-20 chemicals to be identified)	2015-16: Before or on March 24, 2017

2.2 Specifications and Standards

Refer to Section 2.4 relating to specifications on how the work is to be delivered and measured as completed. Refer also to the deliverables outlined in section 2.1.

2.3 Technical, Operational and Organizational Environment

The Contractor must have experience in the performance and management of *in vitro* pharmacokinetic laboratory experiments. The Contractor shall ensure that all necessary resources (e.g., chemicals, reagents, instruments, etc.) will be available to meet the requirements for the completion of the work.

The Contractor shall ensure that all reports are delivered in accordance with the requirements specified in Section 2.1**.** The Contractor shall also ensure that all of the deliverables are compatible with the technical specifications of the Department at the time the deliverables are completed/achieved.

Refer also to sections 1.4 and 1.5 regarding how the work will fit within other initiatives and who will be the ultimate end user of the requirement.

2.4 Method and Source of Acceptance

The Scientific and Technical Authority will review each deliverable (report) submitted by the Contractor and indicate in writing to the Contractor within five (5) working days whether the deliverable has been accepted, and will identify any required changes to the deliverables. The Contractor will have five (5) working days to revise the deliverable unless both parties agree to an alternative deadline. At that point, the Scientific and Technical Authority will re-review the deliverable and determine if it is acceptable.

2.5 Reporting Requirements

The Contractor shall submit to the Scientific and Technical Authority one (1) copy of each deliverable in electronic format as a Microsoft Word document. Other file formats (e.g., Microsoft Excel, etc.) may be employed as required. For all documents containing experimental data and sent to the Scientific and Technical Authority by the Contractor, the Contractor shall ensure that the documents do not contain personal data (or that such data are de-identified) collected by the Contractor. As part of the intellectual property, only the Contractor will keep all personal data. If other, periodic status reports by the Contractor are required, each status report will outline the accomplishments for the given period, open issues, and upcoming milestones.

2.6 Project Management Control Procedures

The Scientific and Technical Authority shall monitor the progress of the work, and ensure that the contract is completed on time and on budget and that the work is of acceptable quality. Any changes to the scope of the analyses outlined in this contract and/or identified by the Contractor will need to be presented in writing for consideration and agreement by the Scientific and Technical Authority. In identifying a proposed change in the Scope or any other element of the Statement of Work, the Contractor shall justify why the change is being recommended, the estimated cost (if any) of the change, the impact on the resources of the Contractor and Health Canada, and the impact on the timeline for the work. The Scientific and Technical Authority shall respond within five (5) working days regarding the decision to approve or not approve the recommended change. If the change is approved, a formal proposal will be required from the Contractor for review and acceptance by Health Canada, and the contract will be amended accordingly.

See also the details identified in sections 2.4, 2.5 and 3.1.

3. Additional Information (Other Terms and Conditions of the SOW)

3.1 Authorities

Authorities will be announced at time of contract award.

3.2 Canada's Obligations

a) Establish tasks, activities, timelines, deliverables, and milestones for the Contractor.
b) Provide access to a staff member who will be available to coordinate activities and provide advice if needed.
c) Review and provide comments on the Contractor's draft reports within five (5) working days of the receipt of these reports. Final reports submitted by the Contractor will be reviewed by the Scientific and Technical Authority, and a response sent to the Contractor within ten (10) working days if changes to the final reports are required.

3.3 Contractor's Obligations

In addition to the requirements and obligations specified elsewhere in this Statement of Work, the Contractor shall: :

i) Update the Scientific and Technical Authority regarding progress and any unanticipated difficulties;

ii) Work closely with the Scientific and Technical Authority to ensure that the generated data/information are of acceptable quality.
iii) Unless otherwise specified, the Contractor must use its own equipment and software for the performance of tasks and activities outlined in this Statement of Work.

Refer to Sections 2.1 through 2.8 for other obligations of the Contractor.

3.4 Location of Work, Work Site, and Delivery Point

All work will be conducted and completed at the Contractor's site/facility. Due to existing workload and deadlines, all personnel assigned to the contract resulting from the Request for Proposal (RFP) must be ready to work in close and frequent contact with the Scientific and Technical Authority and other specified departmental personnel. As such, the Contractor must be available for periodic meetings (e.g., teleconferences).

The contract incorporating this Statement of Work will be interpreted and governed by the laws of the Province of Ontario.

3.5 Language of Work

Any interim or status reports, draft reports, the final report, and any written correspondence with the Scientific and Technical Authority shall be prepared in English.

3.6 Special Requirements

There are no special requirements associated with this requirement.

3.7 Insurance Requirements

It shall be the sole responsibility of the Contractor to determine whether specific insurance coverage is required for its own protection or for its employees to fulfil its obligations under the contract, and to ensure compliance with required federal, provincial or municipal laws, by-laws, and regulations. Any such insurance shall be provided and maintained by the Contractor at its own expense. The Contractor shall ensure that sub-contracted organizations have all work-related insurance in place, including coverage of employees of these organizations.

3.8 Travel and Living

Not applicable (there is no travel anticipated for this requirement).

4. Project Schedule

4.1 Expected Start and Completion Dates

The services of the Contractor will be required for a period of approximately five (5) months commencing on or about the 3rd of December, 2015, with the option of renewing for one additional fiscal year. This period includes at least one month to apply the full acceptance criteria for the final deliverable. The expected completion date of this project is the 31th of March, 2016. Should the option year be exercised, the expected completion date is the 31st of March, 2017.

4.2 Schedule and Estimated Level of Effort (Work Breakdown Structure)

Refer to 2.1 "Tasks, Activities, Deliverables and Milestones."

Payment Schedule:

Payment Date	Deliverable	Amount
Fiscal Year 2015-16		
1) Before or on March 24, 2016	Deliverable 1	$85,000
	Total	**$85,000**
Option Year (2016-17)		
1) Before or on March 24, 2017	Deliverable 2	$55,000
	Total	**$55,000**
	Grand Total	**$140,000**

5. Required Resources or Types of Roles to be Performed

The Contractor is required to provide sufficient resources to complete the tasks, activities, and milestones identified in section 2.1. The work outlined requires the services of a team of skilled research professionals that possess the specific expertise required to carry out the work. Additionally, the work requires that the Contractor have:

a) In-house facility with state-of-the art *in vitro* and analytical equipment on premise;
b) The expertise necessary to perfom drug metabolism pharmacokinetic (DMPK) experiments;
c) The expertise necessary to communicate pharmacokinetic data for environmental chemicals;
d) The relevant experience providing guidance at a senior level in a similar project;

6. Applicable Documents and Glossary

1. Applicable Documents

Reference Documents

Banker, MJ, Clark TH, and Williams JA. (2003). Development and validation of a 96-well equilibrium dialysis apparatus for measuring plasma protein binding. *J Pharm Sci* 92:967-974.

Naritomi, Y., Terashita, S., Kimura, S., Suzuki, A., Kagayama, A., and Sugiyama, Y. (2001). Prediction of human hepatic clearance from in vivo animal experiments and in vitro metabolic studies with liver microsomes from animals and humans. *Drug Metab. Dispos.* 29, 1316–1324.

Obach, R. S. (1999). Prediction of human clearance of twenty-nine drugs from hepatic microsomal intrinsic clearance data: An examination of in vitro half-life approach and nonspecific binding to microsomes. *Drug Metab. Dispos.* 27, 1350–1359.

Waters NJ, Jones R, Williams G, Sohal B. Validation of a rapid equilibrium dialysis approach for the measurement of plasma protein binding. *J Pharm Sci.* 2008 Oct;97(10):4586-95.

Zanelli U, Caradonna NP, Hallifax D, Turlizzi E, Houston JB. Comparison of cryopreserved HepaRG cells with cryopreserved human hepatocytes for prediction of clearance for 26 drugs. *Drug Metab Dispos.* 2012 Jan;40(1):104-10

PART II PROPOSAL REQUIREMENTS

7.0 Administrative Instructions for Completion of the RFP

7.0 Administrative Information

7.1 General Information

7.1.1 Components, Language and Number of Copies

You are invited to submit via e-mail electronic copies in either official language (English or French) of both the Technical and Cost Proposals to:

Robert.Merrick@hc-sc.gc.ca

The RFP Reference Number and the name of the Requirement must be in the subject line of your e-mail and your proposal must be structured in the following manner:

- one covering letter, signed by an authorized representative of your firm;
- *one* (1) *electronic* copy of the Technical Proposal;
- one (1) copy of Certifications (Appendix "A") and;
- *one* (1) copy of the Cost/Price Proposal (Appendix "B") ") **saved as a separate document.**

If the proposal is **greater than 20mb**, the firewall protecting Health Canada's network system will not permit the e-mail to be received. In which case, the bid will have to be physically delivered to the address cited below and an email sent to the Departmental Representative (found on page 1) stating that the bid has been delivered by hand / courier. You **must** send an email to the Departmental Representative to ensure your bid is included in this solicitation. The RFP Reference Number and the name of the Departmental Representative must be marked on all documents, binders and respective envelopes delivered by hand. If you are delivering hard copies, your proposal must be structured in the following manner:

- one covering letter, signed by an authorized representative of your firm;
- four (4) copies of the Technical Proposal;
- one (1) copy of Certifications (Appendix "A") and;
- *one* (1) copy of the Cost/Price Proposal (Appendix "B"), contained in a ***separate sealed envelope*.**

Deliveries by hand / courier are to be sent to the following address:

Health Canada Bid Receiving Unit
Federal Records Centre Building,
161 Goldenrod Driveway (Loading Dock),
Ottawa, Ontario K1A 0K9
Attention: Robert Merrick
RFP Reference Number: 1000175432

Hours of Operation: 07h30 to 16h30 (EST) Monday to Friday

7.1.3 No Payment for Pre-Contract Costs

No payment will be made for costs incurred in the preparation and submission of a proposal in response to this RFP. No costs incurred before receipt of a signed contract or specified written authorization from the Departmental Representative can be charged to the proposed contract.

7.2 Delivery Instructions for Bid / Proposal

As per section 7.1.1

The onus for submitting bids on time at the specified location rests with the bidder. It is the responsibility of the bidder to ensure correct and timely delivery of the entire bid to the Crown, including all required information and proposal pages.

7.3 Non-Acceptance of Proposal by Facsimile

Proposals sent by fax, telex and telegraphic means will **not** be accepted.

7.4 Closing Date and Time

All proposals must be received at the specified on the front page of this Request for Proposal. Proposals received after this time will be returned unopened. The onus for submitting bids on time at the specified location rests with the bidder. It is the bidder's responsibility to ensure correct delivery of its bid to the Crown.

7.5 Time Extension to Closing Date

A request for a time extension to the closing date will be considered only in exceptional circumstances. Any requests for extension must be received in writing by the identified Departmental Representative.

7.6 Non-Compliance / Unacceptable Proposals

Failure to meet the mandatory requirements of this RFP will result in your proposal being declared non-responsive.

Proposals received after the proposal closing time will not be considered and will be returned unopened to the bidder. Further, for any proposals which are found to be non-compliant, the financial part of the bid or proposal will be returned unopened with a letter from Health Canada indicating that the bid/proposal was non-compliant.

7.7 Bidders Conference / Site Visits

There is no site visit with this requirement. However, resource(s) proposed by the Contractor will be interviewed in order to confirm their level of knowledge and experience.

7.8 Announcement of Successful Contractor

Health Canada will communicate to all bidders the name and address of the successful candidate as well as the total dollar value and award date for the contract only after contract sign-off.

7.9 Rights of the Crown

The Crown reserves the right to:

- reject any or all proposals received in response to this RFP;
- accept any proposal in whole or in part; and
- cancel and/or re-issue this requirement at any time.

7.10 Sample Long Form Contract

The successful bidder for this requirement will be expected to enter into agreement with Health Canada as per departmental contract terms and conditions.

7.11 Employment Equity

Not applicable.

7.12 Procurement Business Number (PBN)

Public Works and Government Services Canada (PWGSC) has adopted the Procurement Business Number (PBN) for all its purchasing databases, and now requires that its suppliers have one for each of their offices that may be awarded contracts. Go to **Buyandsell.gc.ca** to register in the Supplier Registration Information (SRI) service and to obtain your PBN. As an existing or potential supplier to the Department, you must obtain a PBN to avoid possible delays of any contract award. It is Health Canada=s intention to use this sourcing system for all its procurements of goods and services to which the trade agreements do not apply.

SRI is a database of suppliers who have registered to do business with the Government of Canada. The PBN is created using your Canada Revenue Agency Business Number to uniquely identify a branch, division or office of your company. Unlike many existing departmental vendor databases, your information in SRI is accessible to all federal government buyers. SRI can help to open up new opportunities with the federal government for requirements not posted on the electronic tendering service, www.buyandsell.gc.ca.

Visit the **Buyandsell.gc.ca** Internet site at https://srisupplier.contractscanada.gc.ca/index-eng.cfm?af=ZnVzZWFjdGlvbj1yZWdpc3Rlci5pbnRybyZpZD00&lang=eng for information and registration procedures.

7.13 Order of Precedence

In the case of any dispute which may arise during the period which may be covered by any ensuing contract, the following documents will be considered in order of precedence in terms of importance in resolving any disputes between the parties:

- The Health Canada Contract;
- Any changes to the terms and conditions contained herein which have been approved by General Counsel for Health Canada;
- The Statement of Work in this RFP; and
- The terms identified in this RFP.

8.0 Technical Proposal

8.1 General Information

Your technical proposal must address all the requirements of the SOW and demonstrate that you are capable of meeting all obligations of the contractor specified in the same.

Your technical proposal must meet **all of the Mandatory Requirements** listed in Section 12.0, as well as the **minimum score identified for the Point Rated Requirements** in Section 13.0.

Furthermore, your technical proposal should include the following:

8.2 Understanding of the Requirements

A brief statement that demonstrates that the contractor understands the requirements of the SOW, including the objectives, scope of work and deliverables.

8.3 Approach and Methodology:

8.3.1 General Approach

A description of the overall approach and strategy to this project.

8.3.2 Methodology

Identify methodologies and techniques to be used, including identifying any proprietary information which is proposed to be used in the program.

8.3.3 Work Plan / Project Schedule

Break down the work by task - show phases, planned start, completion dates and the estimated level of effort (i.e. person days) needed to complete the task. The work plan may include a matrix and/or time line charts. A project schedule structured in weeks, reflecting milestones and deliverables, should be included.

8.3.4 Performance and Quality Control

Specify how you propose to deal with the performance and quality assurance of the work provided by your organization to the Crown. Include information about quality control methods and reporting mechanisms.

8.4 Proposed Team

8.4.1 Personnel

Identify the proposed personnel, including **Project Manager**, who will be assigned to this contract, describe the role they will be performing, including the amount of direct time dedicated to the project by principals and/or senior personnel, and explain why they are well suited for the work, referring to their qualifications, certifications, education and experience.

If applicable, include a list of proposed sub-contractors, with reference to their capabilities, experience and degree of involvement in the work.

The bidder must certify in the technical proposal that the information provided in all the personnel résumés has been verified to be true and accurate. In addition, for every

resource proposed by the bidder who is not an employee of the firm, the actual resource must certify that they are aware that they are being bid as part of the bid/ proposal and state their relationship with the firm.

8.4.2 Contingency Plan

If the contract cannot be completed by the assigned personnel, the following individual(s) will complete the work. *Attach résumés.*

8.5 Contractor Profile

8.5.1 Organization

Provide background information about your company, including its legal name and the province in which the company is incorporated.

8.5.2 Relevant Work Experience

Describe your company's capacity and experience in this field.

8.5.3 References

If references for a firm or proposed resource are requested, identify the number of referenced; the criteria against which they will be applied; and the specific details which the reference will have to address. Caution should be taken when using references: they are not criteria in themselves but are instead ways of verifying compliance with a specific criteria. Further care should be taken to ensure that the person providing the reference is able to provide objective, useful and valid information.

8.6 Résumés of Personnel

Attach résumés of proposed personnel.

9.0 Cost / Price Proposal Please see Appendix B

9.1 General Information

The Price Proposal must contain a detailed breakdown of the **total quoted price**, by phase, or by major tasks, or both. The Price Proposal should address each of the following, if applicable:

9.1.1 *Per Diem*

For each individual and/or labour category to be employed on the project, including subcontractors, indicate the proposed time rate and the estimated time requirement. Although detailed support for the rates is not requested at this time, you should be prepared to substantiate the proposed rates.

9.1.2 Travel

Estimate the cost of travel using the current Treasury Board Travel Directive. **9.1.3**

9.1.3 Other Expenses

List any other expenses which may be applicable, giving an estimated cost for each (e.g. long distance communications, reproduction, shipping, equipment, rentals, materials, etc.).

9.1.4 Goods and Services Tax / Harmonized Sales Tax

Various items in your cost proposal may be subject to GST / HST or custom duties, and this charge must be included in the cost estimates where applicable.

10.0 Enquiries

All enquiries or issues concerning this procurement must be submitted **in writing only** to the Departmental Representative named on the front cover page of this RFP document **not later than seven (7) working days prior to the bid closing date.**

To ensure consistency and quality of information to Bidders, the Departmental Representative will provide, simultaneously to all bidders to which this solicitation has been sent,

- any information with respect to significant enquiries received, and
- the replies to such enquiries without revealing their sources,

provided that such enquiries are received no less than seven (7) working days prior to the bid closing date.

All enquiries and other communications with government officials throughout the solicitation and evaluation period are to be directed **only** to the Departmental Representative named on the front cover page of this RFP document. **Non-compliance with this condition during the bid solicitation and evaluation period may be sufficient reason for bid disqualification.**

PART III BID SELECTION PROCESS

11.0 Introduction

Below are separate mandatory and point-rated criteria to be used to evaluate the bids.

12.0 Mandatory Requirements

12.1 Method of Evaluation

Mandatory requirements are evaluated on a simple pass or fail basis. Failure by bidders to meet any of the mandatory requirements will render the bidder's proposal **non-responsive**. The treatment of mandatory requirements in any procurement process is absolute.

Proposers must meet **all** the mandatory requirements described below. This will be evaluated as either "**Yes**" or "**No**". Proposals not receiving "**Yes**" for any mandatory requirement will ***not*** be considered further.

12.2 Mandatory Requirements

Attention Bidders: Write beside each of the criteria the relevant page number(s) from your proposal that addresses the requirement identified in the criteria.			
Mandatory Criteria	**Page #**	**Yes**	**No**
M1. The bidder's project team must have a team leader with PhD in a biomedical sciences field and analytical expert with a PhD relevant to the work described in the Statement of Work. Provide a description in 500 words or less.			
M2. The bidder's project leader must demonstrate that within the last 5 years, they have undertaken projects to measure drug metabolism pharmacokinetic parameters using of in vitro analysis. Provide a one-page summary for the most recent projects.			
M3. The bidder must have at least 5 years of experience in conducting drug metabolism pharmacokinetics studies.			
M4. The bidder must have at least 5 years of experience employing high end analytical techniques to assess in vitro experiments.			
M5. The bidder must clearly outline the methods that will be employed to meet the technical requirements described in the Statement of Work. Proposed methods must be clearly described, consistent with the SOW's requirements, and be sufficiently detailed so as to demonstrate the bidder's overall competence, experience and grasp of the required services.			

13.0 Point Rated Requirements

13.1 Method of Evaluation

A proposal with a score less than the specified minimum for technical compliance for any one criteria will be considered non responsive, and eliminated from the competition. To be considered responsive, a bid must obtain the required minimum of **36 points** for the criteria which are subject to point rating. The rating is performed on **a scale of 100 points.**

13.2 Point Rated Requirements

Attention Bidders: Write beside each of the criteria the relevant page number(s) from your proposal which addresses the requirement identified in the criteria.				
Point-Rated Criteria	**Page Number**	**Points Allocated for the Criteria**	**Minimum Points Required**	**Score**
R1. Indicate the number of past projects for which the bidder's project team has described in the mandatory criteria that is similar to in terms of scope, size, timeline, and complexity as this proposal. Twenty points for each, up to a maximum of 60 points.		60	20	
R2. Indicate the number of peer-reviewed publications for which the bidder's project team was listed as an author and which dealt with drug metabolism pharmacokinetic analysis. Provide the full reference of article. Two points for each, up to a maximum of 10 points.		10	4	
R3. Indicate the number of years the bidder's project team has conducted research involving in vitro drug metabolism pharmacokinetic experiments. Two points for each, up to a maximum of 10 points.		10	4	
R4. Indicate the number of years the bidder's project team has conducted research involving metabolic stability experiments. Two points for each, up to a maximum of 10 points.		10	4	

R5. Indicate the number of years the bidder's project team has conducted research involving short-term adverse health risks attributable to air pollutionblood protein binding experiments. Two points for each, up to a maximum of 10 points.		10	4	
Total Points		100	36	

14.0 BASIS OF AWARDING CONTRACT

Highest Technical Score within Budget:

It is understood by the parties submitting proposals that, to qualify, bidders **must** meet all mandatory requirements as well as the minimum score identified for the point-rated criteria. The contract will be awarded to the bidder with the highest technical score who stays within the budget of $85,000 for this fiscal year (FY2015-16) and $55,000 for the option year FY2016-17. The total budget for this requirement, including the option year, is $140,000.

CERTIFICATIONS

15.0 In order to confirm the authority of the person or persons signing the certifications or to establish the legal capacity under which the Bidder proposes to enter into Contract, any Bidder who carries on business in other than its own personal name shall, if requested by Canada, provide satisfactory proof of:

(a) such signing authority; and
(b) the legal capacity under which it carries on business;

prior to contract award. Proof of signing authority may be in the form of a certified copy of a resolution naming the signatory(ies) that is (are) authorized to sign this tender on behalf of the corporation or partnership. Proof of legal capacity may be in the form of a copy of the articles of incorporation or the registration of the business name of a sole proprietor or partnership.

Note to Bidders: The following certification requirements apply to this RFP. Bidders complete these certifications by filling in the appropriate spaces below and include them with their proposal.

Legal name and bidder's information (print clearly)

Bidder's Legal Name _____

Bidder's Complete Address _____

_____

_____

Bidder's Phone number (_____)_____

Bidder's Authorized Representative _____

Bidder's Authorized Representative Phone number (_____)_____

Bidder's Authorized Representative e-mail_____

Bidder's GST/HST Number _____

Bidder's province in which he is incorporated. _____

15.1. Bidder Certification

We hereby offer to sell to Her Majesty, in accordance with the Health Canada terms and conditions referred to herein or attached hereto, the goods and/or services listed herein and on any attached sheets at the prices set out therein.

We certify that all information provided herein is accurate. Furthermore we have satisfied ourselves that the personnel proposed by us for this requirement are capable of satisfactorily performing the requirements described herein. In addition, we certify that individuals proposed will be available until completion of the

project. Also, that the work specified herein can be met in a timely manner, and will be achieved with the time frame allocated.

_____ _____

Signature of the Authorized Representative of the Bidder Date

15.2. Bid Validity Certification

We certify that all pricing identified in the bid/ proposal will be valid for a period of one hundred twenty (120) days from the closing date of the RFP.

_____ _____

Signature of Authorized Representative of the bidder Date

15.3 Employment Equity

Not applicable.

15.4. Status of Resources

If we have proposed any person in fulfillment of this requirement who is not an employee (of the Bidder), we hereby certify that we have the written permission from the person to propose his/her services in relation to the Work to be performed in fulfillment of this requirement.

_____ _____

Signature of the Authorized Representative of the Bidder Date

15.5. Price Certification

We certify that the price quoted in this Proposal is not in excess of the lowest price charged anyone else, including its most favoured customer, for like quality and quantity of the products/services, does not include an element of profit on the sale in excess of that normally obtained on the sale of products/services of like quality and quantity, and does not include any provision for discounts to selling agents. **Furthermore, we certify that our total bid price is not in excess of any funding limitations set out herein.**

_____ _____

Signature of the Authorized Representative of the Bidder Date

15.6. Joint Venture Information (if applicable)

A joint venture is an association of two or more parties who temporarily combine their money, property, knowledge, or other resources in a joint business enterprise. There are two primary types of joint ventures, the incorporated joint venture and the contractual joint venture, i.e. formed through a contractual agreement between the parties.

If a contract is awarded to a contractual joint venture, all members of the joint venture shall be jointly and severally or solitarily liable for the performance of the Contract.

If the Bidder is submitting a type of joint venture, the Bidder must provide the following information in the proposal:

(a) indicate the type of joint venture:
- incorporated joint venture
- limited partnership joint venture
- partnership joint venture
- contractual joint venture
- other (explain)

(b) provide the legal names and addresses of all of the members of the joint venture (i.e. the legal name of the firm associated with the Business Number (BN) or Social Insurance Number (SIN) for sole proprietorships), as well as the legal name and address of the joint venture business entity**.**

Appendix "B"

Tableau "A1" – From Contract award to March 31, 2016

A	B	C	D (BxC)
Category of Personnel Insert rows as required	Per Diem Rate(s)	Level of Effort/Number of Days Required	Total Costs for Professional Fees TAXES NOT INCLUDED
1.	$		$
2.	$		$
		Sub-Total 1:	$