



RETURN BIDS TO:
RETOURNER LES SOUMISSIONS À:
Bid Receiving - PWGSC / Réception des
soumissions - TPSGC
11 Laurier St. / 11, rue Laurier
Place du Portage, Phase III
Core 0BZ / Noyau 0BZ
Gatineau, Québec K1A 0S5
Bid Fax: (819) 997-9776

REQUEST FOR PROPOSAL
DEMANDE DE PROPOSITION

Proposal To: Public Works and Government Services Canada

We hereby offer to sell to Her Majesty the Queen 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 therefor.

Proposition aux: Travaux Publics et Services Gouvernementaux Canada

Nous offrons par la présente de vendre à Sa Majesté la Reine 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-annexée, au(x) prix indiqué(s).

Comments - Commentaires

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

Issuing Office - Bureau de distribution
Science Procurement Directorate/Direction
de l'acquisition
de travaux scientifiques
11C1, Phase III
Place du Portage
11 Laurier St. / 11, rue Laurier
Gatineau, Québec K1A 0S5

Title-Sujet REGULATORY AFFAIRS SUPPORT SERVICES	
Solicitation No. - N° de l'invitation W3931-150076	Date 2016-04-22
Client Reference No. - N° de référence du client W3931-150076	
GETS Reference No. - N° de référence de SEAG PW-16-00730603	
File No. - N° de dossier 035sv W3931-150076	CCC No./N° CC - FMS NO. / N° VME
Solicitation Closes - L'invitation prend fin at - à 2:00 PM on - le 2016-06-02	Time Zone Fuseau horaire Eastern Daylight Time (EDT)
F.O.B. - F.A.B Plant-Usine : <input type="checkbox"/> Destination: <input checked="" type="checkbox"/> Other-Autre: <input type="checkbox"/>	
Address Enquiries to: - Adresser toutes questions à: Joseph Hulse	Buyer Id - Id de l'acheteur 035SV
Telephone No. - N° de téléphone 873-469-4832	FAX No. - N° de FAX 819-957-2229
Destination of Goods, Services and Construction: Destinations des biens, services et construction : Specified Herein Précisé dans les présentes	

Instructions : See Herein

Instructions : voir aux présentes

Delivery Required - Livraison exigée See Herein	Delivery Offered - Livraison proposée
Vendor/Firm Name and Address Raison sociale et adresse du fournisseur/de l'entrepreneur	
Telephone No. - N° de telephone Facsimile No. - N° de télécopieur	
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. Introduction

The bid solicitation is divided into seven parts plus attachments and annexes, as follows:

- Part 1 General Information: provides a general description of the requirement;
- Part 2 Bidder Instructions: provides the instructions, clauses and conditions applicable to the bid solicitation;
- Part 3 Bid Preparation Instructions: provides bidders with instructions on how to prepare their bid;
- Part 4 Evaluation Procedures and Basis of Selection: indicates how the evaluation will be conducted, the evaluation criteria that must be addressed in the bid, and the basis of selection;
- Part 5 Certifications: includes the certifications to be provided;
- Part 6 Security, Financial and Other Requirements: includes specific requirements that must be addressed by bidders; and
- Part 7 Resulting Contract Clauses: includes the clauses and conditions that will apply to any resulting contract.

The Annexes include the Statement of Requirement, the Basis of Payment, and DND 626 Task Authorization form.

2. Summary

PWGSC intends to award a contract for the provision of a regulatory affairs and product development specialist team to prepare and file regulatory submissions to meet Health Canada (HC) regulations for drugs, biologics and medical devices on behalf of the Department of National Defence (DND)

The resulting contract is for a period of 3 years, with 2 additional, 1 year option periods, and a 6 month optional transitional period.

There is no security requirement associated with this requirement.

Bidders must provide a list of names, or other related information as needed, pursuant to section 01 of Standard Instructions 2003.

For services requirements, Bidders in receipt of a pension or a lump sum payment must provide the required information as detailed in attachment 3 of Part 5 of the bid solicitation.

The requirement is limited to Canadian goods and/or services.

Canada will own the Intellectual Property Rights in the Foreground Information.
This procurement is subject to the Agreement on Internal Trade (AIT)



"There is a Federal Contractors Program (FCP) for employment equity requirement associated with this procurement; see Part 5 - Certifications, Part 7 - Resulting Contract Clauses and the attachment named Federal Contractors Program for Employment Equity - Certification."

3. Debriefings

After contract award, 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 of receipt of the results of the bid solicitation process. The debriefing may be in writing, by telephone or in person.

4. Communications

As a courtesy and in order to coordinate any public announcements pertaining to this contract, the Government of Canada requests that successful Bidders notify the Contracting Authority 5 days in advance of their intention to make public an announcement related to the recommendation of a contract award, or any information related to the contract. The Government of Canada retains the right to make primary contract announcements.

5. Conflict of Interest

The Work described herein and the deliverable items under any resulting Contract specifically exclude the development of any statement of work, evaluation criteria or any document related to a bid solicitation. The Contractor, its subcontractor(s) or any of their agent(s) directly or indirectly involved in the performance of the Work and/or in the production of the deliverables under any resulting Contract will not be precluded from bidding on any potential future bid solicitation related to the production or exploitation of any concept or prototype developed or delivered under any resulting Contract.

PART 2 - BIDDER INSTRUCTIONS



1. Standard Instructions, Clauses and Conditions

All instructions, clauses and conditions identified in the bid solicitation by number, date and title are set out in the [Standard Acquisition Clauses and Conditions Manual](https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual)(<https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual>) issued by Public Works and Government Services Canada.

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.

The 2003 (2016-04-04) Standard Instructions - Goods or Services - Competitive Requirements, are incorporated by reference into and form part of the bid solicitation.

Subsection 5.4 of 2003, Standard Instructions - Goods or Services - Competitive Requirements, is amended as follows:

Delete: 60 days
Insert: 120 days

2. Submission of Bids

Bids must be submitted only to Public Works and Government Services Canada (PWGSC) Bid Receiving Unit by the date, time and place indicated on page 1 of the bid solicitation.

Due to the nature of the bid solicitation, bids transmitted by facsimile to PWGSC will not be accepted.

3. 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 in Attachment 3 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.

4. Communications - Solicitation Period

All enquiries must be submitted in writing to the Contracting Authority no later than 10 calendar days before the bid closing date. Enquiries received after that time may not be answered.

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 questions or may request that the Bidder do so, so that the proprietary nature of the question is eliminated, and the enquiry can be answered with copies to all bidders. Enquiries not submitted in a form that can be distributed to all bidders may not be answered by Canada.



5. Applicable Laws

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

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.

6. Improvement of Requirement During Solicitation Period

Should bidders consider that the specifications or Statement of Requirement contained in the bid solicitation could be improved technically or technologically, bidders are invited to make suggestions, in writing, to the Contracting Authority named in the bid solicitation. Bidders must clearly outline the suggested improvement as well as the reason for the suggestion. Suggestions that do not restrict the level of competition nor favour a particular bidder will be given consideration provided they are submitted to the Contracting Authority at least 5 days before the bid closing date. Canada will have the right to accept or reject any or all suggestions.

7. Basis for Canada's Ownership of Intellectual Property

The Department of National Defence has determined that any intellectual property rights arising from the performance of the Work under the resulting contract will belong to Canada, on the following grounds: statutes, regulations or previous obligations of Canada to a third party or parties preclude contractor ownership of the Intellectual Property Rights in Foreground Information.

PART 3 - BID PREPARATION INSTRUCTIONS

1. Bid Preparation Instructions



Canada requests that bidders provide their bid in separately bound sections as follows:

- Section I: Technical Bid (4 hard copies and 1 soft copy on CD in .doc 2013, or earlier, format)
- Section II: Financial Bid (1 hard copy and 1 soft copy on CD in .doc 2013, or earlier, format)
- Section III: Certifications (1 hard copy)

If there is a discrepancy between the wording of the soft copy and the hard copy, the wording of the hard copy will have priority over the wording of the soft copy.

Prices must appear in the financial bid only. No prices must be indicated in any other section of the bid.

Canada requests that bidders follow the format instructions described below in the preparation of their bid:

- (a) use 8.5 x 11 inch (216 mm x 279 mm) paper;
- (b) use a numbering system that corresponds to the bid solicitation.

In April 2006, Canada issued a policy directing federal departments and agencies to take the necessary steps to incorporate environmental considerations into the procurement process [Policy on Green Procurement](http://www.tpsgc-pwgsc.gc.ca/ecologisation-greening/achats-procurement/politique-policy-eng.html) (<http://www.tpsgc-pwgsc.gc.ca/ecologisation-greening/achats-procurement/politique-policy-eng.html>). To assist Canada in reaching its objectives, bidders should:

- 1) use 8.5 x 11 inch (216 mm x 279 mm) paper containing fibre certified as originating from a sustainably-managed forest and containing minimum 30% recycled content; and
- 2) use an environmentally-preferable format including black and white printing instead of colour printing, printing double sided/duplex, using staples or clips instead of cerlox, duotangs or binders.

Section I: Technical Bid

In their technical bid, bidders should demonstrate their understanding of the requirements contained in the bid solicitation and explain how they will meet these requirements. Bidders should demonstrate their capability in a thorough, concise and clear manner for carrying out the work.

The technical bid should address clearly and in sufficient depth the points that are subject to the evaluation criteria against which the bid will be evaluated. Simply repeating the statement contained in the bid solicitation is not sufficient. In order to facilitate the evaluation of the bid, Canada requests that bidders address and present topics in the order of the evaluation criteria under the same headings. To avoid duplication, bidders may refer to different sections of their bids by identifying the specific paragraph and page number where the subject topic has already been addressed.

Section II: Financial Bid

- 1. Bidders must submit their financial bid in accordance with the following:



- a) A firm all-inclusive hourly rate for each category of resources listed in Attachment 1 Financial Bid Presentation Sheet for each year of the contract period, for each option period and for the transition period.

The total amount of Applicable Taxes are to be shown separately, if applicable.

No travel and living expenses will be paid for services provided within the National Capital Region (NCR). Further, Canada will not accept any travel and living expenses for travel between the contractor's place of business and the NCR. All of these costs are to be included in the firm all inclusive labour rates requested above.

The information must be provided in accordance with the Financial Bid Presentation Sheet in Attachment 1.

- b) For Canadian-based bidders, prices must be in Canadian funds, Canadian customs duties and excise taxes included, and Applicable tax excluded.

For the purpose of the bid solicitation, bidders with an address in Canada are considered Canadian-based bidders and bidders with an address outside of Canada are considered foreign-based bidders.

1.2 Exchange Rate Fluctuation

C3011T (2013-11-06), Exchange Rate Fluctuation

Section III: Certifications

Bidders must submit the certifications required under Part 5.

PART 4 - EVALUATION PROCEDURES AND BASIS OF SELECTION

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.

1.1 Technical Evaluation

1.1.1 Bidder Experience

Except where expressly provided otherwise, the experience described in the bid must be the experience of one or more of the following:

1. The Bidder itself (which includes the experience of any companies that formed the Bidder by way of a merger but does not include any experience acquired through a purchase of assets or an assignment of contract); or
2. The Bidder's affiliates (i.e. parent, subsidiary or sister corporations, maximum of 4), provided the Bidder identifies and demonstrates the transfer of know-how, the use of toolsets and the use of key personnel from the affiliate for the applicable criterion; or
3. The Bidder's subcontractors (maximum of 4), provided the Bidder includes a copy of the teaming agreements and identifies the roles and responsibilities of all parties under the agreement and how their work will be integrated.

The experience of the Bidder's suppliers will not be considered.

1.1.2 Supporting Information

In the event that the Bidder fails to submit any supporting information pursuant to the technical or financial criteria the Contracting Authority may request it thereafter in writing, including after the closing date of the bid solicitation. It is mandatory that the Bidder provide the supporting information within three (3) business days of the written request or within such period as specified or agreed to by the Contracting Authority in the written notice to the Bidder.

1.2 Mandatory and Point Rated Criteria

Mandatory and Point Rated Technical evaluation criteria are included in Attachment 2.

1.3 Financial Evaluation

1.3.1 Evaluation of Price

The price of the bid will be evaluated in Canadian dollars, Applicable Taxes excluded, Canadian customs duties and excise taxes included.

For evaluation purposes only, the price of the bid will be determined as detailed in Attachment 1, Financial Bid Presentation Sheet.

2. Basis of Selection

2.1 Basis of Selection - Highest Combined Rating of Technical Merit and Price



In this clause, *Technical Merit* refers to the *Technical Evaluation Score*

1. To be declared responsive, a bid must:
 - (a) comply with all the requirements of the bid solicitation;
 - (b) meet all mandatory criteria; and,
 - (c) obtain the required minimum of 60% percent overall score, calculated to 2 decimal points, for the technical evaluation criteria which are subject to point rating.

The rating is performed on a scale of 238 points.
2. Bids not meeting (a) or (b) or (c) will be declared non-responsive.
3. The selection will be based on the highest responsive combined rating of technical merit and price. The ratio will be 60 % for the technical merit and 40 % for the price.
4. To establish the technical merit score, the overall technical score for each responsive bid will be determined as follows: total number of points obtained / maximum number of points available multiplied by the ratio of 60 %.
5. To establish the pricing score, each responsive bid will be prorated against the lowest evaluated price and the ratio of 40 %.
6. For each responsive bid, the technical merit score and the pricing score will be added to determine its combined rating, calculated to 2 decimal points.
7. Neither the responsive bid obtaining the highest technical score nor the one with the lowest evaluated price will necessarily be accepted. The responsive bid with the highest combined rating of technical merit and price will be recommended for award of a contract. In the event that two or more responsive bids have the same combined rating of technical merit and price, the responsive bid with the lowest evaluated price will be recommended for award of a contract.

The table below illustrates an example where all three bids are responsive and the selection of the contractor is determined by a 60/40 ratio of technical merit and price, respectively. The total available points equals 135 and the lowest evaluated price is \$45,000 (45).

Basis of Selection - Highest Combined Rating Technical Merit (60%) and Price (40%)

	Bidder		
	Bidder 1	Bidder 2	Bidder 3
Overall Technical Score	120/135	102/135	115/135
Bid Evaluated Price	\$55,000.00	\$50,000.00	\$45,000.00
	Calculations		
Technical Merit Score	$120/135 \times 60 = 53.33$	$102/135 \times 60 = 45.33$	$115/135 \times 60 = 51.11$
Pricing Score	$45/55 \times 40 = 32.73$	$45/50 \times 40 = 36.00$	$45/45 \times 40 = 40.00$



Combined Rating	86.06	81.33	91.11
Overall Rating	2nd	3rd	1st



**“ATTACHMENT 1”
FINANCIAL BID PRESENTATION SHEET**

For evaluation purposes only, the price of the bid will be determined as follows:

1. The estimated level of effort per year specified is only an approximation of requirements.
2. The Bidder must complete the following table identifying price information for year one through year five. Bidder must indicate a firm all inclusive hourly rate.
3. Total Bid Price for Evaluation Purposes = Cumulative Total for all work categories. Each work category total will be calculated as follows: $g = (a \times b) + (a \times c) + (a \times d) + (a \times e) + (a \times f) + (a \times g)/2$

Quantity	Labour Category	Period					Option Period 1	Option Period 2	Optional Transitional Period	
		Firm All Inclusive Hourly Rate								
		Estimated level of effort per year (a)	Year 1 (b)	Year 2 (c)	Year 3 (d)	Year 4 (e)	Year 5 (f)	6 month (g)	Total (g) = (a x b) + (a x c) + (a x d) + (a x e) + (a x f) + (a x g)/2	
2 resources	Strategic Level Resource	300 hours	\$	\$	\$	\$	\$	\$		
1 resource	General Level Resource	225 hours	\$	\$	\$	\$	\$	\$		
1 resource	Administrative Level Resource	45 hours	\$	\$	\$	\$	\$	\$		
Total Evaluated Bid Price:										



“Attachment 2”

Mandatory and Point Rated Technical Criteria

In their proposals, bidders must demonstrate they meet the following mandatory criteria. Failure to meet any of the mandatory criteria will render the bid non-compliant and it will be given no further consideration.

EVALUATION CRITERIA

- a) The Bidder must submit the résumés of each proposed resource for each labour category to demonstrate the resources experience in response to the mandatory and point rated technical criteria.
- b) The Bidder must demonstrate its experience and each proposed resource's experience in terms of months. Unless otherwise specified, 1 year of experience is equivalent to 1200 hours. For the purpose of calculating months and years of experience, overlapping experience will only be counted once (e.g. Project #1 time frame is July 2016 to December 2016; Project #2 time frame is October 2016 to January 2017; the total experience for these two project references is seven (7) months).
- c) Demonstrated concurrent experience will be accepted for evaluation purposes.
- d) University degree requirements specified under the labour categories must be from a recognized Canadian university, or the equivalent, as established by a recognized Canadian academic credentials assessment service*, if obtained outside Canada.

* The list of recognized organizations can be found under the Canadian Information Centre for International Credentials website, at the following Internet link:
<http://www.cicic.ca/indexe.stm>

- e) Where the post-secondary degree or diploma was completed and obtained outside of Canada, Canada reserves the right to request a Canadian equivalency document to be provided by the Bidder and issued by recognized academic credentials assessment organization showing the academic level obtained.
- f) In evaluating resource past performance experience, compliance must be demonstrated through a well written, coherent, brief (if possible), past project description containing the following as a minimum:
 - Name of the project. (e.g. prepared cardiac drug NDS, etc).
 - Description of the type of Drug or Medical Product
 - Resources position.
 - Resources work start date.
 - Resources work completion date.
 - Duration of the experience in months.
 - Description of the project and other relevant details that document how this experience has been acquired by the Bidder (for corporate level criteria) and proposed resources (for proposed resource criteria).
 - An explanation how this experience meets the specific criteria of this solicitation.
- g) If the Bidder submits more than one resource for one or more of the required resource categories, Canada will evaluate only the first named resource presented in the proposal for each required resource category.



1. Mandatory Criteria

1.1 At bid closing time, the Bidder must comply with the following mandatory criteria and provide the necessary documentation to support compliance. Any bid which fails to meet the following mandatory criteria will be declared non-responsive. Each criterion should be addressed separately.

1.2 The following criteria will be applied to the evaluation. This table should be completed and submitted by each Bidder.

	Mandatory Criteria	Reference page number in proposal
	Corporate Level	
M1	<p>The Bidder must have achieved Health Canada approval of at least ten submissions for Schedule "D" or "F" drugs, as defined in the Canadian <i>Food and Drugs Act</i>. The Bidder must provide evidence of this, with at least two submission approvals in the last 10 years from the date of solicitation closing, from each of the following categories:</p> <ol style="list-style-type: none"> 1. Issuance of Notice of Compliance (NOC) for a New Drug Submissions (NDS); 2. Drug Identification Number (DIN); 3. No Objection Letter (NOL); and, 4. Any other four approvals. <p>Evidence of this track record should not contain proprietary information. Inclusion of dates of approvals along with the drug category is required. Acceptance at screening for further review does not constitute Health Canada approval.</p>	
	Strategic Level Resource	
M2	<p>The proposed Resources must demonstrate that they have successfully completed a Health Sciences PhD degree from an accredited Canadian university, or the equivalent, as established by a recognized Canadian academic credentials assessment service, in one of the following fields:</p> <ul style="list-style-type: none"> • chemistry • toxicology • biochemistry • biology • microbiology • pharmacy • pharmacology • or other Health Scientific equivalent field as recognized by the Faculty of Science of a Canadian University <p>A copy of the degree must be included with the proposal.</p>	
M3	<p>The Proposed Resources must have a minimum of 8 years experience, within the last 15 years, in Canadian Regulatory Affairs, from the date of solicitation closing, in the interpretation of Canadian and international regulatory requirements as they</p>	



	pertain to medical products.	
	General Level Resource	
M4	<p>The proposed Resource must have a Health Sciences BSc. degree from an accredited Canadian university, or the equivalent, as established by a recognized Canadian academic credentials assessment service, in one of the following fields:</p> <ul style="list-style-type: none"> • chemistry • toxicology • biochemistry • biology • microbiology • pharmacy • pharmacology • or other Health Scientific equivalent field as recognized by the Faculty of Science of a Canadian University <p>A copy of the degree must be included with the proposal.</p>	
M5	The proposed Resource must demonstrate a minimum of 3 years experience in Canadian Regulatory Affairs, in drafting regulatory submissions including summarizing study reports and annotating submission sections for medical products.	
	Administrative Level Resource	
M6	The proposed Resource must demonstrate a minimum of 1 year experience in the assembly of regulatory submission binders including the preparation and labeling of dividers, photocopying and document formatting.	

2. Rated Criteria

2.1 The Bidder should complete the table below for each criterion and provide the supporting narrative immediately below each table.

2.1.1 Corporate Level:

No.	Criteria Description	Points Available	Reference page # in proposal
R1	The Bidder should demonstrate its experience in the last 5 years from the date of solicitation closing, in the negotiation of New Drug Submissions (NDS) requirements, including labelling, with Health Canada.		
	1 to 10 submissions;	5 points	



11 to 20 submissions;	10 points	
More than 20 submissions.	15 points	
Maximum Points	15 points	

2.1.2 Strategic Level Primary and Back-up Resource

No.	Criteria Description	Points Available Primary Resource	Points Available Back-up Resource	Reference page # in proposal Primary Resource	Reference page # in proposal Back-up Resource
R1	The Strategic Level Resource holds a Canadian, European Union or a United States Regulatory Affairs Certificate.	5 points	5 points		
	Maximum Points	5 points	5 points		
R2	The Strategic Level Resource should demonstrate its experience acquired in the last 5 years from the date of solicitation closing, in the preparation of the following Canadian regulatory documents for medical products:				
	a. New Drug Submissions (NDS) and related supplements;	2 points per Submission (max 10 points)	2 points per Submission (max 10 points)		
	b. Clinical Trial Application (CTA);	1 point per Application (max 5 points)	1 point per Application (max 5 points)		
	c. Drug Development Plans;	2 points per Plan (max 10 points)	2 points per Plan (max 10 points)		
	d. Medical Device License Applications;	2 points per Application (max 10 points)	2 points per Application (max 10 points)		
	d. Investigational Testing Application (ITA);	1 point per Application (max 5 points)	1 point per Application (max 5 points)		
	e. Medical Device development plans.	1 point per Plan (max 5 points)	1 point per Plan (max 5 points)		
	Maximum Points	45 points	45 points		
R3	The Strategic Level Resource should demonstrate its experience acquired in the last 5 years from the date of solicitation closing, in the development of a pharmaceutical product. Product development experience includes provision of final technical/scientific documents as specified below:				



	a. Requirements analysis, E.g. analysis of currently held documentation and identification of further studies required by Health Canada to complete a submission;	1 point per analysis (max 5 points)	1 point per analysis (max 5 points)		
	b. Technical/scientific reviews of candidate medical products;	1 point per review (max 5 points)	1 point per review (max 5 points)		
	c. Development of pharmaceutical pre-clinical studies and clinical trial designs;	1 point per study and trial (max 5 points)	1 point per study and trial (max 5 points)		
	d. Assessments of the application of Good Laboratory Practices (GLP), Good Clinical Practices (GCP), and Good Manufacturing Practices (GMP), E.g. assessment of current practices, identification of deficiencies and recommendations for deficiency resolution;	1 point per assessment (max 5 points)	1 point per assessment (max 5 points)		
	e. Quality control and assurance assessments, E.g. assessment of current practices, identification of deficiencies and recommendations for deficiency resolution;	1 point per assessment (max 5 points)	1 point per assessment (max 5 points)		
	f. Development of regulatory strategies for candidate products.	1 point per strategy (max 5 points)	1 point per strategy (max 5 points)		
	Maximum Points	30 points	30 points		
R4	The Strategic Level Resource should demonstrate its experience acquired in the last 5 years from the date of solicitation closing, in chairing meetings between Health Canada and sponsor representatives.	2 points per meeting (max 10 points)	2 points per meeting (max 10 points)		
	Maximum Points	10 points	10 points		
R5	The Strategic Level Resource should demonstrate its experience acquired in the last 5 years from the date of solicitation closing, in the critical evaluation of the following, as related to medical products :				
	Pre-clinical study reports;	1 point per evaluation (max 5 points)	1 point per evaluation (max 5 points)		
	Clinical study reports;	1 point per evaluation (max 5 points)	1 point per evaluation (max 5 points)		



Chemistry, Manufacturing & Controls reports.	1 point per evaluation (max 5 points)	1 point per evaluation (max 5 points)		
Maximum Points	15 points	15 points		

2.1.3 General Level Resource

No.	Criteria Description	Points Available	Reference in proposal (page #)
R1	The General Level Resource should demonstrate that it has successfully completed a Canadian post-graduate regulatory certification program or holds a Canadian Regulatory Affairs Certificate (RAC).	5 points	
	Maximum Points	5 points	
R2	General Level Resource should demonstrate its experience acquired in the last 5 years from the date of solicitation closing, in the preparation of the following Canadian regulatory documents for pharmaceutical products :		
	a. NDS and related supplements; and	1 points per Submission (max 5 points)	
	b. Clinical Trial Application (CTA).	1 point per Submission (max 3 points)	
	Maximum Score	8 points	

GRAND TOTAL	Total points available = 238 points	Maximum Allocated Scores:
Minimal total score = 143 points (60%) (Rounded to 2 decimal pts.)		Corporate = 15 Strategic = 210 General = 13



PART 5 - CERTIFICATIONS

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

The certifications provided by bidders to Canada are subject to verification by Canada at all times. 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 may render the bid non-complaint or constitute a default under the Contract.

1. Certifications Required Precedent to Contract Award and Certifications Required with the Bid

1.1 Certifications Required Precedent to Contract Award

1.1.1 Integrity Provisions – Declaration of Convicted Offences

In accordance with 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.

1.1.2 Federal Contractors Program for Employment Equity - Bid Certification

By submitting a bid, the Bidder certifies that the Bidder, and any of the Bidder's members if the Bidder is a Joint Venture, is not named on the Federal Contractors Program (FCP) for employment equity "FCP Limited Eligibility to Bid" list (http://www.labour.gc.ca/eng/standards_equity/eq/emp/fcp/list/inelig.shtml) available from Employment and Social Development Canada (ESDC) - Labour's website.

Canada will have the right to declare a bid non-responsive if the Bidder, or any member of the Bidder if the Bidder is a Joint Venture, appears on the "FCP Limited Eligibility to Bid" list at the time of contract award.

Canada will also have the right to terminate the Contract for default if a Contractor, or any member of the Contractor if the Contractor is a Joint Venture, appears on the "[FCP Limited Eligibility to Bid](#)" list during the period of the Contract.

The Bidder must provide the Contracting Authority with a completed [Federal Contractors Program for Employment Equity - Certification](#), found at Attachment 3 before contract award. If the Bidder is a Joint Venture, the Bidder must provide the Contracting Authority with a completed Federal Contractors Program for Employment Equity - Certification, for each member of the Joint Venture.

1.2 Certifications Required with the Bid

Bidders must complete and submit the certifications in Attachment "3" Certifications Required with the Bid, as part of their bid.



“Attachment 3”

**CERTIFICATIONS PRECEDENT TO CONTRACT AWARD AND
CERTIFICATIONS REQUIRED WITH THE BID**

1.0 Certifications Required Precedent to Contract Award

1.1 Integrity Provisions

1. Bidders should provide, with their bids or promptly thereafter, a complete list of names of:
 - a. suppliers that are corporate entities, including those bidding as joint ventures, must provide a complete list of the names of all current directors or, for a privately owned corporation, the names of the owners of the corporation;
 - b. suppliers bidding as sole proprietors, including sole proprietors bidding as joint ventures, must provide a complete list of the names of all owners; or
 - c. suppliers that are a partnership do not need to provide a list of names.

If such a list has not been received by the time the evaluation of bids is completed, the Contracting Authority will inform the Bidder of a time frame within which to provide the information. Bidders must submit the list before contract award, failure to provide such a list within the required time frame will render the bid non-responsive.

COMPLETE LIST OF BIDDER'S DIRECTORS	
1	4
2	5
3	6

2. The Contracting Authority may, at any time, request that a Bidder provide properly completed and Signed Consent Forms (Consent to a Criminal Record Verification form – PWGSC- TPSGC 229) for any or all individuals named in the aforementioned list within a specified delay. Failure to provide such Consent Forms within the delay will result in the bid being declared non-responsive.
3. **Provision of additional information:** The supplier must provide any further information relevant to the Policy, including certifications and third-party validations, by the time so requested by PWGSC or the contracting authority.

**1.2 FEDERAL CONTRACTORS PROGRAM FOR EMPLOYMENT EQUITY
CERTIFICATION**

I, the Bidder, by submitting the present information to the Contracting Authority, certify that the information provided is true as of the date indicated below. The certifications provided to Canada are subject to verification at all times. I understand that Canada will declare a bid non-responsive, or will declare a contractor in default, if a certification is found to be untrue, whether during the bid evaluation period or during the contract period. Canada will have the right to ask for additional information to verify the Bidder's certifications. Failure to comply with any request or requirement imposed by Canada may render the bid non-responsive or constitute a default under the Contract.

For further information on the Federal Contractors Program for Employment Equity visit [Employment and Social Development Canada \(ESDC\)-Labour's](http://www.esdc.gc.ca/employment-social-development) website.

Date: _____ (YYYY/MM/DD) (If left blank, the date will be deemed to be the bid solicitation closing date.)



Complete both A and B.

A. Check only one of the following:

- A1. The Bidder certifies having no work force in Canada.
 - A2. The Bidder certifies being a public sector employer.
 - A3. The Bidder certifies being a federally regulated employer being subject to the Employment Equity Act.
 - A4. The Bidder certifies having a combined work force in Canada of less than 100 employees (combined work force includes: permanent full-time, permanent part-time and temporary employees [temporary employees only includes those who have worked 12 weeks or more during a calendar year and who are not full-time students]).
- A5. The Bidder has a combined workforce in Canada of 100 or more employees; and
- A5.1. The Bidder certifies already having a valid and current Agreement to Implement Employment Equity (AIEE) in place with ESDC-Labour.

OR

- A5.2. The Bidder certifies having submitted the Agreement to Implement Employment Equity (LAB1168) to ESDC-Labour. As this is a condition to contract award, proceed to completing the form Agreement to Implement Employment Equity (LAB1168), duly signing it, and transmit it to ESDC-Labour.

B. Check only one of the following:

- B1. The Bidder is not a Joint Venture.

OR

- B2. The Bidder is a Joint venture and each member of the Joint Venture must provide the Contracting Authority with a completed annex Federal Contractors Program for Employment Equity - Certification. (Refer to the Joint Venture section of the Standard Instructions)

2.0 Certifications Required with the bid

2.1 Former Public Servant - Competitive Requirements

Contracts with 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 with FPS, bidders must provide the information required below.

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 FPS 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: 2012-2 and the Guidelines on the Proactive Disclosure of Contracts.

Work Force Reduction Program

Is the Bidder a FPS who received a lump sum payment pursuant to the terms of a work force reduction program? 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 reduction program.

For all contracts awarded during the lump sum payment period, the total amount of fees that may be paid to a FPS who received a lump sum payment is \$5,000, including the Goods and Services Tax or Harmonized Sales Tax.

2.2 Status and Availability of Resources



The Bidder certifies that, should it be awarded a contract as a result of the bid solicitation, every individual proposed in its bid will be available to perform the Work as required by Canada's representatives and at the time specified in the bid solicitation or agreed to with Canada's representatives. If for reasons beyond its control, the Bidder is unable to provide the services of an individual named in its bid, the Bidder may propose a substitute with similar qualifications and experience (technical evaluation must be equal or higher). The Bidder must advise the Contracting Authority of the reason for the substitution and provide the name, qualifications and experience of the proposed replacement. For the purposes of this clause, only the following reasons will be considered as beyond the control of the Bidder: death, sickness, maternity and parental leave, retirement, resignation, dismissal for cause or termination of an agreement for default.

If the Bidder has proposed any individual who is not an employee of the Bidder, the Bidder certifies that it has the permission from that individual to propose his/her services in relation to the Work to be performed and to submit his/her résumé to Canada. The Bidder must, upon request from the Contracting Authority, provide a written confirmation, signed by the individual, of the permission given to the Bidder and of his/her availability. Failure to comply with the request may result in the bid being declared non-responsive.

2.3 Education and Experience

The Bidder certifies that all the information provided in the résumés and supporting material submitted with its bid, particularly the information pertaining to education, achievements, experience and work history, has been verified by the Bidder to be true and accurate. Furthermore, the Bidder warrants that every individual proposed by the Bidder for the requirement is capable of performing the Work described in the resulting contract.

2.4 Canadian Content Certification

This procurement is limited to Canadian services.

The Bidder certifies that:

() the service(s) offered is (are) a Canadian service as defined in paragraph 2 of clause A3050T.

2.5 SACC Manual clause A3050T (2014-11-27), Canadian Content Definition

3. Acknowledgment:

By submitting a bid, the Bidder certifies that the information submitted by the Bidder in response to the above requirements is accurate and complete.

The bid must contain no condition. Any condition, whatsoever, will render the bid non-responsive.

Name: _____ Signature: _____ Date: _____



PART 6 - SECURITY, FINANCIAL AND OTHER REQUIREMENTS

This Requirement does not contain a security requirement.



PART 7 - RESULTING CONTRACT CLAUSES

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

1.0 Statement of Requirement

The Contractor must perform the work in accordance with the Statement of Requirement at Annex A.

1.1 Task Authorization

The Work to be performed under the Contract will be on an "as and when requested basis" using a Task Authorization (TA). The Work described in the TA must be in accordance with the scope of the Contract.

1.1.1 Task Authorization Process

- a) The Technical Authority will provide the Contractor with a description of the task using the DND 626, Task Authorization Form specified in Annex D.
- b) The Task Authorization (TA) will contain the details of the activities to be performed, a description of the deliverables, and a schedule indicating completion dates for the major activities or submission dates for the deliverables. The TA will also include the applicable basis (bases) and methods of payment as specified in the Contract.
- c) The Contractor must provide the Technical Authority [and the Contracting Authority](#), within 14 calendar days of its receipt, the proposed total estimated cost for performing the task and a breakdown of that cost, established in accordance with the Basis of Payment specified in the Contract.
- d) The Contractor must not commence work until a TA authorized by the [Technical Authority or Contracting Authority \(whichever is applicable\)](#) has been received by the Contractor. The Contractor acknowledges that any work performed before a TA has been received will be done at the Contractor's own risk.

1.1.2 Task Authorization Limit

The Technical Authority may authorize individual task authorizations up to a limit of **\$25,000.00**, Applicable Taxes included, inclusive of any revisions.

Any task authorization to be issued in excess of that limit must be authorized by the Contracting Authority before issuance.

1.1.3 Minimum Work Guarantee - All the Work - Task Authorizations

1. In this clause,

"Maximum Contract Value" means the amount specified in the "Limitation of Expenditure – Cumulative Total of all Task Authorizations" clause set out in the Contract; and

"Minimum Contract Value" means 10%.



2. Canada's obligation under the Contract is to request Work in the amount of the Minimum Contract Value or, at Canada's option, to pay the Contractor at the end of the Contract in accordance with paragraph 3. In consideration of such obligation, the Contractor agrees to stand in readiness throughout the Contract period to perform the Work described in the Contract. Canada's maximum liability for work performed under the Contract must not exceed the Maximum Contract Value, unless an increase is authorized in writing by the Contracting Authority.
3. In the event that Canada does not request work in the amount of the Minimum Contract Value during the period of the Contract, Canada must pay the Contractor the difference between the Minimum Contract Value and the total cost of the Work requested.
4. Canada will have no obligation to the Contractor under this clause if Canada terminates the Contract in whole or in part for default.

1.1.4 Periodic Usage Reports - Contracts with Task Authorizations

The Contractor must compile and maintain records on its provision of services to the federal government under authorized Task Authorizations issued under the Contract.

The Contractor must provide this data in accordance with the reporting requirements detailed below. If some data is not available, the reason must be indicated. If services are not provided during a given period, the Contractor must still provide a "nil" report.

The data must be submitted on a quarterly basis period to the Contracting Authority.

The quarterly periods are defined as follows:

- 1st quarter: April 1 to June 30;
- 2nd quarter: July 1 to September 30;
- 3rd quarter: October 1 to December 31; and
- 4th quarter: January 1 to March 31.

The data must be submitted to the Contracting Authority no later than 15 calendar days after the end of the reporting period.

Reporting Requirement- Details

A detailed and current record of all authorized tasks must be kept for each contract with a task authorization process. This record must contain:

For each authorized task:

- i. the authorized task number or task revision number(s);
- ii. a title or a brief description of each authorized task;
- iii. the total estimated cost specified in the authorized Task Authorization (TA) of each task, exclusive of Applicable Taxes;
- iv. the total amount, exclusive of Applicable Taxes, expended to date against each authorized task;
- v. the start and completion date for each authorized task; and
- vi. the active status of each authorized task, as applicable.

For all authorized tasks:

- i. the amount (exclusive of Applicable Taxes) specified in the contract (as last amended, as applicable) as Canada's total liability to the Contractor for all authorized TAs; and



- ii. the total amount, exclusive of Applicable Taxes, expended to date against all authorized TAs.

1.1.5 Task Authorization - Department of National Defence (DND)

The administration of the Task Authorization process will be carried out by DND. This process includes monitoring, controlling and reporting on expenditures of the contract with task authorizations to the Contracting Authority.

2. Standard Clauses and Conditions

All clauses and conditions identified in the Contract by number, date and title are set out in the [Standard Acquisition Clauses and Conditions Manual](https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual) (https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual) issued by Public Works and Government Services Canada.

2.1 General Conditions

2040 (2016-04-04), General Conditions - Research & Development, apply to and form part of the Contract.

2.2 SACC Manual Clauses

K3410C (2015-02-25) Canada to Own Intellectual Property Rights in Foreground Information
A9113C (2014-11-27) Handling of Personal Information

3. Security Requirement

There is no security requirement applicable to the Contract.

4. Term of Contract

4.1 Period of the Contract

The Contract is for a 3 year period from date of contract award.

4.2 Option to Extend the Contract

The Contractor grants to Canada the irrevocable option to extend the term of the Contract by up to 2 additional 1 year period(s) 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.

Canada may exercise this option at any time by sending a written notice to the Contractor at least 1 calendar day prior to the Contract expiry date. The option may only be exercised by the Contracting Authority, and will be evidenced for administrative purposes only, through a contract amendment.

4.3 Transition Period

The Contractor acknowledges that the nature of the services provided under the Contract requires continuity and that a transition period may be required at the end of the Contract. The Contractor agrees that Canada may, at its discretion, extend the Contract by a period of 6 months under the same conditions to ensure the required transition. 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.

The Contracting Authority will advise the Contractor of the extension by sending a written notice to the Contractor at least 1 calendar days before the contract expiry date. The extension will be evidenced for administrative purposes only, through a contract amendment.

5. Authorities

5.1 Contracting Authority

The Contracting Authority for the Contract is:

Joseph Hulse
Public Works and Government Services Canada
Acquisitions Branch
Science Procurement Directorate
Place du Portage, Phase III, 11C1
11 Laurier Street
Gatineau, Quebec
K1A 0S5
11 Laurier Street
Gatineau, Quebec
K1A 0S5

Telephone: (873) 469-4832
Facsimile: (819) 997-2229
E-mail address: Joseph.Hulse@pwgsc.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.

5.2 Technical Authority

The Technical Authority for the Contract is:

(To be entered at contract award)

Name: _____
Title: _____
Organization: _____
Address: _____

Telephone: ____-____-_____
Facsimile: ____-____-_____
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 Technical 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.



5.3 Procurement Authority

The Procurement Authority for the Contract is:

(To be entered at contract award)

The Procurement Authority is the representative of the department or agency for whom the Work is being carried out under the Contract. The Procurement Authority is responsible for the implementation of tools and processes required for the administration of the Contract. The Contractor may discuss administrative matters identified in the Contract with the Procurement Authority however the Procurement Authority has no authority to authorize changes to the scope of the Work. Changes to the scope of Work can only be made through a contract amendment issued by the Contracting Authority.

5.4 Contractor's Representative

(To be entered at contract award)

6. Proactive Disclosure of Contracts with Former Public Servants

SACC Manual Clause A3025C (2013-03-21)

7. Payment

7.1 Basis of Payment

One of the following types of basis (bases) of payment will form part of the approved Task Authorization (TA). The task price must be determined in accordance with the Basis of Payment at Annex B.

(a) Firm Lot Price TA

In consideration of the Contractor satisfactorily completing all of its obligations under the authorized Task Authorization (TA), the Contractor will be paid the firm lot price(s) in accordance with the Basis of Payment as specified in the authorized TA. Customs duties are included and Applicable Taxes are extra.

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

(b) Ceiling Price TA

The Contractor will be reimbursed its costs reasonably and properly incurred in the performance of the Work, as determined in accordance with the Basis of Payment, to the ceiling price specified in the authorized TA. Customs duties are included, and Customs duties are included and Applicable Taxes are extra.

The ceiling price is subject to downward adjustment so as not to exceed the actual costs reasonably incurred in the performance of the Work and computed in accordance with the Basis of Payment.



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 Technical Authority before their incorporation into the Work.

(c) TA subject to a Limitation of Expenditure

The Contractor will be reimbursed for the costs reasonably and properly incurred in the performance of the Work specified in the authorized Task Authorization (TA), as determined in accordance with the Basis of Payment, to the limitation of expenditure specified in the authorized TA.

Canada's liability to the Contractor under the authorized TA must not exceed the limitation of expenditure specified in the authorized TA. Customs duties are included and Applicable Tax are extra.

No increase in the liability of Canada or in the price of the Work specified in the authorized TA resulting from any design changes, modifications or interpretations of the Work will be authorized or paid to the Contractor unless these design changes, modifications or interpretations have been authorized, in writing, by the Technical Authority or Contracting Authority (whichever is applicable) before their incorporation into the Work.

7.2 Limitation of Expenditure – Cumulative Total of all Task Authorizations.

1. Canada's total liability to the Contractor under the Contract for all authorized Task Authorizations (TAs), inclusive of any revisions, must not exceed the sum of \$ _____ (amount to be inserted at contract award) . Customs duties are included and Applicable Taxes are extra.
2. No increase in the total liability of Canada will be authorized or paid to the Contractor unless an increase has been approved, in writing, by the Contracting Authority.
3. The Contractor must notify the Contracting Authority in writing as to the adequacy of this sum:
 - (a) when it is 75 percent committed, or
 - (b) four (4) months before the Contract expiry date, or
 - (c) as soon as the Contractor considers that the contract funds provided are inadequate for the completion of the Work, inclusive of any revisions,whichever comes first.
3. If the notification is for inadequate contract funds, the Contractor must provide to the Contracting Authority a written estimate for the additional funds required. Provision of such information by the Contractor does not increase Canada's liability.

7.3 Method of Payment

7.3.1 Payments will be made not more frequently than once a month.

7.3.2 Depending on the method of payment specified in the applicable TA, one of the following method of payment clauses will apply.

7.3.2.1 Single Payment (For a TA subject to a Limitation of Expenditure or a Ceiling Price or a Firm Price)



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

- (a) an accurate and complete claim for payment using [PWGSC-TPSGC 1111](#), and any other documents 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.

7.3.2.2 Milestone Payments (For a Firm Price TA)

Canada will make milestone payments in accordance with the Schedule of Milestones detailed in the Task Authorization and the payment provisions of the Contract if:

- (a) an accurate and complete claim for payment using [PWGSC-TPSGC 1111](#), Claim for Progress Payment, and any other document required by the Contract have been submitted in accordance with the invoicing instructions provided in the Contract;
- (b) all the certificates appearing on form [PWGSC-TPSGC 1111](#) have been signed by the respective authorized representatives;
- (b) all work associated with the milestone and as applicable any deliverable required has been completed and accepted by Canada.

7.3.2.2.1 Schedule of Milestones

The schedule of milestones for which payments will be made in accordance with the Contract is as follows:

Milestone No.	Description OR Deliverable	Firm Amount	Due Date OR Delivery Date

7.3.2.3 Progress Payments (For a TA subject to a Limitation of Expenditure or a Ceiling Price)

- (a) Canada will make progress payments in accordance with the payment provisions of the Task Authorization and the Contract for cost incurred in the performance of the Work if:
 - (i) an accurate and complete claim for payment using [PWGSC-TPSGC 1111](#), Claim for Progress Payment, and any other document required by the Contract have been submitted in accordance with the invoicing instructions provided in the Contract;
 - (ii) the amount claimed is in accordance with the Basis of payment and the Task Authorization;
 - (iii) all the certificates appearing on form [PWGSC-TPSGC 1111](#) have been signed by the respective authorized representatives;



- (b) Progress payments are interim payments only. Canada may conduct a government audit and interim time and cost verifications and reserves the right to make adjustments to the Contract from time to time during the performance of the Work. Any overpayment resulting from progress payments or otherwise must be refunded promptly to Canada.

7.4 SACC Manual Clauses

A9117C (2007-11-30), T1204 - Direct Request by Customer Department
C0711C (2008-05-12), Time Verification
C0305C (2014-06-26), Cost Submission
C2000C (2007-11-30), Taxes - Foreign-based Contractor
C2605C (2008-05-12), Canadian Customs Duties and Sales Tax - Foreign-based Contractor

7.5 Discretionary Audit

C0100C (2012-01-11), Discretionary Audit - Commercial Goods and/or Services

8. Invoicing Instructions

1. The Contractor must submit a claim for payment using form [PWGSC-TPSGC 1111](#), Claim for Progress Payment.
Each claim must show (if applicable from the resulting TA):
 - a. all information required on form [PWGSC-TPSGC 1111](#);
 - b. all applicable information detailed under the section entitled "Invoice Submission" of the general conditions;
 - c. for T.A.s subject to Progress Payments, a copy of time sheets to support the time claimed;
 - d. a copy of the invoices, receipts, vouchers for all direct expenses, and all travel and living expenses;
 - e. a copy of the monthly progress report,
 - f. for milestone payments, the description and value of the milestone claimed as detailed in the Contract.
2. The Contractor must prepare and certify an original claim on Form PWGSC-TPSGC 1111, and forward it to the Contracting Authority for certification in an electronic format to the electronic mail address identified under section entitled "Authorities" of the Contract. Portable Document Format (.pdf) format is acceptable. The Contracting Authority will then forward the certified claim, in an electronic format, to the Technical Authority for appropriate certification after inspection and acceptance of the Work takes place, and onward submission to the Payment Office for the remaining certification and payment.
3. The Contractor must not submit claims until all work identified in the claim is completed.

9. Certifications

9.1 Compliance

Compliance with the certifications and related documentation provided by the Contractor in its bid is a condition of the Contract and subject to verification by Canada during the entire contract period. If the Contractor does not comply with any certification, provide the related documentation or if it is determined that any certification made by the Contractor in its bid is untrue, whether made knowingly or unknowingly, Canada has the



right, pursuant to the default provision of the Contract, to terminate the Contract for default.

9.2 Federal Contractors Program for Employment Equity - Default by the Contractor

The Contractor understands and agrees that, when an Agreement to Implement Employment Equity (AIEE) exists between the Contractor and Employment and Social Development Canada (ESDC)-Labour, the AIEE must remain valid during the entire period of the Contract. If the AIEE becomes invalid, the name of the Contractor will be added to the "[FCP Limited Eligibility to Bid](#)" list. The imposition of such a sanction by ESDC will constitute the Contractor in default as per the terms of the Contract.

9.3 SACC Manual Clause

A3060C (2008-05-12) Canadian Content Certification

10. Applicable Laws

The Contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in (to be inserted at contract award).

11. Priority of Documents

If there is a discrepancy between the wordings 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.

- (1) the Articles of Agreement;
- (2) SACC Manual Clause K3410C (2015-02-25), Canada to Own Intellectual Property Rights in Foreground Information;
- (3) the general conditions 2040 ([2015-09-03](#)), General Conditions - Research & Development;
- (4) Annex A, Statement of Requirement;
- (5) [Annex B, Basis of Payment](#);
- (6) Annex C, DND 626Task Authorization Form ; [and](#),
- (7) the Contractor's bid dated _____.

12. Insurance

SACC Manual clause G1005C (2008-05-12), Insurance

13. Foreign Nationals (Canadian Contractor)

SACC Manual clause A2000C (2006-06-16), Foreign Nationals (Canadian Contractor)

14. Canadian Forces Site Regulations

The Contractor must comply with all standing orders or other regulations, instructions and directives in force on the site where the Work is performed.



ANNEX A Statement of Requirement

1.0 OBJECTIVE

- 1.1 The objective of this requirement is to acquire the services of a team of regulatory affairs and product development specialists to prepare and file regulatory submissions to meet Health Canada (HC) regulations for drugs, biologics and medical devices. The team must comprise of:
- 1.2 2 Regulatory Affairs Professional as the Strategic Level Resource (1 Primary and 1 Back-up);
- 1.3 1 General Level Resource, and;
- 1.4 1 Administrative Level Resource.

2.0 BACKGROUND

- 2.1 It is the mandate of Regulatory Affairs of the Department of National Defence (DND)/Canadian Armed Forces (CAF) to seek regulatory approval, for operationally required drugs, biologics and medical devices. These regulatory approvals are sought from Health Canada (HC) through its Special Access Programme and other HC processes.
- 2.2 A team knowledgeable in the Canadian *Food and Drug Act* and Regulations is required to assist DND with a wide variety of regulatory and product development issues related to drugs, biologics and medical devices (henceforth referred to as medical products), as well as to research, prepare, review and negotiate regulatory submissions for medical products of interest to DND. Therefore, there is a requirement to prepare and file regulatory submissions to meet HC regulations and to develop and/or review complex industry documentation for scientific and regulatory suitability.

3.0 SCOPE

- 3.1 The Contractor must provide a team of four (4) resources as follows:
- 3.1.1 Strategic Level Support: providing in-depth technical regulatory advice, input and oversight on all deliverables, including drafting regulatory strategies and interpretation of Canadian and international regulatory requirements as they pertain to medical products. Although the Strategic Resource may not action all components of a deliverable, this Resource must be responsible for oversight and sign-off on all deliverables;
- 3.1.2 General Level Support: providing mid-level regulatory input such as submission drafting, including summarizing study reports and annotating submission sections; and
- 3.1.3 Administrative Level Support: providing administrative support, including photocopying, assembling submission binders, preparing and labelling dividers, and document formatting.
- 3.2 The Contractor must be able to commence work no later than five (5) business days subsequent to the receipt of each task authorization, not including Federal Government statutory-holidays.;



3.3 Email and phone inquiries from the Technical Authority must be acknowledged by the contractor within 24 hours of receipt; not including weekends and Federal Government statutory-holidays.

3.4 The Work may require occasional presence of the resource outside of business hours (7:00am – 5:00pm), on weekends, and Federal Government statutory-holidays.

3.5 When necessary, the Contractor must agree to dedicate additional resources to the tasking to ensure its timely completion. Additional resources must be evaluated and approved by the Technical Authority, and achieve the same or higher technical score as the current pre-qualified resources, prior to undertaking the work.

4.0 TASKS AND DELIVERABLES

4.1 The Contractor must provide services on an “as and when requested” basis, in accordance with the Task Authorization process described in the Contract. Tasks to be completed include, but are not limited to:

4.1.1 Preparing, reviewing, publishing and filing Canadian regulatory submissions in a format acceptable to Health Canada or other International Conference on Harmonization (ICH) countries;

4.1.2 Determining the suitability of foreign or domestic dossiers for filing;

4.1.3 Creating Product Monographs, Investigator’s Brochures, Quality Overall Summaries, Certified Product Information Documents and summary/overview documents for filing;

4.1.4. Providing drug development analysis and formulating drug development plans;

4.1.5. Attending meetings/teleconferences and participating in discussions and negotiations with HC, other medical regulatory agencies, allied medical product projects, medical product firms and other stakeholders;

4.1.6. Preparing and delivering briefings to senior managers and officials up to the ministerial level;

4.1.7. Liaising with industry with respect to product manufacturing, storage, and testing;

4.1.8 Researching and providing documentation for regulatory issues, such as regulatory compliance, product development, and Good Laboratory, Clinical and Manufacturing Practices;

4.1.9 Developing training materials, and quality assurance and control processes relating to deliverables to the Crown; and

4.1.10 Providing advice on regulatory and product development aspects of medical products.

4.2 Upon completion of the tasking, all deliverables must be submitted to the Technical Authority for approval. All deliverables completed in response to the task authorisation will be evaluated, on the basis of suitability, quality and adherence to established schedule and standards; as defined by the Task Authorization.

4.3 Format of Deliverables

4.3.1 All deliverables must be in, one or both of, the following formats, as designated by the Technical Authority (TA) in each Task Authorization.



- 4.2.1.1 Microsoft (MS) Office Suite of software applications and an eCTD software, including but not limited to: MS Word, Excel and PowerPoint; and or,
- 4.2.1.2 Paper format.

4.3.2 All documentation, reports and working papers must be legible, properly indexed and cross-referenced in the format approved by the Technical Authority as specified by the Task Authorization.

5.0 WORK LOCATION

- 5.1 The Work must be conducted primarily on the premises of the Contractor. The Contractor may be required to attend occasional meetings of one (1) day duration at DND premises in the National Capital Region (NCR), at the discretion of the Technical Authority. It is anticipated that these meetings will be held approximately three (3) times per year. The Contractor will not be reimbursed for travel to/from and/or within the NCR.
- 5.2 The work may arise in regions throughout Canada, the United States and overseas, for which travel may be required. These travel requirements may arise at short notice and the Contractor must be responsive to these requirements.

6.0 LANGUAGE OF WORK

- 6.1 All Work must be performed in the English language. It is a requirement that the Contractor be fluent in the English language, both for oral and written communications.

7.0. CLIENT SUPPORT

- 7.1 The Technical Authority will provide information to the Contractor, as specified in each individual Task Authorization. This may include, but is not limited to:
 - 7.1.1 Background information;
 - 7.1.2 Guidance on Government and DND requirements and practices; and
 - 7.1.3 Access to any available documentation required for the completion of each task.
- 7.2 The Contractor must return all documentation provided by the TA upon the completion of a Task.



ANNEX B
BASIS OF PAYMENT

1. LABOUR:

The Contractor will be paid firm all-inclusive hourly rates for work performed in accordance with the Contract. Customs duties are included and Applicable Taxes are extra, if applicable. The Back-Up Strategic Level Resource will be paid at the same hourly rate as the Primary.

Labour Category	Contract Period		Option Period 1	Option Period 2	Optional Transition Period	
	Year 1	Year 2	Year 3	Year 4	Year 5	
	Firm All Inclusive Hourly Rate					
	Year 1	Year 2	Year 3	Year 4	Year 5	6 Months
Strategic Level Resource	\$	\$	\$	\$	\$	\$
General Level Resource	\$	\$	\$	\$	\$	\$
Administrative Level Resource	\$	\$	\$	\$	\$	\$

TOTAL ESTIMATED LABOUR (Contract Period): \$ _____
(Applicable Taxes extra)

2. TRAVEL AND LIVING EXPENSES:

- (a) Canada will not accept any travel and living expenses incurred by the Contractor in the performance of the Work, for:
 - (i) services provided within the National Capital Region (NCR). The National Capital Region (NCR) is defined in the *National Capital Act*, R.S.C. 1985, c.N-4, S.2. The *National Capital Act* is available on the Justice Website: <http://laws.justice.gc.ca/eng/N-4/20100210/> and
 - (ii) any travel between the Contractor's place of business and the NCR.
- (b) For services to be provided outside the NCR, the Contractor will be reimbursed its authorized travel and living expenses reasonably and properly incurred in the performance of the Work, at cost, without any allowance for profit and/or administrative overhead, in accordance with the meal, private vehicle and incidental expenses provided in Appendices B, C and D of the Treasury Board Travel Directive (<http://www.njc-cnm.gc.ca/directive/travel-voyage/index-eng.php>), and with the other provisions of the directive referring to "travellers", rather than those referring to "employees". The Treasury Board Secretariat's Special Travel Authorities, http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/tbm_113/statb-eng.asp, also apply.
- (c) Canada will not accept any travel and living expenses incurred by the Contractor as a consequence of any relocation of personnel required to satisfy the terms of this Contract.
- (d) All travel must have prior authorization of the Technical Authority as evidenced through an authorized Task Authorization. All payments are subject to government audit.

Est.: \$ _____
(Applicable Taxes extra)



**ESTIMATED COST TO A LIMITATION OF EXPENDITURE CUMULATIVE TOTAL OF ALL
TASK AUTHORIZATIONS:** \$ _____
(Applicable Taxes extra)

With the exception of the firm rate(s), the amounts shown in the various items specified above are estimates only. Minor changes to these estimates will be accepted for billing purposes as the Work proceeds, provided that these changes have the prior approval of the Technical Authority, and provided that the estimated cost does not exceed the aforementioned Limitation of Expenditure.



Travaux publics et
Services gouvernementaux
Canada

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Government Services
Canada

ANNEX C
DND 626 Task Authorization form