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SOLICITATION AMENDMENT
MODIFICATION DE L'INVITATION

The referenced document is hereby revised; unless otherwise indicated, all other terms and conditions of the Solicitation remain the same.

Ce document est par la présente révisé; sauf indication contraire, les modalités de l'invitation demeurent les mêmes.

Comments - Commentaires

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Title-Sujet SERVICES DE SOUTIEN AUX AFFAIRES RÉGLEMENTAIRES REGULATORY AFFAIRS SUPPORT SERVICES		
Solicitation No. - N° de l'invitation W3931-150076	**Amendment No. – No modif** 004	**Date** 2016-06-08
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 2016/06/16**		**Time Zone** **Fuseau horaire** Eastern Daylight Time (EDT)
F.O.B. – F.A.B **Plant-Usine :** ☐ **Destination:** ■ **Other-Autre:** ☐		
Address Enquiries to: - Adresser toutes questions à: Joseph Hulse		**Buyer Id – Id de l'acheteur**
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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**
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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**	

Canada

French

Titre: SERVICES DE SOUTIEN AUX AFFAIRES RÉGLEMENTAIRES

La présente modification no 4 vise à :

A) répondre aux questions 13 et 16.
B) modification de l'invitation – en anglais seulement.

Questions

13) On demande de décrire l'expérience de la ressource de niveau stratégique relativement aux médicaments (R2A) et au matériel (R2B). Est-ce que la ressource proposée pour le matériel doit résumer son expérience relative aux médicaments? Et est-ce que la ressource proposée relativement aux médicaments doit résumer son expérience par rapport au matériel? Il peut être rare qu'une ressource relative au matériel ait l'expérience requise au critère R2A et qu'une ressource relative aux médicaments dispose de l'expérience requise au critère R2B pour obtenir 25 points dans chacune de ces catégories.

Réponse – Les ressources proposées doivent résumer toute expérience légitime ou pertinente, et elles obtiendront des points par conséquent. Nous comprenons qu'il peut être rare que les ressources proposées disposent de l'expérience relative aux médicaments et au matériel, et c'est pourquoi il s'agit de critères cotés. Les critères obligatoires tiennent compte de l'expérience combinée des ressources.

14) Veuillez confirmer que les pages 25 et 26 de la DP initiale (en anglais) devraient être supprimées.

Réponse – Oui, c'est exact, et cela s'applique uniquement aux critères d'évaluation de la version anglaise. Veuillez consulter la modification de la version anglaise de la DP.

15) Le critère C2 demande également deux ressources de niveau général. Est-ce que la ressource proposée pour les médicaments doit préciser son expérience relative au matériel (expérience des demandes d'homologation de matériel médical et des demandes d'essai expérimental) et est-ce que la ressource proposée pour le matériel doit avoir de l'expérience relative aux médicaments (PNM et documents supplémentaires connexes et DEC)?

Réponse – On s'attend à ce que les deux ressources proposées aient une combinaison d'expérience relative aux médicaments et au matériel, comme décrit dans le critère obligatoire O7. Les ressources proposées doivent résumer toute expérience légitime ou pertinente, et elles obtiendront des points par conséquent. Si l'expérience indiquée ne respecte pas les exigences des critères côtés, aucun point ne sera accordé.

16) Est-ce que les notes pour les demandes d'homologation de matériel médical sont correctes, les troisième et quatrième colonnes (2 points par demande, pour un maximum de 5 points) ou est-ce que ça devrait être 1 point par demande?

Réponse – Oui, cela devrait être 1 point par demande. Cela s'applique uniquement aux critères d'évaluation de la version anglaise. Veuillez consulter la modification de la version anglaise de la DP.

English

Title: REGULATORY AFFAIRS SUPPORT SERVICES

Amendment # 4 is raised for the following:

A) Answer questions 13-16
B) Amend the Solicitation

Questions:

13) The RFP request the description of experience for both drugs (R2A) and devices (R2B) by the proposed strategic resource. Is the proposed device resource to summarize drug experience, and is the proposed drug resource to summary device experience? It may be rare for a device resource to have R2A experience and for a drug resource to have R2B experience to obtain 25 points in each of these categories.

Answer – Proposed resources are to summarize any legitimate/ relative experience that will result in points. We understand that it may be rare for a proposed resource to have both device and drug experience and that is why it is a point rated criteria, and the mandatory criteria takes into consideration the combined experience of both resources.

14) Please confirm that pages 25 & 26 are from the initial RFP and should be deleted.

Answer – yes, this is correct and relevant only to the English evaluation criteria. See correction to the English RFP only.

15) R2 criteria also request 2 general level resources. Is the expectation for the proposed drug resource to include device experience (Medical Device License Applications and ITA experience) and the device resource to have drug experience (NDS and related supplements and CTA experience)?

Answer – the expectation is that both proposed resources have a combination of drug and device experience, as described in mandatory criteria M7. Proposed resources are to summarize any legitimate/ relative experience that will result in points. If the proposed experience is not within the requirements of rated criteria, then no points will be received.

16) Is the scoring for Medical device licensing applications correct, 3rd and 4th columns (2 points per application for a max of 5 points) or should this be 1 point per application?

Answer – yes, it should be 1 point per application. This is relevant only to the English evaluation criteria. See correction on the English RFP only.

Amendment

4. At "Attachment 2", Evaluation Criteria,

DELETE:

No.	Criteria Description	Points Available Resource #1	Points Available Resource #2	Reference page # in proposal Resource #1	Reference page # in proposal Resource #2
R1	Each 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	Each 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)		
	a. Medical Device License Applications;	2 points per Application (max 10 points)	2 points per Application (max 10 points)		
	b. Investigational Testing Application (ITA);	1 point per Application (max 5 points)	1 point per Application (max 5 points)		
	c. Medical Device development plans.	2 point per Plan (max 10 points)	2 point per Plan (max 10 points)		
	Maximum Points	**50 points**	**50 points**		
R3	Each 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	Each 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	Each 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 Team (maximum of 2 individuals)

No.	Criteria Description	Points Available Resource #1	Points Available Resource #2	Reference in proposal (page #) Resource #1	Reference in proposal (page #) Resource #2
R1	Each 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	5 points		
	Maximum Points	**5 points**	**5 points**		
R2	Each 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 medical products :				
	a. NDS and related supplements; and	1 points per Submission (max 5 points)	1 points per Submission (max 5 points)		
	b. Clinical Trial Application (CTA).	1 point per Submission (max 3 points)	1 point per Submission (max 3 points)		
	Maximum Points:	**8 points**	**8 points**		
	a. Medical Device License Applications;	2 points per Application (max 5 points)	2 points per Application (max 5 points)		
	b. Investigational Testing Application (ITA);	1 point per Application (max 3 points)	1 point per Application (max 3 points)		
	Maximum Score	**8 points**	**8 points**		

INSERT:

2.1.3 General Level Resources (2 individuals)

No.	Criteria Description	Points Available Resource #1	Points Available Resource #2	Reference in proposal (page #) Resource #1	Reference in proposal (page #) Resource #2
R1	Each 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	5 points		
	Maximum Points	**5 points**	**5 points**		
R2	Each 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 medical products :				

	a. NDS and related supplements; and	1 points per Submission (max 5 points)	1 points per Submission (max 5 points)		
	b. Clinical Trial Application (CTA).	1 point per Submission (max 3 points)	1 point per Submission (max 3 points)		
	Maximum Points:	**8 points**	**8 points**		
	a. Medical Device License Applications;	1 point per Application (max 5 points)	1 point per Application (max 5 points)		
	b. Investigational Testing Application (ITA);	1 point per Application (max 3 points)	1 point per Application (max 3 points)		
	Maximum Score	**8 points**	**8 points**		

ALL OTHER TERMS AND CONDITIONS REMAIN UNCHANGED