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**GOOD MANUFACTURING PRACTICES –  
FOREIGN SITE INSPECTION SERVICES AGREEMENT FORM (FRM-0214)**

Between: Health Canada

And: Insert name of Requester (the “Requester”) [redacted]  
Address Block [redacted]  
Schedule inspection date [redacted]

## 1.0 Definitions

In this Agreement, unless the context otherwise requires,

"Agreement" means this written Agreement between Health Canada and the Requester, these general conditions, any supplemental general conditions specified in this written Agreement and every other document specified or referred to in any of them as forming part of this Agreement, all of which may be amended by written Agreement of the Parties, from time to time.

"Compliant (C) rating" means, at the time of providing the Inspection Services, the establishment has demonstrated that it is in control of regulated activities pertaining to the *Food and Drugs Act* and its associated Regulations;

"Departmental Representative" means the person designated as such in this Agreement, or by notice to the Requester, to act as the representative of Health Canada in the management of this Agreement.

"Foreign Site" means the following site: [REDACTED];

"Host Country" means the country in which the Inspection Services will be provided;

"Inspection Services" means assessing the Foreign Site's compliance with all relevant sections of Division 2 of the *Food and Drug Regulations*. The guidance document entitled "Good Manufacturing Practices (GMP) Guidelines (GUI-0001)", as well as any other document referenced therein, may be consulted for further guidance;

"Inspector" means any person designated as an inspector for the purpose of the enforcement of the *Food and Drugs Act* under subsection 22(1);

"Non compliant (NC) rating" means, at the time of providing the Inspection Services, the establishment has not demonstrated that it is in control of regulated activities pertaining to the *Food and Drugs Act* and its associated Regulations;

"Parties" means Health Canada and the Requester, both of which are signatories to this Agreement;

"Requester Representative" means the person designated as such in this Agreement, or by notice to Health Canada, to act as the representative of the Requester in the management of this Agreement;

"Site Master File" means a document that contains specific information about the quality assurance, the production and/or quality control of pharmaceutical manufacturing operations carried out at the Foreign Site and any closely integrated operations at adjacent and nearby buildings. The guidance document entitled « [Explanatory Notes for Industry on the Preparation of a Site Master File](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/directives/gui_0005_tc-tm-eng.php) » ([http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/directives/gui\\_0005\\_tc-tm-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/directives/gui_0005_tc-tm-eng.php)) may be consulted for further guidance.

## 2.0 Objective

**Objective:** The objective of this Agreement is to conduct Inspection Services of the Foreign Site.

## 3.0 Time Frame of the Inspection Services

This Agreement will commence on the date of its signature by both Parties and will end once the responsibilities of both Parties have been fulfilled.

#### **4.0 Roles and Responsibilities of Health Canada**

- 4.1 Health Canada, through its Inspector(s), will complete the Inspection Services of the Foreign Site as requested by the Requester.
- 4.2 Health Canada reserves the right to cancel and/or reschedule the Inspection Services of the Foreign Site at its discretion and/or if any of the Requester's responsibilities outlined in this Agreement are not met.
- 4.3 Health Canada will cover any costs incurred by the Inspector(s) and/or Departmental Representative and/or any person(s) accompanying them as a result of the Inspection Services requested, in compliance with the [Treasury Board of Canada Travel Directives](http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/tbm_113/td-dv-eng.asp). ([http://www.tbs-sct.gc.ca/pubs\\_pol/hrpubs/tbm\\_113/td-dv-eng.asp](http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/tbm_113/td-dv-eng.asp))
- 4.3.1 Accommodation;
  - 4.3.2 Transportation;
  - 4.3.3 Additional business expenses;
  - 4.3.4 Meals;
  - 4.3.5 Incidental expenses; and
  - 4.3.6 Any other expenses related to the Inspection Services requested, including, but not limited to, translation services.

For additional information, the [Treasury Board Travel Directives](http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/TBM_113/td-dv_e.asp) may be consulted at the following address:

([http://www.tbs-sct.gc.ca/pubs\\_pol/hrpubs/TBM\\_113/td-dv\\_e.asp](http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/TBM_113/td-dv_e.asp))

- 4.4 Health Canada will invoice the Requester for the costs incurred as a result of the Inspection Services, as set out in Section 4.3:
- 4.4.1 After the Inspection Services have been completed by the Inspector(s); OR
  - 4.4.2 After the Inspector(s) has attempted to conduct the Inspection Services, but has been unable to do so due to, but not limited to:
    - 4.4.2.1 The actions or inactions of the Requester and/or the Foreign Site; OR
    - 4.4.2.2 Any other situation that may jeopardize the safety and/or security of the Inspector(s) and/or the Departmental Representative and/or any person(s) accompanying them.
- 4.5 The Inspector(s) will present his/her official Health Canada identification card upon arrival at the Foreign Site.
- 4.6 Health Canada will advise the Foreign Site, in writing, of all deviations from the requirements of the *Food and Drug Regulations* that are noted during the performance of the Inspection Services.
- 4.7 Health Canada will assign a rating ("C rating" or "NC rating") to the Foreign Site, in accordance with the guidance document entitled « [Risk Classification of GMP Observations \(GUI-0023\)](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui_23_tc-tm-eng.php) », ([http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui\\_23\\_tc-tm-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui_23_tc-tm-eng.php)) and will advise the Foreign Site and the Requester, if different, in writing, of the rating that is assigned.

#### **5.0 Roles and responsibilities of the Requester**

- 5.1 The Requester will submit a Site Master File on the Foreign Site to Health Canada no later than 30 days prior to: [REDACTED] (*schedule inspection date*).
- 5.2 The Requester will investigate any security and safety issues in the Host Country and/or at the Foreign Site and will communicate this information, in an expeditious manner, to the Departmental Representative and/or, if applicable, to the Inspector(s), prior to and/or during the provision of the Foreign Site Inspection Services.

- 5.3 The Requester will ensure that all possible steps are taken to ensure the safety and security of the Inspector(s) and/or Departmental Representative and/or any person(s) accompanying them as he/she performs the Inspection Services at the Foreign Site.
- 5.4 The Requester shall take all necessary steps to coordinate the visit(s) of the Inspector(s) and/or the Departmental Representative and/or any person(s) accompanying them to the Foreign Site for the provision of the Inspection Services requested.
- 5.5 The Requester will ensure that the Inspector(s) has access to all areas, personnel and documentation necessary to conduct the Inspection Services at the Foreign Site.
- 5.6 The Requester will reimburse the costs incurred as a result of the Inspection Services requested, as set out in Section 4.3, within 30 days of the invoice date.
- 5.7 The Requester is aware of and will comply with the Treasury Board of Canada Travel Directives.

**6.0 Notice**

- 6.1 The Departmental Representative designated as primary contact for Health Canada:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

- 6.2 The Requester Representative designated as primary contact for the Requester:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**7.0 Assignment**

- 7.1 This Agreement shall not be assigned in whole or in part by either Party without the prior written consent of the other Party, and any assignment made without such consent shall be void and of no effect.

**8.0 Conflict of Interest**

- 8.1 It is a term of this Agreement that no current or former public servant or public office holder to whom [The Conflict of Interest and Post-Employment Code for the Public Service, The Values and Ethics Code for the Public Services or the Conflict of Interest Act](http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/tb_851/vec-cve-eng.asp) ([http://www.tbs-sct.gc.ca/pubs\\_pol/hrpubs/tb\\_851/vec-cve-eng.asp](http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/tb_851/vec-cve-eng.asp)) applies, shall derive any direct benefit from this Agreement, including any employment, payments or gifts, unless the provision and receipt of such benefits is in compliance with such Codes or Act.
- 8.2 No member of the House of Commons shall be admitted to any share or part of this Agreement or to any benefit to arise therefrom.

**9.0 Indemnification**

The Requester shall indemnify and save harmless at its own cost, Health Canada from and against all claims, demands, losses, damages, costs (including solicitor and own-client costs), actions, suits or other proceedings, all in any manner based upon, arising out of, related to, occasioned by or attributable to, any acts or conduct of the Requester (whether by reason of

negligence or otherwise) in the performance or breach by the Requester of the provisions of this Agreement or any activity undertaken or purported to be undertaken under the authority or pursuant to the terms of this Agreement.

**10.0 Applicable Law**

10.1 This Agreement shall be governed by and construed in accordance with the laws of [redacted] (*applicable legal jurisdiction of host country*) and the applicable laws of Canada.

**11.0 Entire Agreement**

11.1 This Agreement constitutes the entire Agreement between the Parties with respect to the provision of the Inspection Services and supersedes all previous negotiations, communications and other agreements relating to it, unless they are incorporated by reference herein.

**12.0 Amendments**

12.1 The Parties agree that this Agreement shall not be altered or amended without the written mutual consent of both the Departmental Representative and the Requester Representative.

**FOR HEALTH CANADA:**

*(Sign above line; type name, title, division/branch beneath line)*

[redacted] \_\_\_\_\_

**Name:**

**Title:**

**DATE:** [redacted]

**FOR REQUESTER:**

*(Sign above line; type name, title, division/branch beneath line)*

[redacted] \_\_\_\_\_

**Name:**

**Title:**

**DATE:** [redacted]