Instructions for Completing Good Manufacturing Practices – Audit Report Form (FRM-0211)

Applicants may submit a corporate or consultant audit report, using the Audit Report Form, as evidence to establish the compliance of a foreign site with Division 2 (Good Manufacturing Practices) of the Food and Drug Regulations (FDR), so long as the criteria outlined in *"Guidance: How to demonstrate foreign building compliance with drug good manufacturing practices (GUI-0080)*" are met.

The audit must be conducted by an individual(s) that possesses sufficient knowledge of and experience with Good Manufacturing Practices (GMP) and is qualified according to section C.02.006 of the FDR.

Box #	INSTRUCTIONS
	BUILDING INFORMATION
	A. Building Information
1	The registered name of the building
2-9	Indicate the street address, city/town, province/state, postal/zip code, country where the building is located. Building refers to one location, one address. When an applicant carries out activities in more than one building at different addresses, an Audit Report must be completed for each address.
10	Indicate the activities conducted at the building identified under part A.
	GENERAL INFORMATION
	B. Application Information
11a	Indicate the date(s) when the audit was conducted.
11b	Define the purpose of audit by checking off one of the following boxes: • **New Establishment Licence Application:** First-time applications • **Amendment to Establishment Licence:** Submission for amendment • **Renewal of Establishment Licence:** Submission for renewal • **In support of a Drug Submission:** If this audit report is being submitted in support of a drug submission, indicate the submission control number, along with the name of the product for which the submission has been filed.
12a	Date of the last inspection/audit at the building identified under part A.

Box #	INSTRUCTIONS
12b	Define the type of the last inspection/audit by checking off one of the following boxes: • **Corporate audit**: inspection was conducted internally • **Consultant audit**: inspection was conducted by an independent person(s) or organization • **Regulatory Authority**: as defined in Section C.01A.001(1) of the FDR, a government agency or other entity in a Mutual Recognition Agreement (MRA) country that has a legal right to control the use or sale of drugs within that country and that may take enforcement action to ensure that drugs marketed within its jurisdiction comply with legal requirements • **Qualified Authority**: an authority member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) or the United States Food and Drug Administration (USFDA) • **Other**: any other type of inspection
13	Indicate the reason for submission.
AUDIT INFORMATION	
C. Auditor Information	
14	Identify the name of the auditor(s).
15	Indicate how the person(s) identified in box #14 is considered to be qualified by specifying his/her education, training, technical knowledge, etc.
16	Define the type of audit that was conducted by checking off one of the following boxes: • **Corporate**: audit was conducted internally • **Consultant**: audit was conducted by an independent person(s) or organization
D. Scope of Audit	
17	Indicate the operation(s) that is(are) being performed in this building: manufacturing, packaging, labelling and/or testing.
18	Indicate the product(s) that were covered during the audit. Include the product(s)'s Drug Identification Number, if assigned, along with its dosage form(s).
E. Personnel	
19a	The list of attendees present at the opening meeting, along with their title.

Box #	INSTRUCTIONS
19b	The list of attendees present at the closing meeting, along with their title.
	F. Background Information
20	Include general information with respect to the layout of the facility. It is recommended that a site map be included for facilities with numerous buildings. In addition, include a brief history of the facility, including any changes that have occurred since the last inspection, as well as any other information that is not captured under any of the above boxes. If the audit was product-specific, include an overview of the product's manufacturing process, as well as any other pertinent information.
	RATING
21	Indicate the number of observations per Risk type.
22	Check off the response to the statement as either YES that the statement is correct or NO that the statement is not correct.

DETAILED REPORT

Division 2 of the FDR sets out the GMPs that manufacturers, packagers, labellers, testers, importers, distributors and wholesalers must meet before an Establishment Licence (EL) will be issued.

Statements/Questions: Yes/No

The statements/questions in this report are divided into sections in accordance with those outlined in Division 2 of the FDR.

Check off the response to the question as either YES that the question is correct or NO that the question is not correct. If the question is unclear, refer to the appropriate section(s) in the *Good manufacturing practices guide for drug products* (GUI-0001) for assistance.

If the answer to the statement/question is yes, clearly describe, in the space provided, how the site complies with the referenced section of FDR.

If the answer is no, provide a clear rationale, in the space provided, as to why the statement/question is not applicable to the activities conducted at the site.

Note: Additional pages may be attached if the space provided is not sufficient. Identify the additional pages that have been attached under the Attachments section.

Deviations

For each statement/question, list in the provided table all of the deviations from Division 2 of the FDR that were observed during the audit. Assess the risk associated with each observation, based on Health Canada's guide *"Risk classification guide for drug good manufacturing practices observations (GUI-0023)"*:

"Risk 1" (critical) describes a situation that is likely to result in a product that may result in an immediate or latent health risk, or that involves fraud, misrepresentation or falsification of processes, products or data.

"Risk 2" (major) describes a situation that may result in the production of a drug not consistently meeting its marketing authorization. Some Risk 2 observations may be upgraded to Risk 1, for example in cases where the issue identified is not isolated to one area or system – these are indicated with an arrow (↑).

"Risk 3" (other) describes a situation that is neither critical nor major, but is a departure from the GMPs. Any Risk 3 observation could be upgraded to Risk 2.

Corrective Actions

If deviation(s) were listed above, describe in the space provided the details of the corrective action(s) that were taken or will be taken, along with time lines, in addition to any preventive measures to avoid recurrence, as needed.

For each listed deviation(s), a corrective action plan may be attached and listed under the Attachments section.

Attachments

List all supporting documentation as described above (SOP(s), corrective action plan(s), etc.), and attach the document(s) directly behind the statement/question page.

For each statement/question, the applicant is required to list the title(s) and the number(s) of the relevant standard operating procedure(s) that are in use at the site. However, the actual SOP(s) does not need to be attached, unless the applicant feels that the SOP(s) will help in the assessment of the site's compliance with *Division 2* of the FDR. In addition, a copy of any SOP may be requested at any time during the assessment of the site's compliance with *Division 2*

of the FDR.

OVERALL RATING

A judgement is required on the part of the auditor(s) as to the overall compliance, based on Health Canada's guide "*Risk classification guide for drug good manufacturing practices observations (GUI-0023)*", of the site with *Division 2* of the FDR.

If the answer to the statement/question is yes, clearly describe, in the space provided, how the site complies with Division 2 of the FDR.

If the answer is no, provide a clear rationale, in the space provided, as to why the site does not comply with Division 2 of the FDR.

ATTESTATION

The person(s) that conducted the audit, as identified in box #14, is(are) required to PRINT and SIGN his/her name and DATE this part of the Audit Report Form.

In addition, if deviations were observed during the audit, it is requested that an official with signing authority, from the audited foreign site, PRINT and SIGN his/her name and DATE the second attestation.