RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Food and Drugs Inspection and Safety Monitoring Department	
Document Type: **Standard Operating Procedure**		Doc. Number	: QMS/SOP/079
RWANDA FDA Rwanda Food and Drugs Authority	Title: **CONDUCTING GMP INSPECTIONS OF PHARMACEUTICAL MANUFACTURING FACILITIES**	Revision Number	:15 May 2021
		Revision Date:	:15 May 2021
		Effective Date	:
		Review Due Date	:21 May 2023

STANDARD OPERATING PROCEDURE (SOP) FOR CONDUCTING GMP INSPECTIONS OF PHARMACEUTICAL MANUFACTURING FACILITIES

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Title				Quality Management Systems	Director General	Page 1 of 9
Signature & Date						

1.0 Purpose

This Standard Operating Procedure is to ensure that:

1.1 To ensure that a standardized procedure is followed by all inspectors when performing GMP inspections

1.2 To ensure consistency in performance between different GMP inspectors.

1.3 To ensure that GMP inspectors are equipped with relevant tools

2.0 Scope

This Standard Operating Procedure:

2.1 Applies to conducting GMP inspections for manufacturers of Finished Pharmaceutical Products and of Active Pharmaceutical Ingredients applied within the NRA.

3.0 Responsibility

3.1 The Director General is responsible for consideration and approval of GMP certificates

3.2 Head of Food and Drugs Inspection & Safety Monitoring Department is responsible for ensuring that the review and assessment of GMP applications is done as per this procedure.

3.3 The Division manager, Food and Drugs Inspection & Compliance is responsible for coordinating the GMP inspections

3.4 Quality assurance analyst ensures the use of update version of the SOP, recalls obsolete documents and keeps document master list.

3.5 GMP Inspectors are responsible for review and assessment of GMP applications and conduct GMP inspections as per the procedure

4.0 Distribution

4.1 Director General
4.2 The Head of Food and Drugs Inspection and Safety Monitoring Department
4.3 Division Manager of Food and Drugs Inspection and Compliance
4.4 Quality assurance analyst
4.5 GMP Inspectors.

5.0 Procedures

The Inspectors should identify themselves at the entrance of the site before entering the inspection site

5.1 All inspections should be started with an opening meeting. See Annex I for guidance on what should be covered during the meeting.

5.2 Confirm the inspection plan to the company and refer to the standard(s) against which the inspection will be done.

5.3 Circulate the attendance record form at Annex II to enable all persons present to record names, positions in the company and email address.

5.4 Conduct the inspection through assessment of compliance with GMP according to the inspection plan. Adjust the inspection plan if necessary.

5.5 During routine inspections all aspects described in the GMP guidelines should be assessed as far as possible. Emphasis should be placed on specific areas based on a risk approach and time allocated accordingly.

5.6 Verify selected source data where possible. This is done by requesting documentation, records and raw data. It may be helpful to make a list of documents requested to ensure that all requested are provided and reviewed. See Annex III - optional.

5.7 Maintain notes during the inspection and keep this record for filing on the company

file after completion of the inspection.

5.8 Observations should be discussed with the company representatives at the time that they are noted.

5.9 In addition provide feedback to the company / laboratory / organization on the observations (deficiencies) made during the inspection. This should normally be done at the end of each day. No deficiencies should be included in the report if these were not mentioned / discussed with the company.

5.10 At the end of the inspection, arrange for a closed meeting between inspectors to discuss the deficiencies in preparation for the closing meeting.

5.11 End the inspection with a closing meeting where the lead inspector should summarize the findings with the representatives of the company. The importance of the deficiencies should be mentioned. See Annex I for guidance on what should be covered during the meeting.

5.12 At any stage during the inspection, if serious deficiencies are observed that may lead to possible serious risk to patients, the Lead Inspector should immediately contact the Head, Regulatory body and Head of GMP Inspectorate (as appropriate for each country) to decide what action should be taken. The company should be so informed.

5.1 Materials and equipment

5.1.1. Rwanda FDA GMP database

5.1.2 GMP inspection Checklist

5.1.3 Updated list of countries considered as Stringent Regulatory Authorities (SRA)

5.1.4 EAC NMRAs

6.0 Records

6.1 The inspection plan, meeting attendance record, notes made during the inspection, any

checklists used, record of documents requested (if used), copies of any documents requested during the inspection, should be filed on the company file after the inspection report has been prepared and sent to the company. (Annex III)

6.2. All documents mentioned in the section 6.1.should be filed in the company file by the relevant secretary who arranged the inspection.

7.0Annex

Annex 1: Guidance points for opening and closing meeting
Annex II: Record of persons present in the opening and closing meeting
Annex III: Record of documents requested during an inspection (optional)

ANNEX 1: GUIDANCE POINTS FOR OPENING AND CLOSING MEETING

Opening meeting

Opening the meeting should at least include but not limited to the following;

- Introduction of the inspectors
- Ask the company to introduce the people present and to make a brief presentation
- Explain how the inspection is to be conducted
- Scope of the inspection
- Inspection plan
- Discuss Inspection Time Table
- How the feedback will be given e.g. end of each day
- Which are the standards that will be applied (EAC- GMP)

Closing meeting

- Thank the company for their cooperation
- Provide brief feedback on some of the positive points noted in the inspection
- Explain the process and timelines for the report and corrective action plan

- Explain that the closing meeting allows providing a summary of the observations made - and the intention is not to list each observation

(Note: You should have discussed the observations made at the end of each day or at some point during the inspection. No surprises in the inspection report!)

- Provide a summary of issues of concern under different areas such as

oQuality Assurance
oDocumentation
oPersonnel
oPremises
oEquipment
oMaterials
oCleaning/sanitation/Hygiene
oProduction
oQuality control
oValidation
oUtilities

- Mention, if relevant, whether there are any critical or major deficiencies
- Ask if the company needs clarification on any point

ANNEX II: RECORD OF PERSONS PRESENT IN THE OPENING AND CLOSING MEETING

Manufacturer:	**Address:**
Inspector(s):	
Opening meeting Time:	**Closing meeting** Time:

To be completed by representatives of the manufacturer:

Name (please print)	Position in the organization	E-mail address	Signature

ANNEX III: RECORDS OF DOCUMENTS REQUESTED FOR DURING THE INSPECTION

Manufacturer:

Inspector:

Date:

Sr No	Document	Document no.	Time requested	Time presented
1				
2				
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8.0Document Revision History

				NA	New

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Title	Drug and Food Inspectorate	Head, Drug Inspectorate Services	Head, Drug Assessment & Registration	Head, Quality Management	Executive Secretary /Registrar	9 of 9
Signature & Date						

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