RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Food and Drugs Inspection and Safety Monitoring Department	
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RWANDA FDA Rwanda Food and Drugs Authority	Title: **SOP FOR FOLLOW UP ON NON-COMPLIANCES AFTER GMP INSPECTION**	Revision Number	:
		Revision Date:	:15 May 2021
		Effective Date	:15 May 2021
		Review Due Date	:21 May 2023

SOP FOR FOLLOW UP ON NON-COMPLIANCES AFTER GMP INSPECTION

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Rwanda Food and Drugs Authority

	Author	Checked by			Authorized by	
Title				Quality Management Systems	Director General	Page 1 of 5
Signature & Date						

RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance	
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1.0 Purpose

This Standard Operating Procedure is to ensure that:

1.1 To outline the procedure for NRA to follow up on non-compliances observed after GMP inspections of manufacturing facilities and implement administrative actions where necessary.

2.0 Scope

This Standard Operating Procedure:

2.1 Applies to NRA GMP inspections of manufacturers of Finished Pharmaceutical Products and of Active Pharmaceutical Ingredients.

3.0 Responsibility

3.1 Head of Food and Drugs Inspection & Safety Monitoring Department Ensure decisions on all manufacturing facilities are implemented in a timely manner and in accordance with the legislation to protect human health

3.2 The Division manager, Food and Drugs Inspection & Compliance ensures that administrative or enforcement actions are undertaken as appropriate and update databases and prepare communication by letter or email

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

3.4 GMP Inspectors are responsible for generating a GMP inspection report with conclusion on the status of the manufacturing facility and to review the CAPA and submit comments

3.5 The Peer Review/Technical Committee is responsible for reviewing the inspection report and make a final conclusion on the submitted GMP inspection report

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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 After generation of a GMP inspection report with classification of all non compliances as critical, major and minor therein and peer review; a site shall be considered compliant if it has:
- 5.1.1 No critical non compliance.
- 5.1.2 Minor non compliances
- 5.1.3 Major non compliances that are rectified and Corrective And Preventive Action (CAPA) submitted by the manufacturer; review of CAPA by the NRA and found satisfactory

5.2 A site shall be considered non compliant if it has:
- 5.2.1 One or more critical non compliances
- 5.2.2 Several major non compliances that imply a failure in the quality assurance system

5.3 The NRA shall issue a GMP certificate and /or a manufacturing license where applicable for a site that is compliant i.e has no critical or has minor observations

5.4 The NRA shall demand for a corrective and preventive action report for review and where possible a follow up inspection for a site that has major non compliances may be done prior to issue of a GMP certificate and close out of the inspection.

5.5 The NRA shall not issue a GMP certificate to a non compliant manufacturing facility that has critical or several major non compliances

5.6 Local manufacturers shall require physical re-inspection for a site that has critical or several major non compliances until a satisfactory report is achieved

5.7 The re-inspection of a non compliant facility shall be after submission of corrective action report and an application together with payment of the inspection fee.

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5.8 Manufacturing facilities that fail to comply with GMP shall have:

5.8.1 their products removed from the national medicine register thus halting further manufacture or importation of the products

5.8.2 Their products recalled from the market depending on the criticality of the findings

5.9 The NRA may decide to close down the whole site by withdrawing the GMP certificate and/or manufacturing license or a section of the site depending on the critical observations identified by the inspection team

5.10 Upon careful consideration of the findings in the inspection report and where these affect the health of patients in a critical manner; the NRA may consider raising a rapid alert to NRAs, health care workers and patients

5.1 Materials and equipment

5.1.2 GMP inspection Checklist

6.0 Records

6.1 The quality manuals, master distribution list file, obsolete documents file and general list of documents shall be kept and maintained by HQM for a period specified in the respective document

6.2 Department list of documents shall be kept and maintained by respective Head Department

6.3 Records shall be destroyed by tearing/shredding/burning or any other appropriate means.

7.0Document Revision History

				NA	New

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						Page 5 of 55
		Checked by				
Title	Drug and Food Inspectorate	Head, Drug Inspectorate Services	Head, Drug Assessment & Registration	Head, Quality Management	Executive Secretary /Registrar	
Signature & Date						

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