Format: QMS/FMT/001 Revision No: 0 Effective Date: 13 Jan 2020	Department/Division	Food and Drugs Inspection and Safety Monitoring Department
Document Type: **Standard Operating Procedure**		Doc. Number : DIS/SOP/141 Revision Number : 0 Revision Date : 09 Jul 2021 Effective Date : 16 Jul 2021 Review Due Date : 16 Jul 2024
RWANDA FDA Rwanda Food and Drugs Authority	Title: **PROCEDURE FOR ANNUAL INSPECTION PLANS FOR ALL LICENSED PHARMACEUTICAL ESTABLISHMENTS**	

	Author	Checked by		Approved by
Title	Drugs Inspection and Compliance Analyst	Quality Assurance Analyst	DM/DFIC	HoD/FDISM
Names	Clarisse AYINKAMIYE	Dr. Vedaste HABYALIMANA	Dr. Marylin M. MURINDAHABI	Alex GISAGARA
Date	16/07/2021	16/07/2021	16/07/2021	16/07/2021
Signature				

1.0 Purpose

This Standard Operating Procedure is to:

1.1 Guide the preparation of the inspection plan to ensure that licensed pharmaceutical establishments comply with laws and regulations governing the manufacture, labeling, and handling of medical products that are commercially distributed in Rwanda.

2.0 Scope

This Standard Operating Procedure:

2.1 Applies to all pharmaceutical manufacturing premises
2.2 Applies to all wholesale pharmacies and Retail Pharmacies

3.0 Policy

3.1 The Law Nº 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning states in:
Article 3 (13) … *"premises used in the manufacture of products regulated by this Law"* and

3.2 ISO 9001:2015 Clause 7.5.3.1 states that "*Documented information required by the quality management system and by this International Standard shall be controlled".*

4.0 Definition and Abbreviation

4.1 **"Manufacturer"** means a person or corporation or other entity engaged in the business of manufacturing of medical products

5.0 Responsibility

5.1 Head of Department of food and drugs inspection and safety monitoring is responsible ensures that this SOP is correctly and consistently implemented during the inspection plan of pharmaceutical establishments.
5.2 The Division Manager of food and drugs inspection and compliance ensures staff adherence to this SOP.
5.3 Quality Assurance Analyst who is a person in charge of quality management system ensures the use of the updated version of this SOP, recalls obsolete version of this SOP and record this SOP in a master list document of the Authority.
5.4 Drugs Inspection & Compliance Analyst prepares and submits the inspection plan to the Division Manager of food and drugs inspection and compliance
5.5 Analyst and Specialist are responsible to adhere to the inspection plan of pharmaceutical establishments

6.0 Distribution

6.1 Head of Food and Drugs Inspection and Safety Monitoring
6.2 Division Manager, Food Inspections & Compliance Division
6.3 Drugs Inspection & Compliance Analyst
6.4 Quality Assurance Analyst
6.5 Specialist/Analyst
6.6 A QMS shared folder on Rwanda FDA head office server on the following link: (\\rwandafdaserver\qms\sops\)
6.7 Hard copies to staff that have no access to the Rwanda FDA server.

7.0 Safety Precautions

Not applicable to this SOP

8.0 Materials and equipment

8.1 Database of licensed pharmaceutical establishments

9.0 Procedure

9**.1** Each local licensed pharmaceutical establishment will be inspected by the Authority at least once a year.

9.2 In the first month of each fiscal year, the Drugs Inspections & Compliance Analyst updates the database of licensed pharmaceutical establishments and then prepares an annual inspection plan covering all licensed pharmaceutical establishments with detailed schedule of their inspection.

9.3 The prepared annual inspection plan is sent to the Division Manager of Food and Drugs Inspection and Compliance for verification and then submitted to the Head of Department of Food and Drugs Inspection and Safety Monitoring for approval. The annual inspection plan of licensed pharmaceutical establishments shall be approved not later than the last day of the first month of the fiscal year/financial year.

9.4 The approved annual inspection plan is shared with food and drugs inspection and compliance division for their preparedness and implementation.

9. 5 Signed annual inspection plan shall be maintained at the registry for a period of five years and then disposed of by tearing/burning/shredding or any other appropriate method

10.0 References

10.1 The Rwanda FDA Law Nº 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning.

10.2 Rwanda FDA Suitability and Licensing of Premises Regulations and Guidelines.

11.0 Appendices

N/A

12.0 Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
16 Jul 2021	0	Rwanda FDA Staff	First Issue

End of Document