Document Type: **Standard Operating Procedure**		Doc. Number : QMS/SOP/068 Revision Number : 0 Revision Date : 15 May 2021 Effective Date : 21 May 20201 Review Due Date : 21May 2023
RWANDA FDA Rwanda Food and Drugs Authority	Title: PROCEDURE FOR INSPECTION PLANS USING QRM PRINCIPLES	

1.0 Purpose

To plan for the risk assesment based inspection of products regulated by Rwanda FDA

2.0 Scope

This procedureapplies to all regulated products by Rwanda FDA

3.0 Responsibility

Division Manager of Food and drugs Inspection and compliance division

4.0 Accountability

Head of food and drugs inspection and safety monitoring department

5.0 Distribution

5.1 Head food and drugs inspection and safety monitoring department
5.2 Division Manager of Food and drugs Inspection and compliance division
5.3 Quality Assurance Analyst
5.4 Inspectors: Analysts and Specialists

6.0 Procedure

6 Procedure for planning an inspection using risk assessment principles

6.1 Division Manager of Food and Drugs Inspection and compliance shall appoint the team and designate the team leader with the adequate competency as per the inspection to be undertaken The appointed team under the coordination of the Team Leader shall examine the product safety/quality risks factors from production environment, processes, products composition and the history of products to compliance with existing quality and safety management.

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Signature & Date					

6.2 The appointed team shall select method of inspection.and prioritise establishments to inspect as the results of the analysis of the risks factors of product safety/ quality.

6.3 The appointed team shall submit the risk categories of establshments depending on their products and prioritization of establishments for inspection to the division Manager of Food and drugs Inspection and compliance for review.

6.4 The reviewed risk assesment based inspection plan shall be submitted to The Head food and drugs inspection and safety monitoring department for approval.

6.5 After the approval of the plan, the inspectorate shall officially inform the manufacturer on the proposed date(s) of the inspection

6.6 The inspection plan shall be implemented as scheduled

7.0 Records

8.1 All used forms, various meeting minutes, records of methodology used for the risk categorization of establishments, proof for periodic review of the inspection plan shall be maintained in appropriate files.

7.2 Records shall be kept for a period of five years and thereafter disposed by using appropriate means.

8.0 Document Revision History

Date of revision	Revision number	Document Number	Author(s)	Summary of Changes	Reasons for revision
				NA	New

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Title	Director food and drugs Inspection	QM Specialist	Division manager food and drugs inspection and safety monitoring	Head food and drugs inspection and safety monitoring department	Director General
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Title	Senior Licensing Officers, Drug and Food Inspectorate	Head, Drug Inspectorate Services	Head, Drug Assessment & Registration	Head, Quality Management	Executive Secretary /Registrar	
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