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RWANDA FDA Rwanda Food and Drugs Authority	Title: **Coordination And Workflow In Food And Drugs Inspection And Compliance Division**	

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1.0 Purpose

This standard operating procedure (SOP) provides guidance on coordination among structures and workflow of activities related to Food and Drugs Inspection and Compliance.

2.0 Scope

This SOP applies to all activities in the scope including Food and Drugs Inspection and Compliance.

3.0 Policy

3.1 Law N° 003/2018 of 9/2/2018 establishing Rwanda FDA, determining its mission, organization, and functioning.
3.2 Regulation CBD/TRG/001governing licensing to manufacture pharmaceutical products or to operate as wholesale or a retail seller of pharmaceutical products.
3.3 Regulation CBD/TRG/014 governing licensing to operate online Pharmacy.
3.4 Guidelines N° DIS/GDL/002 on Good Manufacturing Practice for Medicinal Products - Part 1
3.5 Guidelines N° DIS/GDL/003 on Good Manufacturing Practice for Medicinal Products - Annexes
3.6 Guidelines N° DIS/GDL/031for Licensing to Manufacture, to Operate as Wholesale and Retail Seller of Medical Products.
3.7 Guidelines N° DIS/GDL/032 for Good Distribution Practices of Medical products.
3.8 Guidelines N° DIS/GDL/005 for Registration and Licensing of Food Premises.
3.9 Guidelines N° DIS/GDL/006 for Good Manufacturing Practices of Food.

4.0 Definitions and Abbreviations

4.1 Definitions

Workflow: the sequence of steps, administrative, or other processes through which activities passes from initiation to completion

4.2 Abbreviations

QMS: Quality-Management System
FDIC: Food and Drugs Inspection and Compliance
GMP: Good Manufacturing Practices

5.0 Responsibility

5.1 Director General is responsible for the overall approval of annual work plan and coordination mechanism
5.2 Director General is responsible for ensuring all structures required in vigilance, market control and clinical trial oversight are established
5.3 Head of department of food & Drug inspection and Safety monitoring is responsible for:
5.3.1Review, providing regulatory guidance on management
5.3.2 Approve concept notes, field investigation reports and meeting reports.
5.3.3 Ensure the division, structures involved are in vigilance, market control and clinical trial have conducive environment for the proper performance
5.4 The Division manager of Food and Drugs Inspection and Compliance is responsible for:
5.5 The oversight of planning and implementation of Inspection and Licensing activities.
5.5.1 Provide leadership and line management to the division of FDIC and oversight of internal staff as well as coordination of all stakeholders including committees
5.5.2 Coordinate the functioning of all structures involved in the Food and Drugs Inspection and Compliance.
5.5.3 Prepare and control work plan, direct supervision of daily activities of all staff in the division
5.6 Analysts and Specialists in FDIC division are responsible for implementation of duties and responsibilities described in relevant job description and work plan
5.7 Established committees are responsible for implementation of respective tasks as per terms of references.
5.8 Quality Assurance Analyst ensure that this SOP is regularly updated

6.0 Distribution

6.1 Director General
6.2 Head of Department of Food and Drugs Inspection and Safety Monitoring
6.3 Division Manager of Food and Drugs Inspection and Compliance,
6.4 Drugs Inspection and Compliance Analyst,
6.5 Food Inspection and Compliance Analyst,
6.6 GMP &GLP Analyst,
6.7 Pharmaceutical Establishment Licensing Specialist,
6.8 Cosmetics and Household Chemicals Establishments Inspection Specialist,
6.9 Food Establishment Licensing Specialist,
6.10 Food Industry&Outlet Inspection and Compliance Specialist,
6.11 Quality assurance Analyst

7.0 Safety Precautions

N/A

8.0 Materials and equipment

N/A

9.0 Procedure

I. COORDINATION AND WORKFLOW OF FOOD AND DRUGS INSPECTION AND COMPLIANCE

DIVISION FOR FDIC

9.1 The Division manager of FDIC ensures annual action plan is developed to strengthen the quality system in the country.

9.2 The specialist and analysts implement the Food and Drugs Inspection and Compliance routine activities.

9.3 The Division manager submit the weekly report, monthly , quarterly and annual report to Head of department.

9.4 The division manager of FDIC present the schedule plan and achievement in the weekly meeting organized by the department

COORDINATION OF INSPECTION FOR LICENSING

9.5 Preparation of concept note of the licensing inspection

The concept note must show the *general introduction*, the *Rationale of the inspection for the targeted applications, the inspectors, the budget of the inspection and expected results*

9.6 Preparation for the inspection

9.6.1 The Division Manager of food and drugs inspection and compliance plans and coordinates the inspection, and designates at least two inspectors to conduct licensing inspection

9.6.2 The Division Manager assigns the staff to draft the concept note and mission authorization of the inspection for approval,

9.6.3 For new applications, renewal of the license and relocation of premise; inspectors shall conduct the inspection within 10 working days in Kigali City and outside Kigali City from the reception date of the application in the Division.

9.6.4 Before conducting the inspection, the inspectors shall prepare and/or have the following:
9.6.5 The inspection plan that include the list of premises to be inspected

9.6.6 Application forms for the premises to be inspected

9.6.7 Inspection report templates and checklists for conducting the inspections

9.7 Inspection materials

Once the concept note is approved, inspectors prepare all required tools to conduct the inspection and according to the premise category, different tools will be used but not limited to:

9.7.1 Inspection checklist books

9.7.2 PV de Constant measuring tape and camera/tablet in good condition and if any dysfunctional issue is noticed with tools to be used, it must be declared before the inspection

9.8 Conducting the inspection

9.8.1 The inspection should be conducted professionally in a calm and respectful mood,

9.8.2 The inspectors introduce themselves to the applicant and explain the reason and importance of the inspection and be identified by their uniforms, service cards or badges,

9.8.3 The applicant introduces the responsible technician to provide technical details,

9.8.4 The inspectors verifies if the technician (s) introduced at the site of inspection are the same with the ones in the submitted application,

9.8.5 Inspectors use the inspection checklist to obtain required information,

9.8.6 Recommendations are given using the PV,

9.8.7 When filling the PV, the inspector should start with the critical, major, moderate and end with minor recommendations

9.8.8 After the inspection, the inspectors discuss and agree with applicant on the inspection findings and both parties sign the PV. The inspectors give the signed copy of the PV to the applicant

9.8.9 The inspectors prepare a feedback letter highlighting all recommendations given to the applicant for hierarchy approval and the feedback has to reach to the applicant within 10 working days from the inspection date,

9.8.10 Applications whose premises are inspected and found to be satisfactory are tabled for approval in the internal committee meeting chaired by the Head of Food and drugs inspection and safety monitoring department every week. If the presentation is satisfactory, the application is recommended for approval.

9.9 Internal Committee Review For Licensing Activities

9.9.1 During this session, inspectors present their findings to the committee preferably with pictures to help members of the committee to take better decision,

9.9.2 When the committee finds the inspection results fulfil the minimum requirements as per regulations and guidelines, the application is given the approval and,

9.9.3 The inspection book, reports of the inspection and minutes of the internal committee review are handled to the staff assigned with the dossier to incorporate them in the application dossier,

9.9.4 The staff assigned with the dossier, prepares the operational license and submits the license for hierarchy approval and it must be issued within 10 days from committee review date.

COORDINATION OF GMP INSPECTIONS

9.10 Planning For GMP Inspections

Receipt of application for GMP inspection:
9.10.1 The GMP analyst shall receive the application for GMP inspection and check for the availability and completeness of the following;

9.10.2 Duly completed GMP inspection application form
9.10.3 Current Site Master File

9.10.4 Receipt of payment for inspection

9.10.5 Department of Drug and Food assessment and Registration request form (for new manufacturing sites)

9.11 Scheduling of Premises for inspection

The Division Manager shall allocate dates and duration of inspection based on:
9.11.1 Type of inspection to be performed and the purpose of the inspection or visit.

9.11.2 Anticipated duration of inspection based on plant size, number of blocks/production lines and activities. A combination of all, or some of the factors for selection as appropriate.

9.11.3 Scheduling to be carried out within a period of six months and allocate tentative dates and will be checked and reviewed regularly within the specified period.

9.11.4 The Division Manager of Food and Drugs Inspection and Compliance department shall appoint the inspection team and designate the lead inspector with the adequate competency as per the inspection to be undertaken. He/she will forward the tentative draft schedule of facilities to be inspected to the Head of Department Food and Drugs Inspection, Safety and Monitoring Department.

9.11.5 The Head of Department Food and Drugs Inspection and Safety Monitoring Department shall:
9.11.5.1 Review and approve the inspection schedules

9.11.5.2 Communicate the proposed inspection dates to the manufacturing site for Confirmation

9.11.5.3 Receive the confirmation of the inspection dates whether by email or hard copy and forward them to the GMP analyst to liaise with team lead inspector to prepare for the inspection as per SOP for preparation for GMP inspection.

9.12 Conducting GMP inspections

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

9.12.2 All inspections should be started with an opening meeting for guidance on what should be covered during the meeting.

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

9.12.4 Circulate the attendance record form to enable all persons present to record names, positions in the company and email address.

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

9.12.6 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.

9.12.7 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.

9.12.8 Maintain notes during the inspection and keep this record for filing on the company file after completion of the inspection.

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

9.12.10 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.

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

9.12.12 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. should be covered during the meeting.

9.12.13At 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.

9.12.14The 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.

9.12.15All documents mentioned should be filed in the company file by the relevant GMP inspection team leader of who arranged the inspection.

9.13 Peer Review and Approval of the GMP Inspection Report
The Lead GMP Inspector, accompanied by the team inspector (s), shall present the draft GMP Inspection Report to the GMP Peer Review Committee (GPRC) meeting

9.13.1 The GMP Peer Review Committee members, serving as per the GPRC Terms of References,
shall; read the reports, assess their text, context and facts and agree or disagree with the recommendations of the GMP audit team during committee meetings

9.13.2 A site shall be rated compliant to GMP if it has:
a) No "non-compliance"
b) No "critical" or "major" non-compliances but has only "other" non-compliances
c) Major non-compliances that are rectified and corrective action and preventative action (CAPA) submitted by the manufacturer not more than three months from the date of the report has been evaluated found satisfactory within six months from the date of inspection.

9.13.3 A site shall be rated non-compliant to GMP if it has:
a) One or more "critical" non-compliances
b) One or more "major" non-compliances for which the CAPA submitted has been found unsatisfactory or the CAPA has not been submitted to Rwanda FDA three months from date of the GMP inspection report.

9.13.4 The GMP Inspection team shall make conclusion of their assessment of the acceptability of
the GMP status of the facility for the range of products manufactured, using one of the examples below that is appropriate for the rating.

9.13.4.1 *"Based on the areas inspected, the people met and the documents reviewed, and* considering the findings of the inspection, including the observations listed in the Inspection Report, the facility was considered to be operating at an acceptable level of compliance with Rwanda FDA GMP guidelines and Rwanda FDA GMP requirements

However, the observations (non-compliances with guidelines) listed below must be addressed in a timely manner. The manufacturer is expected to respond to all observations and for each include a description of the corrective action implemented or planned to be implemented, and the date of completion or target date for completion. The acceptability of corrective actions will be assessed through evaluation of the response to each observation and will be followed *up during the next inspection."*Or

9.13.4.2 *"Based on the areas inspected, the people met and the documents reviewed, and* considering the findings of the inspection, including the observations listed in the in the Inspection Report, the facility was considered to be operating at an unacceptable level of compliance with Rwanda FDA GMP requirements. Another inspection will be required to verify the implementation of corrective actions before *the manufacturer's level of GMP compliance can be reconsidered."*

9.13.5 The inspection team shall sign the final inspection report and forward it to the GMP Analyst within 1 working day after the meeting.

9.13.6 GMP certificate of compliance shall be issued only after a site has been rated compliant . Both a GMP certificate and manufacturing license in case of local facilities in Rwanda, shall be issued if a site is rated compliant, however, a manufacturing license shall only be issued if a site's compliance status is to be made after approval of the corrective action and preventative action report. GMP certificate of compliance,

9.13.7 Rwanda FDA shall demand for corrective actions and preventative actions to be done and a compliance report with evidence of implementation of corrective actions and supporting documentation submitted for review and approval before the GMP certificate of compliance is issued.

9.13.8 where necessary, and depending on the risk category, a follow-up inspection may be undertaken for a site that has major non- compliances prior to close-out of the inspection and issuance of a GMP certificate of compliance .

9.13.9 The GMP analyst shall forward the signed report, covering letter together with the GMP certificate of compliance (only for facilities rated as GMP compliant) for review and verification by Division Manager of Food and Drugs Inspection and Compliance.

9.13.10 The GMP analyst shall then forward the signed report, covering letter together with the GMP certificate for endorsement by the Director General.

9.13.11 The GMP analyst shall then scan and email the signed report, covering letter giving the time frame for the plan for corrective measures together with the GMP certificate (the latter applies only if a facility is rated compliant to GMP) to the applicant and/ or contact person in the manufacturing facility within 45 working days from the date GMP inspectors return to office.

9.13.12 The hard copy of the report shall be sent to the site of manufacture by courier and a copy sent to the local technical representative in Rwanda.

9.13.13 The time frame for corrective measures may be dependent on the risk category of the noncompliance and the inspection rating but generally, the company is given one month from the date of the report to respond to the inspection report and provide a plan for corrective measures and preventative actions.

9.14 GMP Certification

Upon conduction of successful GMP desk assessment/ GMP inspection of facility. The assessment/inspection report is scheduled for committee review and validation.

9.14.1 Once the application has been reviewed and validated, the GMP inspector will prepare a GMP certificate and submit it to the for Food and Drugs Inspection and Compliance Division Manager.

9.14.2 The Division Manager of Food and Drugs Inspection and Compliance will then review the dossier and submit it to the Head of Food and Drugs Inspection and compliance department.

9.14.3 The Head of Food and Drugs Inspection and compliance department shall forward the completed report and GMP certificate of compliance for endorsement by the Director General.

9.14.4 The endorsed report and GMP certificate shall be scanned and emailed to the contact person at the manufacturing site.

10.0 References

Job description /Rwanda Food and Drugs Authority
Scope of work for division

11.0 Appendices

N/A

12.0 Document Revision History

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

End of Document