RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR GOOD MANUFACTURING PRACTICES INSPECTIONS FOR PHARMACEUTICAL PRODUCTS MANUFACTURING FACILITIES

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FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by Law Nº 003/2018 of 09/02/2018 determining its mission, organization and functioning. One of its main powers is to formulate regulations and guidelines for regulating the manufacture of Pharmaceutical products to ensure that they comply with the quality standards required for good manufacturing practices.

Given the provisions of *the Regulations Nº FDISM/FDIC/TRG/005, governing Good Manufacturing Practices for medical products.* Rwanda FDA issues the following guidelines entitled Guidelines Nº DD/PIL/GDL/012 Rev_0 on Good Manufacturing Practices Related to Inspections for Pharmaceutical Products Manufacturing Facilities.

These guidelines repeal and replace all previous guidelines which were used for regulation of Good Manufacturing Practices namely "Guidelines on Good Manufacturing Practices for Finished Pharmaceutical Products - Part 1, Doc. No.: FDISM/FDIC/GDL/001", "*Guidelines on Good Manufacturing Practices for Active Pharmaceutical Products - Part 2*" and *Guidelines on Good Manufacturing Practices on Medical Products _ Annexes, Doc. No.: FDISM/FDIC/GDL/002*."

Poorly manufactured pharmaceutical products' effects are one of the public health concerns not only in our country but also all over the world. It is in this context that the Rwanda Food and Drugs Authority intends to put in place guidelines that provide for good manufacturing practices of pharmaceutical products to ensure that manufactured medicines do not constitute harmful effects to public health.

It is expected that these guidelines will offer a clear understanding to manufacturers on requirements and regulators during the evaluation process; they will protect consumers and the pharmaceutical manufacturing industry, thus promoting health protection, business as well as the national economy as a whole.

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Director General

DOCUMENT DEVELOPMENT HISTORY

First issue date	Refer to approval date
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DOCUMENT REVISION HISTORY

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1	This first issue combines previous GMP guidelines; namely "Guidelines on Good Manufacturing Practices for Finished Pharmaceutical Products - Part 1, Doc. No.: FDISM/FDIC/GDL/001, Guidelines on Good Manufacturing Practices for Active Pharmaceutical Products - Part 2 and Guidelines on Good Manufacturing Practices on Medical Products _ Annexes, Doc. No.: FDISM/FDIC/GDL/002" which will become obsolete while this version becomes effective.

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ACRONYMS AND ABBREVIATIONS

API	Active Pharmaceutical Ingredient
CAPA	Corrective and Preventive Actions
EAC	East African Community
EMA	European Medicines Agency
GMP	Good Manufacturing Practices
HVAC	Heating, Ventilation and Air Conditioning
ICH	International Council for Harmonization
IAEA	International Atomic Energy Agency
PIC/S	Pharmaceutical Inspection Cooperation Scheme
Rwanda FDA	Rwanda Food and Drugs Authority
TRS	Technical Report Series
WHO	World Health Organization
US FDA	United States Food and Drugs Authority

GLOSSARY / DEFINITIONS

"Active pharmaceutical ingredient (API) or Drug substance" Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body;

"Batch or lot" A unique combination of numbers, letters, and/or symbols that identifies a batch (or lot) and from which the production and distribution history can be determined;

"Cross-contamination" Contamination of a material or product with another material or product;

"Finished product" A product that has undergone all stages of production, including packaging in its final container and labelling. A finished pharmaceutical product may contain one or more active pharmaceutical ingredients;

"Manufacture" All operations of receipt of materials, production, packaging, repackaging, labelling, relabelling, quality control, release, storage, and distribution of API and related controls;
All operations of purchase of materials and products, Production, Quality Control, release, storage, distribution of medicinal products and the related controls;

"Manufacturer" A company that carries out operations such as production, packaging, repackaging, labelling and labelling of products regulated, by Rwanda FDA;

"Manufacturing process" For convenience, when the term "manufacturing process(es)" is used, it also includes facilities and equipment that might impact on critical processing parameters and, thereby, on product quality;

"Marketing authorization" Approval from Rwanda FDA necessary to market and sell a product in Rwanda. This is a legal document that establishes the detailed composition and formulation of the product and the pharmacopoeia or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life;
A legal document issued by Rwanda FDA for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality;

"Pharmaceutical product" Any substance capable of preventing, treating human or animal diseases and any other substance intended for administration to a human being or an animal in order to diagnose diseases, restore, correct or carry out modification of organic or mental functions. It also means products used in disinfecting premises where food and drugs are manufactured, prepared or stored, cleaning hospitals, equipment and farm houses;

"Production" All operations involved in the preparation of medicinal products, from receipt of materials, through processing and packaging, to its completion as a finished product;
All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and re-labelling, to completion of the

finished product;

"Validation" Action of proving, in accordance with the principles of Good Manufacturing Practices, that any procedure, process, equipment, material, activity or system actually leads to the expected result;

1. CHAPTER I: INTRODUCTION

1.1. BACKGROUND

Rwanda FDA was established by Law Nº 003/2018 of 09/02/2018 Determining its mission, organization and functioning. The mandate of Rwanda FDA is to protect public health through regulation of human and veterinary medicines, vaccines and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco and tobacco products.

1.2. Purpose of these guidelines

These guidelines consist of links for the World Health Organization (WHO) Technical Report Series (TRS) and other internationally recognized guidelines which provide for Good Manufacturing Practices (GMP) requirements for various aspects applicable to manufacturing facilities.

These guidelines replace *Guidelines on Good Manufacturing Practices for Finished Pharmaceutical Products - Part 1, Doc. No.: FDISM/FDIC/GDL/001, Guidelines on Good Manufacturing Practices for Active Pharmaceutical Products - Part 2* and *Guidelines on Good Manufacturing Practices on Medical Products _ Annexes, Doc. No.: FDISM/FDIC/GDL/002*.

These guidelines are intended to provide guidance that should be followed by all entities involved in any aspect of manufacturing pharmaceutical products. It targets both domestic and foreign manufacturers who intend to obtain marketing authorization for their pharmaceutical products in Rwanda.

Therefore, these guidelines shall form the basis of GMP inspection by Rwanda Food and Drugs Authority (Rwanda FDA) as one of the requirements for registration of pharmaceutical products in Rwanda.

1.3. Legal framework

Article Nº 9, paragraph 1 of the Law Nº 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning grants Rwanda FDA with the power to formulate regulations and guidelines for regulating the manufacture, import and export, distribution, sale and use of regulated products.

Article 8 paragraph 2 of the above law states also that Rwanda FDA regulates compliance with quality standards relating to the manufacture, storage, sale, distribution, use, import and export, labels, packages and raw materials used in the manufacture of products regulated under this Law.

One of the means of regulating the manufacture of pharmaceutical products is through compliance with Good Manufacturing Practices (GMP) requirements as laid down in these guidelines. These guidelines were also developed in accordance with Regulations Nº FDISM/FDIC/TRG/005 governing Good Manufacturing Practices for medical products.

1.4. Scope

These guidelines shall be used for GMP inspection of all manufacturers of pharmaceutical products within and outside Rwanda whose products are registered or subjected to registration in Rwanda; irrespective of their size, type of products, product range or location of the manufacturing facilities. Manufacturers that are GMP compliant shall be awarded certificates of compliance with GMP.

2. CHAPTER II: GOOD MANUFACTURING PRACTICES INSPECTION

2.1 Types of Inspections

There shall be five types of GMP inspections, which shall be divided into the following categories:

i. Routine inspection;
ii. Concise inspection;
iii. Follow-up inspection;
iv. Special inspection; and
v. Any other types that Rwanda FDA may designate.

The inspection shall be conducted as follows:

a. The routine inspection is a full inspection of all applicable components of GMP and licensing provisions. It shall be conducted at any time when the product is to be registered or have been registered but before the expiry of validity of registration of such product. It may be indicated when the manufacturer:

   i. requests for a manufacturing license or a renewal of a manufacturing license;
   ii. has a history of non-compliance with GMP;
   iii. has introduced new product lines or new products, or has made significant modifications to manufacturing methods or processes, or has made changes in key personnel, premises, equipment, etc;
   iv. has not been inspected during the last 3 to 5 years.

b. Concise GMP inspections are the evaluation of limited aspects relating to GMP compliance within a facility. The manufacturers with a consistent record of compliance with GMP through previous routine inspections are eligible for concise inspections. The focus of a concise inspection is on a limited number of GMP requirements selected as indicators of overall GMP performance, plus the identification of any significant changes that could have been introduced since the last inspection. Collectively, the information obtained will indicate the overall attitude of the firm towards GMP. Evidence of unsatisfactory GMP performance observed during a concise inspection should trigger a more comprehensive inspection.

c. Follow-up GMP inspections (reassessment or re-inspection) are made to monitor the result of corrective measures. They are normally carried out from 6 weeks to 6 months after the initial inspection, depending on the nature of the defects and the work to be undertaken. They are limited to specific GMP requirements that have not been observed or that have been inadequately implemented.

d. Special GMP inspections may be necessary to undertake spot checks following complaints, recalls related to suspected quality defects in products or reports of adverse drug reactions. Such inspections may be focused on one product, a group of related products, or specific operations such as mixing, sterilization, or labeling. Special visits may be also made to establish how a specific product is manufactured as a prerequisite for marketing approval or issuance of an export certificate. A further reason for special visits to gather specific information on or to investigate specific operations and to advise the manufacturer of regulatory documents.

e. Any other types as Rwanda FDA may designate. This may include pre-approval inspection for newly established facilities.

2.2 Application for GMP

The manufacturer or applicant who intends to apply for Good Manufacturing Practices inspection shall submit an application dossier to Rwanda FDA through the Integrated Regulatory Information Management System (IRIMS) available at Rwanda FDA website.

The requirements for application for GMP inspection of finished pharmaceutical products and active pharmaceutical ingredients manufacturing facilities are detailed in annexes 1 and 2 of these guidelines. Notwithstanding the provisions above, the inspection shall not be conducted at the facility which has not submitted applications for product registration or a facility that did not apply for manufacturing license.

The Application should be accompanied by prescribed fees as provided in Regulations governing tariff/fees and charges on services rendered by Rwanda Food and Drugs Authority.

2.3 Risk-Based GMP Inspection Planning

Rwanda FDA shall apply a risk-based approach when planning, prioritizing and scheduling GMP inspections. The annual GMP inspection plan shall be prepared based on applications received, public health priorities, product risk, compliance history and available regulatory intelligence.

The following factors may be considered when assigning inspection priority:

a) type and risk category of products manufactured, including sterile products, biological products, vaccines, blood products, high-potency products, cytotoxic products, hormones, beta-lactams and other sensitizing products;

b) previous GMP compliance history of the manufacturing site;

c) history of critical or repeated major deficiencies;

d) history of product complaints, recalls, quality defects, adverse regulatory actions or market surveillance findings;

e) introduction of new products, new dosage forms, new technologies or new manufacturing activities;

f) substantial changes to premises, equipment, utilities, processes, personnel or outsourced activities;

g) validity status of existing GMP certificates issued by Rwanda FDA or other regulatory authorities;

h) importance of the product to public health and availability of alternative sources;

i) reliance or recognition opportunities based on decisions of trusted regulatory authorities.

Rwanda FDA may revise the annual GMP inspection plan where necessary based on emerging risks, public health needs, regulatory intelligence or resource availability.

2.4 GMP Reliance and Recognition of Regulatory Decisions

Rwanda FDA may apply reliance or recognition of GMP regulatory decisions issued by other competent regulatory authorities, including WHO Listed Authorities, members of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), the WHO Prequalification Programme, regional regulatory frameworks to which Rwanda belongs, or authorities with which Rwanda FDA has established cooperation arrangements (MOU).

Reliance or recognition shall not constitute automatic acceptance of an external regulatory decision. Rwanda FDA shall retain full regulatory responsibility and may accept, partially accept, reject or request additional information based on its own scientific and regulatory assessment.

An applicant requesting consideration through reliance or recognition shall submit the following, where applicable:

a) application letter;

b) valid GMP certificate issued by the reference authority;

c) latest GMP inspection report;

d) evidence of CAPA closure or current CAPA status;

e) current Site Master File;

f) list of products manufactured at the site and those intended for the Rwandan market;

g) manufacturing licence or equivalent authorization issued by the country of origin;

h) evidence of product registration or application for registration in Rwanda, where applicable;

i) declaration of any regulatory actions, warning letters, import alerts, suspension, revocation, recalls or serious quality defects associated with the site or products;

j) any additional information requested by Rwanda FDA.

Rwanda FDA may conduct a desk assessment and may issue a GMP certificate through reliance or recognition where the submitted evidence demonstrates acceptable GMP compliance. However, Rwanda FDA may require an on-site inspection where the site is high risk, the information submitted is incomplete, regulatory concerns exist, or the scope of the reference certificate does not cover the products or activities intended for Rwanda.

The validity of a GMP certificate issued through reliance or recognition shall not exceed the validity period of the reference GMP certificate.

2.5 Virtual GMP Inspections

Rwanda FDA may conduct virtual or remote GMP inspections where physical inspection is not feasible or where a risk-based assessment determines that a virtual inspection is appropriate.

Virtual inspections may be considered in the following circumstances:

a) force majeure or emergency situations preventing physical inspection;

b) foreign manufacturing sites with acceptable compliance history;

c) follow-up verification of CAPA implementation;

d) inspection of limited GMP activities;

e) sites supported by valid GMP evidence from trusted regulatory authorities;

f) other circumstances determined by Rwanda FDA.

Before a virtual inspection, the applicant shall ensure availability of suitable information technology systems, secure document sharing platforms, live video access to relevant areas, real-time interaction with responsible personnel and access to GMP records.

Rwanda FDA may request pre-inspection submission of documents including the Site Master File, quality manual, validation reports, product quality reviews, deviation and CAPA records, change control records, complaints and recall records, environmental monitoring data, batch manufacturing records and any other relevant documents.

The limitations of virtual inspection shall be considered in determining the inspection outcome. Rwanda FDA may require a follow-up on-site inspection where the virtual inspection is insufficient to confirm GMP compliance.

2.6 Temporary Waiver of On-site GMP Inspection During Emergency Situations

Rwanda FDA may grant a temporary waiver of on-site GMP inspection during emergency situations, public health emergencies, force majeure events, product shortage situations or other circumstances where physical inspection cannot be conducted within the required timelines.

A temporary waiver shall be granted only after a documented risk-based assessment. The applicant shall submit adequate evidence demonstrating that the manufacturing site is operating under acceptable GMP conditions.

The application for temporary waiver shall include:

a) justification for the waiver request;

b) valid GMP certificate or equivalent evidence of GMP compliance;

c) latest inspection report from a competent regulatory authority;

d) CAPA status from the most recent inspection;

e) Site Master File;

f) list of products intended for Rwanda;

g) quality defect, complaint and recall history;

h) declaration of any regulatory actions affecting the site;

i) proposed period for which the waiver is requested.

A temporary waiver shall be valid for a defined period and may be subject to conditions, including submission of periodic compliance updates, product quality reviews or commitment to undergo inspection when feasible.

Rwanda FDA may revoke the waiver where new information indicates potential risk to product quality, safety, efficacy or public health.

2.7 Inspection frequency

The Manufacturing facility shall be inspected once after every 3 years. However, a facility may be inspected at any time whenever deemed necessary as per the risk rating score of the facility

2.8 Preparation for inspection

The annual GMP inspection plan, spanning from July to the following June, is prepared and it is subject to adaptation based on quality risk management of received GMP inspection applications and the priorities of licensing, marketing authorisations and post-marketing surveillance.

Rwanda FDA shall inform the facility of the proposed inspection date before the inspection takes place unless it is a special inspection or other type of inspection that Rwanda FDA designated. The inspector shall be responsible for communicating with the facility regarding the modality and plan of inspection.

The respective facility shall make the necessary preparations for inspection at the agreed time.

Under exceptional circumstances and with proper justification, a facility wishing to change the agreed inspection dates shall do so in writing proposing the most convenient date for both parties.

Cancellation of a scheduled GMP inspection after confirmation of inspection dates requires a submission of a new application for inspection, along with paying the prescribed fees again. This ensures that the inspection process is properly rescheduled, allowing for the assessment of compliance with GMP standards to proceed in a timely manner. A new application entails new timelines that become effective from the date of application receipt as per these guidelines.

2.9 GMP Inspection Team Composition and Responsibilities

Rwanda FDA shall appoint qualified inspectors to conduct GMP inspections of domestic and foreign manufacturing facilities.

The inspection team may include:

a) Lead Inspector;

b) Co-inspector;

c) Technical expert, where specialized expertise is required;

d) Observer, where applicable;

e) representative of another regulatory authority during joint inspections.

The Lead Inspector shall coordinate the inspection, communicate with the applicant, lead opening and closing meetings, ensure documentation of findings and coordinate preparation of the inspection report.

All inspectors, experts and observers shall declare any potential conflict of interest before participating in an inspection. Inspectors shall maintain confidentiality of all information obtained during GMP inspection, desk assessment, virtual inspection, reliance assessment or other regulatory review.

Where a conflict of interest is identified, Rwanda FDA shall take appropriate measures, including replacement of the concerned inspector or restriction of access to relevant information.

2.10 Execution of GMP inspection

During the inspection, inspectors shall observe, verify and review manufacturing processes, procedures and records to establish compliance with the GMP requirements stipulated in these guidelines.

The inspector shall inspect using these guidelines.

At the end of an inspection, observations shall be documented in the GMP inspection Memorandum Form as annex 7, which shall be signed by both parties and a copy given to the inspectee.

Inspection of one facility shall take 3 to 5 days depending on the number of production blocks or lines available at the facility.

2.11 Reporting and communication of inspection findings

Inspection reports shall be prepared and communicated to the inspectee within 60 working days from the last date of inspection.

Compliant inspected facilities and regulatory actions taken against manufacturers are published on the Rwanda FDA website.

2.12 Classification of inspection findings

The categorization of GMP inspection findings will be as described in PIC/S guidance on the classification of GMP deficiencies, PI 040-1,3 Appendices,1 January 2019.

Non – compliances found during inspections are classified into the following three categories:

a) **Critical non-compliance:** A non-compliance which has produced, or leads to a significant risk of producing either a product which is harmful to the human or veterinary patient or a product which could result in a harmful residue in a food-producing animal.

Critical non-compliances may include:

i. Lack of sterilization validation (relevant to all sterile products).
ii. Lack of adequate control measures resulting in an actual, or significant risk of cross–contamination above the level of the health-based exposure limit in subsequent products.
iii. Evidence of gross pest infestation (relevant to all manufacturers).
iv. Falsification or misrepresentation of analytical results or records (relevant to all manufacturers).
v. Failure to ensure the quality and/or identity of starting materials (relevant to all manufacturers).
vi. No master batch documents (relevant to all manufacturers).
vii. Absence, falsification or misrepresentation of manufacturing and packaging records (relevant to all manufacturers).
viii. Water system for sterile products not validated (for manufacturers of sterile products).
ix. HVAC system for sterile products not validated (for manufacturers of sterile products).
x. Grossly unsuitable premises so that there is a high or likely risk of contamination (relevant to all manufacturers).
xi. No evidence that mandated recall processes have been complied with (relevant to all manufacturers).

b) **Major non-compliance may include;**

A deficiency that is not a “Critical” deficiency, but which:

i. has produced or may produce a product which does not comply with its Marketing Authorisation, Clinical Trial Authorisation, product specification; pharmacopoeia requirements or dossier;
ii. does not ensure effective implementation of the required GMP control measures;
iii. indicates a major deviation from the terms of the manufacturing authorisation;
iv. indicates a failure to carry out satisfactory procedures for release of batches or (within PIC/S) failure of the authorised person to fulfil his/her duties;
v. consists of several “Other” related deficiencies, none of which on its own may be “Major”, but which may together represent a “Major” deficiency or systems failure and should be explained and reported as such.

Major Deficiencies may include:

i. Lack of validation of critical processes (applicable to all medicines, but could be "Critical" for low dose/high potency products; particularly sterilization processes for sterile products)
ii. No or grossly inadequate air filtration to minimise airborne
iii. Contaminants (applicable to all medicines manufacturers - could be "Critical" if possible contaminants are a safety concern and "Critical "for sterile medicines)
iv. Missing or ineffective control measures to provide adequate confidence that cross-contamination will be controlled within the health-based exposure limit in subsequent products. (would be "Critical" if resulting cross-contamination has or is likely to exceed the health-based exposure limit)
v. Damage (holes, cracks, peeling paint) to walls/ceilings in manufacturing areas where a product is exposed in non-sterile areas
vi. Design of manufacturing area that does not permit effective cleaning Insufficient manufacturing space that could lead to mix-ups
vii. No raw material sampling area for medicine manufacturers (could be classed as "Other" if adequate precautions are taken)
viii. Sanitary fittings not used on liquid/cream manufacturing equipment
ix. Stored equipment not protected from contamination
x. Individuals in charge of QC/production not qualified by education, competency training and experience
xi. Inadequate initial and ongoing training and/or no training records
xii. Cleaning procedures not documented and/or no cleaning records
xiii. Production equipment cleaning procedures not validated
xiv. Reduced QC testing of raw materials without data to certify suppliers
xv. Incomplete testing of raw materials
xvi. Test methods not validated
xvii. Complex production processes for non-critical products not validated
xviii. Unapproved/undocumented changes to master batch or equivalent documents
xix. Deviations from instructions not approved
xx. No or inadequate internal inspection program
xxi. No proper release for supply procedure
xxii. Product reworked without proper approval
xxiii. No system/procedures for handling complaints or returned goods
xxiv. Inadequate testing of packaging materials
xxv. No ongoing stability program and/or stability data for all products not available
xxvi. Insufficient lighting in production or inspection areas
xxvii. Containers from which samples have been taken not identified
xxviii. The temperature of critical temperature controlled storage areas not monitored and alarmed
xxix. Inadequate change control system
xxx. Inadequate deviation system
xxxi. No investigation into alarms and temperature excursions for deviations from storage or transport requirements

c) Other non-compliances may include:

A deficiency which cannot be classified as either critical or major, but which indicates a departure from good manufacturing practice. A non-conformance may be "other" either because it is judged as minor, or because there is insufficient information to classify it as critical or major.

2.13 Decision on compliance

2.8.1 The status of compliance with these guidelines should be determined by the nature and number of deficiencies:

a) When there are other deficiencies other than major or critical deficiencies
   i. The site is considered to be operating at an acceptable level of GMP compliance,
   ii. The manufacturer is expected to provide CAPAs,
   iii. CAPAs are evaluated and followed up during the next routine inspection

b) When there are minor and less than six (<6) major non-compliance observations from different six quality systems namely, pharmaceutical quality; production; facilities and equipment; laboratory control; materials; and packaging and labelling systems:
   i. The site is compliant with GMP after assessing the CAPAs,
   ii. CAPAs for all deficiencies to include actions implemented and/or planned, timelines and documented evidence of completion, as appropriate,
   iii. CAPAs are evaluated on paper and may or may not include an on-site, follow-up inspection.

c) When there are critical or six or more (≥6) major non-compliance observations from different quality systems:
   i. The site is considered to be operating at an unacceptable level of compliance with GMP guidelines,
   ii. Another inspection will normally be required,
   iii. Administrative and/or legal enforcement actions are applied as necessary.

2.8.2 The next date for inspection of the site should be determined depending on the level of compliance and risk category as defined under national or regional procedures.

2.8.3 The report shall be signed by all inspection team members, but may be signed by the lead inspector after consultation with and on behalf of the inspection team, and reviewed in accordance with the quality system of the inspectorate.

2.14 Guidance on responding to inspection findings

The facility shall prepare and implement a CAPA plan where applicable upon receiving inspection findings.

The CAPA plan and evidence for its implementation shall be prepared based on quality risk management principles and submitted to Rwanda FDA within 90 calendar days from the date of the inspection report cover letter.

If the company fails to submit a CAPA report within the prescribed period without any request for an extension, the facility shall be considered to be non-compliant.

The CAPA report shall indicate root cause analysis, corrections, corrective actions and preventive actions, timelines and evidence for implementation for each non-compliance observation as per the format provided in Annex Ill of these guidelines.

2.15 Regulatory Actions Following GMP Inspection

Rwanda FDA may take regulatory or administrative action where a manufacturer fails to comply with GMP requirements, the GMP Regulations, these guidelines or conditions under which the GMP certificate was issued.

Regulatory actions may include:

a) request for corrective and preventive actions;

b) request for additional information;

c) warning letter;

d) follow-up inspection;

e) suspension of GMP certificate;

f) revocation of GMP certificate;

g) suspension or withdrawal of marketing authorization;

h) restriction of importation or exportation;

i) product recall;

j) publication of regulatory action on the Rwanda FDA website;

k) administrative fines in accordance with applicable regulations.

The regulatory action shall be proportionate to the nature, severity and risk of the non-compliance.

For minor deficiencies, Rwanda FDA may require corrective action within a specified timeframe.

For major deficiencies, Rwanda FDA may require a comprehensive CAPA plan, warning letter, follow-up inspection or other regulatory action.

For critical deficiencies, Rwanda FDA may suspend or revoke the GMP certificate, recommend suspension or withdrawal of marketing authorization, require product recall or take any other action necessary to protect public health.

2.16 Certification

A GMP certificate is issued on the basis of a completed GMP inspection of a manufacturer operating in accordance with the Rwanda FDA GMP regulations and guidelines. The certificate is issued provided that adequate documentation on the inspection follow-up is submitted.

The GMP certificate declares that the manufacturer complies with GMP, and the certificate includes a reference to the most recent date of the actual inspection, as well as which activities and under which legislation they have been inspected. A GMP certificate is issued to a site and refers to one specific address. For each site, one GMP certificate can be issued per domain that has been inspected.

2.17 Suspension, Revocation and Restoration of GMP Certificate

Rwanda FDA may suspend or revoke a GMP certificate where the manufacturing site is no longer compliant with GMP requirements, where the conditions under which the certificate was issued no longer exist, where serious quality defects are identified, where inspectors are denied access, or where false or misleading information was submitted.

A manufacturer whose GMP certificate has been suspended or revoked shall cease the affected manufacturing, importation, exportation or supply activities as directed by Rwanda FDA.

The manufacturer may request restoration of the suspended or revoked GMP certificate by submitting evidence that the causes of suspension or revocation have been satisfactorily addressed.

Rwanda FDA may conduct a desk assessment, virtual assessment or on-site inspection before restoring the GMP certificate.

Restoration shall only be granted where Rwanda FDA is satisfied that the manufacturer has effectively implemented corrective and preventive actions and that the site is capable of maintaining GMP compliance.

2.18 Appeals Against GMP Decisions

Any applicant or manufacturer aggrieved by a GMP regulatory decision may submit a written appeal to Rwanda FDA within thirty (30) calendar days from the date of notification of the decision.

The appeal shall include:

a) name and address of the applicant;

b) reference number of the application or GMP certificate;

c) decision being appealed;

d) grounds for appeal;

e) supporting evidence or justification;

f) contact details of the responsible person.

Submission of an appeal shall not automatically suspend the regulatory decision unless Rwanda FDA determines otherwise in writing.

Rwanda FDA shall review the appeal in accordance with applicable internal procedures and communicate its decision within thirty (30) working days from receipt of the appeal, unless additional time is required.

Rwanda FDA may uphold, vary or overturn the original decision.

2.19 Validity and renewal of GMP certificate

A GMP certificate is valid for three years but the period of validity can be shortened under special circumstances. All applications for renewal of GMP certificate shall be submitted six months before the expiration date.

2.20 Publication of GMP Compliance Status

Rwanda FDA shall publish and regularly update the list of GMP-compliant manufacturing facilities on its official website.

The published information may include:

a) name and physical address of the manufacturing site;

b) country;

c) GMP certificate number;

d) contact details of the manufacturing site

f) date of certification;

g) expiry date of the GMP certificate;

Rwanda FDA may also publish information on suspended, revoked or expired GMP certificates where necessary to protect public health or support regulatory transparency.

Confidential commercial information shall be protected in accordance with applicable laws and Rwanda FDA procedures.

2.21 Application for Substantial Changes or Modifications

2.21.1 General Requirements

Any manufacturer holding a valid GMP certificate or manufacturing licence shall notify Rwanda FDA of any proposed substantial change or modification that may affect the quality, safety, efficacy, identity, strength, purity, or GMP compliance status of pharmaceutical products manufactured at the site.

No substantial change shall be implemented before obtaining written approval from Rwanda FDA unless otherwise specified by the Authority.

The manufacturer shall maintain an approved internal change control system and perform documented quality risk assessments for all proposed changes.

2.21.2 Examples of Substantial Changes Requiring Prior Approval

The following changes shall require prior review and approval by Rwanda FDA:

a) Premises and Facilities

- Construction of new manufacturing buildings.
- Addition, removal, or modification of production areas.
- Changes to cleanroom classification.
- Changes affecting personnel or material flow.
- Relocation of manufacturing operations to another site.

b) Utilities

- Installation or replacement of water treatment systems.
- Changes to Water for Injection (WFI), Purified Water (PW), clean steam systems.
- Major modifications to HVAC systems.
- Changes affecting environmental control systems.

c) Equipment

- Installation of new critical manufacturing equipment.
- Replacement of critical equipment with equipment of different design or operating principle.
- Changes affecting validated status of equipment.

d) Manufacturing Process

- Introduction of new manufacturing technologies.
- Significant modifications to manufacturing processes.
- Changes in sterilization methods.
- Changes affecting validated process parameters.
- Technology transfer activities.

e) Products and Product Lines

- Introduction of new dosage forms.
- Introduction of new product categories.
- Introduction of highly potent, sensitizing, cytotoxic, hormonal, biological, or beta-lactam products.
- Expansion of manufacturing activities beyond those covered by the current GMP certificate.

f) Quality Control

- Introduction of new testing laboratories.
- Significant modifications to analytical methods.
- Outsourcing of quality control activities.
- Changes to microbiology laboratories supporting product release.

g) Computerized Systems

- Implementation of new computerized systems used in GMP activities.

- Major upgrades to computerized systems impacting data integrity, batch release, or quality management systems.

h) Key Personnel

- Changes in Head of Production.
- Changes in Head of Quality Control.
- Changes in Authorized Person/Qualified Person or equivalent responsible personnel.

i) Contracted Activities

- Introduction of new contract manufacturers.
- Introduction of new contract testing laboratories.
- Significant changes to outsourced GMP activities.

2.21.3 Application Requirements

Applications for substantial changes shall be submitted through the Rwanda FDA Integrated Regulatory Information Management System (IRIMS).

The application shall include:

1. Cover letter describing the proposed change.
2. Completed application form for substantial changes.
3. Detailed description of the proposed change.
4. Justification for the change.
5. Quality Risk Assessment report.
6. Change Control documentation.
7. Validation Master Plan or relevant validation protocols and reports, where applicable.
8. Updated Site Master File sections affected by the change.
9. Updated facility layouts, engineering drawings, or process flow diagrams, where applicable.
10. Impact assessment on registered products.
11. Proposed implementation timeline.
12. Any additional information requested by Rwanda FDA.

2.21.4 Regulatory Assessment

Rwanda FDA may:

a) Approve the proposed change based on document review;

b) Request additional information;

c) Conduct a virtual assessment;

d) Conduct an on-site GMP inspection before approval;

e) Reject the proposed change where GMP compliance cannot be demonstrated.

2.21.5 Timelines

Applications for substantial changes shall be submitted at least **30 working days before the planned implementation date**.

Rwanda FDA shall review the application and communicate its decision within **30 working days** from receipt of a complete application.

The review timeline may be extended where additional information or inspection activities are required.

2.21.6 Regulatory Outcome

Following evaluation, Rwanda FDA may issue:

- An Approval Letter;
- A Conditional Approval Letter;
- A Request for Additional Information; or
- A Rejection Letter.

Where applicable, the GMP certificate and/or manufacturing licence may be amended to reflect the approved changes.

2.21.7 Notification Changes

Changes considered minor and not affecting GMP compliance, product quality, safety, or efficacy may be notified to Rwanda FDA without prior approval. Such changes shall be documented within the manufacturer's pharmaceutical quality system and made available during GMP inspections.

Rwanda FDA reserves the right to determine whether a change requires notification, approval, or GMP inspection.

3. CHAPTER III: GMP INSPECTION REFERENCE GUIDELINES

The reference guideline documents listed below are the current WHO guidelines and may be updated from time to time. The latest versions of each guideline as revised by the WHO shall be applicable in each case. Other international guidelines such as PIC/S, ICH, US FDA, EAC and EMA may be used as supplementary guidance documents while establishing compliance of facilities to GMP requirements.

GMP main principles

WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eight Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. Short name: WHO TRS No. 986, Annex 2

https://www.who.int/publications/m/item/trs986-annex2

GMP for active pharmaceutical ingredients (bulk drug substances)

WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2
https://www.who.int/publications/m/item/annex-2-trs-957

Water for pharmaceutical use
WHO good manufacturing practices: water for pharmaceutical use. WHO Technical Report Series, No.1033, 2021, Annex 3. Short name: WHO TRS No. 1033, Annex 3
https://www.who.int/publications/m/item/annex-3-trs-1033

Water for injection by means other than distillation
TRS 1025 - Annex 3: Production of water for injection by means other than distillation. WHO Technical Report Series, no. 1025,20 April 2020
https://www.who.int/publications/m/item/trs-1025-annex-3-water-for-injection

Heating Ventilation and Air conditioning, HVAC
- Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8. Short name: WHO TRS No. 1010, Annex 8
  https://www.who.int/publications/m/item/Annex-8-trs-1010

- WHO good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (part 2): interpretation of guidelines. Annex 2, WHO Technical Report Series 1019, 2019
  https://www.who.int/publications/m/item/trs1019-annex2

Good manufacturing practices for sterile pharmaceutical products
WHO good manufacturing practices for sterile pharmaceutical products
Annex 2, WHO Technical Report Series 1044, 2022.Short name: WHO TRS 1044 - Annex 2:
https://www.who.int/publications/m/item/trs1044-annex2

Good manufacturing practices for medicinal gases
TRS 1044 - Annex 5: WHO good manufacturing practices for medicinal gases
Annex 5, WHO Technical Report Series 1044, 2022
https://www.who.int/publications/m/item/trs1044-annex5

Good manufacturing practices for biological products
TRS 996 - Annex 3: WHO good manufacturing practices for biological products (jointly with the Expert Committee on Biological Standardization).
https://www.who.int/publications/m/item/trs996-annex3

Blood products
WHO guidelines on good manufacturing practices for blood establishments, Annex 4; World Health Organization. WHO Technical Report Series, No. 961, 2011.

https://www.who.int/publications/m/item/trs961-annex4

Hold-time studies
WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4. Short name**:** WHO TRS No. 992, annex 4.
https://www.who.int/publications/m/item/trs992-annex4

Quality risk management
WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2. Short name: WHO TRS No. 981, Annex 2
https://www.who.int/publications/m/item/trs981-annex2

Validation
WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-third report (WHO Technical Report Series, No. 1019). Short name: WHO TRS No. 1019, Annex 3
https://www.who.int/publications/m/item/trs1019-annex3

Health-Based Exposure Limits (HBELs) in cleaning validation
TRS 1033 - Annex 2: Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation Annex 2, WHO Technical Report Series, No.1033, 2021
https://www.who.int/publications/m/item/annex-2-trs-1033

Technology transfer
TRS 1044 - Annex 4: WHO guidelines on technology transfer in pharmaceutical manufacturing Annex 4, WHO Technical Report Series 1044, 2022
https://www.who.int/publications/m/item/trs1044-annex4

Data integrity
TRS 1033 - Annex 4: WHO Guideline on data integrity
Annex 4, WHO Technical Report Series, No.1033, 2021
https://www.who.int/publications/m/item/annex-4-trs-1033

Sampling
WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4. Short name: WHO TRS No. 929, Annex 4
https://www.who.int/publications/m/item/trs-1025-annex-4

Investigational products
- WHO good manufacturing practices for investigational products, WHO Technical Report Series 1044, 2022, Annex 7. Short name: WHO TRS 1044 - Annex 7:
https://www.who.int/publications/m/item/trs1044-annex7

-IAEA/WHO guideline on good manufacturing practices for investigational Annex 3, WHO Technical Report Series 1044, 2022.Short name: WHO TRS 1044 - Annex 3:
https://www.who.int/publications/m/item/trs1044-annex3

Antimicrobial resistance
Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance, WHO Technical Report Series, no. 1025, Annex 6. Short name: TRS 1025 - Annex 6:
https://www.who.int/publications/m/item/trs-1025-annex-6

Herbal medicines
-WHO good manufacturing practices for the manufacture of herbal medicines, WHO Technical Report Series 1010, 2018, Annex 1. Short name WHO TRS 1010 - Annex 1:
https://www.who.int/publications/m/item/trs1010-annex1

-WHO good manufacturing practices for the manufacture of herbal medicines, WHO Technical Report Series 1010, 2018, Annex 2. Short name WHO TRS 1010 - Annex 2
https://www.who.int/publications/m/item/trs1010-annex2

Hazardous Substances
WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. Short name: WHO TRS No. 957, Annex 3
https://www.who.int/publications/m/item/trs957-annex3

Site master file
WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14. Short name: WHO TRS No. 961, Annex 14
https://www.who.int/publications/m/item/trs961-annex14

Quality Control Laboratories
WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty Seventh Report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No.1052, Annex 4. Short name: WHO TRS No. 1052, Annex 4
https://www.who.int/publications/m/item/who-good-practices-for-pharmaceutical-quality-control-laboratories

Good chromatography practices
WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025, Annex 4. Short name: WHO TRS No. 1025, Annex 4
https://www.who.int/publications/m/item/trs1025-annex4

Chemical reference standards
General guidelines for the establishment, maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-First Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3. Short name: WHO TRS No. 943, Annex 3 https://www.who.int/publications/m/item/trs943-annex3

Good practices for pharmaceutical microbiology laboratories
WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2. Short name: WHO TRS No. 961, Annex 2 https://www.who.int/publications/m/item/trs961-annex2

Stability studies
WHO guidelines on stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Technical Report Series 1010, 2018, Annex 10. Short name: WHO TRS 1010-Annex 10 https://www.who.int/publications/m/item/trs1010-annex10

Prevention and control of nitrosamines
WHO good practice considerations for the prevention and control of nitrosamines in pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty Eighth Report Geneva, World Health Organization, 1060,2025, Annex 2. Short name: TRS 1060 Annex 2
https://www.who.int/publications/m/item/trs-1060---annex-2--who-good-practice-considerations-for-the-prevention-and-control-of-nitrosamines-in-pharmaceutical-products

Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products
Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9. Short name: WHO TRS No. 961, Annex 9
https://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport

WHO Technical Supplements to Model Guidance for Storage and Transport of Time and temperature-sensitive pharmaceutical Products
WHO Technical supplements to Model Guidance for storage and transport of time — and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5. Short name: WHO TRS No. 992, Annex 5
https://www.who.int/publications/m/item/trs992-annex5

Non-Penicillin Beta-Lactam Drugs
Guidance for Industry; Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross Contamination
https://www.fda.gov/files/drugs/published/Non-Penicillin-Beta-Lactam-Drugs--A-CGMP-Framework-for-Preventing-Cross-Contamination.pdf

Veterinary Medicinal Products

-PIC/S Guide to good manufacturing practices for medicinal products part II, PE 009-17 (Part II), 25 August 2023 https://picscheme.org/docview/6607

-PIC/S Guide to good manufacturing practices for medicinal products part I, PE 009-17 (Part I),25 August 2023
https://picscheme.org/docview/6606

-PIC/S Guide to good manufacturing practices for medicinal products annexes, PE 009-17 (Annexes),25 August 2023
https://picscheme.org/docview/6608

ENDORSEMENT OF THE GUIDELINES

	Prepared by	**Checked by**		**Approved by**
Title	**Division manager of Pharmaceutical Inspection and Licensing**	**Head of Drug Department**	**QMS Division Manager**	**Director General**
Names	Dr. Marilyn M. MURINDAHABI	Dr. Vedaste HABYALIMANA	Mrs. Marie Ange UWASE	Prof. Emile BIENVENU
Signature				
Date				

APPENDICES

Annex 1: Requirements for GMP Inspection Application for Finished Pharmaceutical Products & Active Pharmaceutical Ingredients Manufacturing Facilities

a. Application letter addressed to the DG of Rwanda FDA
b. Filled and signed application form
c. Proof of payment of prescribed fees
d. Site master file (Annex 14, WHO Technical Report Series, No. 961) that is not older than one year from its approval date and any forecasted modifications, including legible colored printouts of water treatment, air-handling systems, including pipeline and instrumentation drawings (P&IDs) in A3 or A2 format
e. Current manufacturing license for foreign facilities and for domestic facilities to attach application form and proof of payment of manufacturing license.
f. Current GMP Certificate (GLP, ISO/IEC 17025 accreditation Certificate or WHO prequalification for outsourced laboratory)
g. List of all the products (medicinal or other) that include proprietary names and international non-proprietary names (INN) manufactured on site
h. List of products including proprietary names and international non-proprietary names (INN) intended for supply in Rwanda

Additional documents will be required for GMP desk assessment, virtual inspection and temporary waiver as listed in the Guidelines on Virtual GMP Inspection, Quality Audit of Manufacturing Facilities and Temporary Waiver Issuance during Emergencies

RWANDA FDA
Rwanda Food and Drugs Authority

Doc No: DD/PIL/FOM//001
Version No:2
Effective Date: 01/06/2024

ANNEX 2: APPLICATION FORM FOR GOOD MANUFACTURING PRACTICES INSPECTION FOR PHARMACEUTICAL PRODUCTS MANUFACTURING FACILITIES

Applicant to fill the following sections

1. **Particulars of the Applicant**

Name_____
Physical Address_____
Country_____Telephone_____
E-mail_____

2. **Particulars of Manufacturing Site to be Inspected**

Name of site_____
Physical Address (if different from 1. above)
_____
Country_____Tel_____
E-mail:_____
***Note**: Separate application to be filled in for each individual site*

3. **Contact Person on Site**

Name of contact person_____
Tel: _____Fax:_____
E-mail:_____

4. **Authorized Representative/Agent in Rwanda**

Name of Local Technical Representative_____
Tel: _____ E-mail: _____

5. **Type of Medicines/ Active Pharmaceutical Ingredients**

Type of medicines manufactured *(double click to check applicable box)*

Human ☐ Veterinary ☐ Human & Veterinary ☐ Herbal ☐

6. **Registration of Products in Rwanda**

Have you registered any products in Rwanda YES ☐ NO ☐

Have you submitted a product dossier for registration from the production line(s) applied for inspection? YES ☐ NO ☐ (If "YES", list of the products in the table below)

Trade Name (if any)	Generic Name	Dosage Form	Strength	Primary Packaging

7. Inspection Applied for *(Double click to check applicable box*)

☐ First Inspection

☐ Routine Inspection (state previous inspection dates ……*DD/MM/YYYY*)

☐ Re-inspection (after failure)

☐ Other *(please specify)* ……

8. Major Site Changes Since Last Inspection

Provide summary of changes to personnel, equipment, buildings, specifications, computer systems, products (type, range or category), suppliers and contractors since last inspection, below or as an Attachment to this form.

……..
……
……
……

9. **Production Lines to be Inspected** (Please tick or fill in the applicable boxes)

Production Lines				Classes							Category		
Dosage forms	Yes	No	Block name/ number	Beta Lactams				Non-beta lactam	Cyto toxic	Hormones	Human	Veterinary	Herbal
				Penicillins	Cephalosporins	Carbapenems	Monobactams						
1. MANUFACTURING OPERATIONS													
1.1 Sterile products													
1.1.1 Aseptically prepared													
a. Large volume liquids													
*b.*Lyophilisates													
*c.*Semi-solids													

*d.*Small volume liquids													
*e.*Solids and implants													
*f.*Other aseptically prepared products													
1.1.2 Terminally sterilized													
a.Large volume liquids													
b.Semi-solids													
c.Small volume liquids													
d.Solids and implants													
e.Other terminally sterilised products													
1.2 Non-sterile products													
Capsules, hard shell													
Capsules, soft shell													
Impregnated matrices													
Liquids for external use													
Liquids for internal use													

Dry powders for oral suspension													
Powders /granules in sachets													
Tablets													
Semi-solids													
Suppositories													
Medicated lozenges													
Other solid dosage forms													
Medicinal gases													
Pressurised preparations													
Radionuclide generators													
Transdermal patches													
Veterinary premixes													
Other non-sterile medicinal products													
1.3 Biological medicinal products													
Blood products													
Immunological products													

: vaccines													
Immunological products : sera													
Other immunological products													
Cell therapy products													
Gene therapy products													
Biotechnology products													
Human or animal extracted products													
Biosimilar products													
Others													
1.4 Other products or manufacturing activity													
Herbal products													
Homoeopathic products													
Biological active starting materials													
Active pharmaceutical ingredients (chemical)													
Other													
2.0 STERILISATION OF ACTIVE SUBSTANCE/EXCIPIENTS/FINISHED PRODUCT													

Filtration													
Dry heat													
Moist heat (steam, superheated water)													
Chemical (ethylene oxide, ozone)													
Gamma irradiation													
Electric beam													
3.0 QUALITY CONTROL TESTING													
Microbiological: sterility													
Microbiological: non-sterility													
Biological													
Animal													
Stability													

9. Declaration

I hereby certify that the above information is correct and apply for Good Manufacturing Practices inspection of the above-named site(s). I also commit to welcome the Rwanda FDA GMP inspectors for the inspection.

Signature of applicant……Date……

Name……Designation.....

***Notes**:*

1. *Please submit a copy of the current Site Master File and all required documents as per the Rwanda FDA GMP guidelines together with this application form*
2. *Submit the completed application together with proof of payment of the appropriate fees, to the Director General Rwanda Food and Drugs Authority.*

ANNEX 3: GMP INSPECTION REPORT

RWANDA FDA
Rwanda Food and Drugs Authority

Doc No: DD/PIL/FMT/019
Version No:2
Effective Date: 01/06/2024

GMP INSPECTION REPORT

Inspection dates:	**Report date:**
1.0 General Information	
1.1 Inspected Site(s)	
a) Name: **b) Physical address:** **c) City:** **d) Country:**	
e) Telephone: **f) Email address :**	
g) Manufacturing license number:	
h) Contact person(s) of the inspected site or facility:	
1.2 Activities carried out by the company at the inspected site	
1.3 GMP Inspectors	
Name of Rwanda FDA Lead Inspector:	
Names of Rwanda FDA GMP Inspectors that carried out the inspection:	
1.4 Name of expert if applicable:	
1.5 Foreign National Regulatory Authority Participation:	
1.6 Type of inspection:	
1.7 Purpose of Inspection:	
1.8 Introduction	
1.9 Other manufacturing activities carried out on the site:	
1.10 Use of outside scientific, analytical, or other technical assistance in manufacture and quality control	
1.11 Previous inspections conducted by:	
1.12 Other Regulatory Authorities	
1.13 Major changes since the previous inspection	
1.14 Samples taken and results obtained (if applicable)	
2.0 Brief Report of the Inspection activities undertaken	
2.1 Scope of Inspection	
2.2 Observations and Findings	
2.2.1 Pharmaceutical Quality System	

2.2.2 Personnel
2.2.3 Premises
2.2.4 Utilities
2.2.5 Equipment
2.2.6 Documentation
2.2.7 Good practices in production
2.2.8 Good practices in quality control
2.2.9 Outsourced Activities
2.2.10 Complaints and Product Recalls
2.2.11 Self-Inspection, Quality Audits, Supplier's Audits
3.0 Summary of non-conformances to GMP
4.0 Recommendations and Conclusion
4.1 Recommendations
4.2 Conclusion – inspection outcome

NAMES OF THE INSPECTORS AND SIGNATURES

Full Name	Role	Signature

End of Report

RWANDA FDA
Rwanda Food and Drugs Authority

Doc No: DD/PIL/FOM//001
Version No:2
Effective Date: 01/06/2024

ANNEX 4: APPLICATION FORM FOR SUBSTANTIAL CHANGES AND MODIFICATIONS TO GMP-CERTIFIED MANUFACTURING FACILITIES

SECTION 1: APPLICANT INFORMATION

1. Particulars of the Applicant

Name_____
Physical Address_____
Country_____Telephone_____
E-mail_____

2. Particulars of Manufacturing Site

Name of Manufacturer: _____
Manufacturing License Number: _____
GMP Certificate Number: _____
Physical Address of Manufacturing Site: _____

Country: _____
Telephone: _____
Email: _____
Contact Person: _____
Position: _____

3. Authorized Representative/Agent in Rwanda

Name of Local Technical Representative_____
Tel: _____ E-mail: _____

4. Type of Medicines/ Active Pharmaceutical Ingredients

Type of medicines manufactured *(double click to check applicable box)*

Human ☐ Veterinary ☐ Human & Veterinary ☐ Herbal ☐

SECTION 2: TYPE OF APPLICATION

☐ Prior Approval Application

☐ Notification Only

☐ Urgent Change (Public Health / Supply Continuity)

☐ Other (Specify) _____

SECTION 3: DESCRIPTION OF PROPOSED CHANGE

Title of Change:

Unique Change Control Number:

Proposed Implementation Date:

Reason for Change:

SECTION 4: CATEGORY OF CHANGE

A. Premises and Facilities

☐ New building

☐ Facility expansion

☐ New production block

☐ Modification of cleanrooms

☐ Change in personnel/material flow

☐ Warehouse expansion

☐ Other (Specify)

B. Utilities

☐ HVAC modification

☐ Water treatment system

☐ Purified Water system

☐ WFI system

☐ Clean steam system

☐ Compressed air system

☐ Other

C. Equipment

☐ New manufacturing equipment

☐ Replacement of critical equipment

☐ New packaging equipment

☐ New sterilization equipment

☐ Other

D. Products and Product Lines

☐ New dosage form

☐ New product category

☐ New manufacturing activity

☐ Technology transfer

☐ New biological product

☐ New beta-lactam product

☐ New cytotoxic product

☐ Other

E. Manufacturing Process

☐ Process change

☐ Process optimization

☐ Sterilization process change

☐ Scale-up

☐ Scale-down

☐ Other

F. Quality Control

☐ New laboratory

☐ New analytical technology

☐ Outsourced testing

☐ Change in release testing

☐ Other

G. Computerized Systems

☐ New computerized system

☐ Software upgrade

☐ Data integrity-related modification

☐ Other

H. Personnel

☐ Head of Production

☐ Head of Quality Control

☐ Qualified Person

☐ Other key personnel

I. Outsourced Activities

☐ Contract manufacturing

☐ Contract testing

☐ Contract sterilization

☐ Other

SECTION 5: QUALITY RISK ASSESSMENT

Has a Quality Risk Assessment been conducted?

☐ Yes

☐ No

Risk Assessment Reference Number:

Risk Classification:

☐ Low

☐ Medium

☐ High

Summary of Risk Assessment:

SECTION 6: IMPACT ASSESSMENT

Will the change affect:

Item	Yes	No
Product Quality	☐	☐
Product Safety	☐	☐
Product Efficacy	☐	☐
Validation Status	☐	☐
Environmental Monitoring	☐	☐
Cleaning Validation	☐	☐
Process Validation	☐	☐
Stability Program	☐	☐
Registered Products	☐	☐
GMP Certificate Scope	☐	☐

Provide justification:

SECTION 7: SUPPORTING DOCUMENTS

Attached Documents:

☐ Change Control Record

☐ Quality Risk Assessment

☐ Validation Protocol

☐ Validation Report

☐ Updated Site Master File

☐ Updated Facility Layout

☐ Updated P&ID

☐ Equipment Qualification Documents

☐ Impact Assessment

☐ Updated Organization Chart

☐ Other

SECTION 8: DECLARATION

*I hereby certify that the above information is correct and T*hat the proposed change shall not be implemented prior to Rwanda FDA approval where applicable.

Signature of
applicant……Date……

Name……Designation.....

Notes*:*

1. *Please submit a copy of the current Site Master File and all required documents as per the Rwanda FDA GMP guidelines together with this application form*
2. *Submit the completed application together with proof of payment of the appropriate fees, to the Director General of Rwanda Food and Drugs Authority.*

ANNEX 5: FORMAT OF CERTIFICATE OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICES

Doc Nº: DD/PIL/FMT/001
Version: 5
Effective Date:

RWANDA FDA
Rwanda Food and Drugs Authority

Certificate Nº: ***Application Ref Nº-00000***

CERTIFICATE OF COMPLIANCE
with
Good Manufacturing Practices

Pursuant to Law Nº. 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organisation and functioning, especially in its article 9 (2);

Rwanda FDA hereby issues this certificate of compliance with current Good Manufacturing Practices requirements to the manufacturing site with details described below:

Name of manufacturing site: []

Manufacturing license number: []

Site address: []

Country: []

Phone number: []

Email: []

On the basis of the **physical inspection/recognition/desk assessment carried out on DD/MM/YYYY,** Rwanda FDA certifies that the manufacturing site indicated on this certificate complies with Good Manufacturing Practices guidelines for product category(ies), dosage form(s), and activities listed in the table below:

Nº	Product category(ies)	Dosage form(s)	Activitiy(ies)
1.			

Validity: **Three (3) years** from the **[last date of inspection/date of assessment]**.

Name of Director General
Director General

Rwanda FDA, P.O.Box:1948 Kigali-Rwanda, Email: info@rwandafda.gov.rw
Website: www.rwandafda.gov.rw, Toll Free:9707

Important notice

1. The responsibility for the quality of the individual batches of products manufactured through this process lies with the manufacturer;

2. This certificate becomes invalid if the activity(ies) or the category(ies) certified change or if the facility is no longer rated to comply with Good Manufacturing Practice;

3. This certificate is valid for three (3) years from the **[last date of inspection/assessment]** unless otherwise revoked or suspended by the Rwanda FDA;

4. The application for GMP certificate renewal shall be done six months before its date of expiry.

ANNEX6: VARIATION SUBSTANCIAL MODIFICATION APPROVAL LETTER

RWANDA FDA
Rwanda Food and Drugs Authority

Kigali on … /… /....

Ref. Nº: Dpt or Office/Div or unit/……/FDA/20..

Recipient's Name and Full Address

Dear Sir/ Madam,

Re: **Approval of Variation(s)**

Pursuant to Law Nº 003/2018 of 09/02/2018 establishing the Rwanda Food and Drugs Authority and determining its mission, organization, and functioning, especially in its article 9(2);

Further reference is made to Application Nº XXXXXXX notifying Rwanda FDA of variation(s) [to License/certificate Nº XXXXXXXX], with the details below:

- **Company name:**
- **Company code:**
- **Premises registration number**:
- **Location of the premises (sales):** ……City/Province, …….District, ……Sector, …….Cell, ……. Village.

Rwanda FDA hereby approves and records the requested variation(s) with the following details:

1. **…..**
2. **……**
3. **……**

This approval is limited to the variation (s) specified above.

Sincerely,

By Authority Delegation

XXXXXX
Head of Drugs Department

CC:

- **Director General/ Rwanda FDA**
- **Deputy Director General/ Rwanda FDA**

Annex 7:

Rwanda Food and Drugs Authority
Nyarutarama Plaza, KG 9 Avenue
P.O. Box: 1948 Kigali - Rwanda
Email: info@rwandafda.gov.rw
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QMS	Nº:
FDISM/FDIC/FMT/028	
Revision No: 0	
Effective Date: 30/09/2022	

GMP INSPECTION MEMORANDUM FORM

Dates of inspection:

Name of Facility: **Physical Address:**	
Item(s) requiring attention:	**Action(s) to be taken:**

Annex 8:

RWANDA FDA
Rwanda Food and Drugs Authority
P.O. Box 1948 Kigali
info@rwandafda.gov.rw
www.rwandafda.gov.rw

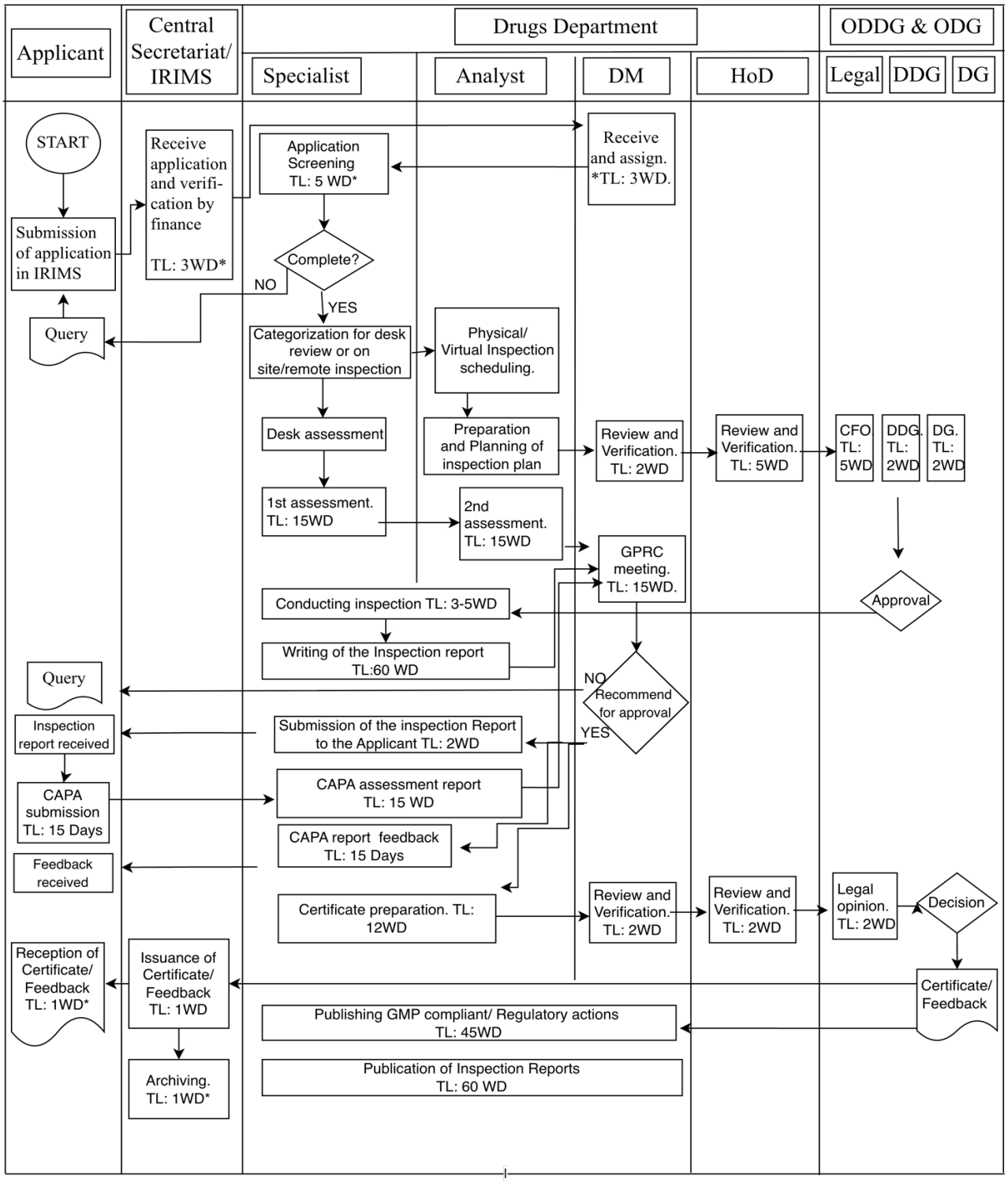
CRITERIA FOR DETERMING DURATION OF GMP INSPECTION

Duration /length of GMP inspection is determined by a number of factors, including the type of inspection to be performed, the number of inspectors, the size of the company and the purpose of the inspection.

The following elements can be considered during the planning for Inspection;

1. Number of Inspection lines
    - For 4 production lines or less, 2 days will be allocated. (For any additional line a separate day will be allocated.)
    - Beta lactam and non-beta Lactam production lines will be visited on separate days
2. 1 separate day will be allocated to verify QRM systems for a manufacturing facility site.
3. For Vaccines and other biologicals (5 to 7 days) will be planned
4. Non-biological sterile products (3 to 5 days) will be planned
5. Other products (2 to 3 days) shall be sufficient

ANNEX 9: GMP PROCESS FLOW CHART



Note: Local manufacturers will be offered a manufacturing license upon successful GMP inspection

Legend:

DG: Director General GPRC: GMP Peer Review Committee
DDG: Deputy Director General GMP: Good Manufacturing Practices
DM: Division Manager HOD: Head of Department
TL: Timeline WD: Working Day(s)
IRIMS: Integrated Regulatory Information Management System