RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES ON VIRTUAL GMP INSPECTION, QUALITY AUDIT OF MANUFACTURING FACILITIES, AND TEMPORARY WAIVER ISSUANCE DURING EMERGENCIES

SEPTEMBER, 2022

Doc. No.: FDISM/FDIC/GDL/011	Revision Date: 13/05/2022	Review Due Date: 12/05/2025
Revision No.: 0	Approval date: 23 /09 /2022	Effective Date: 30/09/2022

FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the 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 quality standards required for Good Manufacturing Practices (GMP) and quality audit.

Poor quality of pharmaceutical products is one of the public health concerns worldwide. Rwanda FDA plays a critical role in protecting the Rwandan public from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic.

It is in this context that Rwanda FDA intends to put in place guidelines describing how temporary waivers are provided, voluntary virtual inspections and quality audits of medical products manufacturing facilities are conducted during public health emergencies and times determined to be Force Majeure.

It is expected that these guidelines will provide a clear understanding to manufacturers and other stakeholders concerned by the guidelines during the evaluation process.

Dr. Emile BIENVENU
Director General

RWANDA FOOD AND DRUGS AUTHORITY • RWANDA FDA

GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO	13/05/2022
ADOPTION BY RWANDA FDA	01/08/2022
STAKEHOLDERS CONSULTATION	31/08/2022
ADOPTION OF STAKEHOLDERS' COMMENTS	05/09/2022
DATE FOR COMING INTO EFFECT	30/09/2022

DOCUMENT REVISION HISTORY

Date of revision	Revision number	Changes made and/or reasons for revision
07/10/2022	0	First issue

TABLE OF CONTENTS

FOREWORD 2

GUIDELINES DEVELOPMENT HISTORY 3

Document Revision History 3

TABLE OF CONTENTS 4

ACRONYMS AND ABBREVIATIONS 5

GLOSSARY / Definitions 6

CHAPTER ONE: INTRODUCTION 10

1.1 Aim and objectives of the guidelines 11

1.2 Scope of the guidelines 11

CHAPTER 2: CONSIDERATION AND CRITERIA FOR TEMPORARY WAIVER OF ON-SITE GMP INSPECTION AND QUALITY AUDIT 12

2.1 New GMP and quality audit applications 12

2.1.1 Type of products 12

2.1.2 Products of public health importance 12

2.1.3 On-site audit history by other regulatory authorities 12

2.1.4 Acceptance of information in the product dossier 13

2.2 Renewal Applications 13

2.2.1 On-site audit history by the Authority 13

2.2.2 Market Complaints 13

2.2.3 Communication 13

CHAPTER 3: CONSIDERATION FOR GMP AND QUALITY AUDIT VIRTUAL INSPECTION 14

3.1 Criteria for Virtual Inspection 14

3.2 Application procedures 14

3.3 Communication 14

3.4 Planning a virtual inspection/ audit 14

3.4.1 Selecting and Notifying the Facility 14

3.4.2 Preparing for a Virtual Inspection 15

3.4.3 Pre-Testing IT systems and inspection site selection 16

3.4.4 Conducting Virtual Inspection 16

3.4.5 Technological Requirements 17

3.4.6 Virtual evaluation of documents and records 17

CHAPTER 4: RESPONSIBILITIES OF THE APPLICANT 18

ENDORSEMENT OF THE GUIDELINES **Error! Bookmark not defined.**

ACRONYMS AND ABBREVIATIONS

APIs	Active Pharmaceutical Ingredients
CAPA	Corrective and Preventive Action
EAC	East African Community
FPP	Finished Pharmaceutical Product
GMP	Good Manufacturing Practice
GxP	Good Practice
ICH	International Conference on Harmonisation
INN	International Non-proprietary Names
IVD	In-Vitro Diagnostics
NMRAs	National Medicines Regulatory Authorities
NRA	National Regulatory Authorities
QCLs	Quality Control Laboratories
Rwanda FDA	Rwanda Food and Drugs Authority
SRA	Stringent Regulatory Authority
WHO	World Health Organization
WHO PQT	WHO Prequalification Team
WLAs	WHO Listed Authorities

GLOSSARY / DEFINITIONS

The definitions given below apply to the terms used in these guidelines. They may have different meanings in other contexts:

1. **"Agent or Local Technical Representative"** any applicant who is not resident in Rwanda shall appoint a local technical representative who must be a company incorporated in Rwanda and authorized by Rwanda FDA to deal in medicinal products and must hold a wholesale operating license. The appointment shall be notified to the Authority by submitting a letter of appointment supported by original copy of power of attorney duly notarised in country of origin**.**

2. **"Applicant"** an applicant is a person who applies for registration of a medical product to Rwanda FDA, who must be the owner of the product. He may be a manufacturer or a person to whose order and specifications, the product is manufactured. The applicant shall therefore be responsible for signing the registration application form. In the event that the applicant wants another person to register the medicinal product on his/her behalf, then Powers of Attorney, duly notarised in the country of origin, and registered with the Registrar of Companies in Rwanda shall be provided. After the product is registered, the applicant shall be the Marketing Authorisation Holder.

3. **"Class A medical device"** a medical device with risk low to public health and personal. e.g. Specimen receptacles; products for general lab use, accessories with no critical characteristics, buffers, washes, culture media, histological stains if intended for specific test; instruments intended for IVD procedures.

4. **"Class B medical device"** a medical device with low risk to public health and moderate to low risk to Personal. e.g.; clinical chemistry tests, some specific self-test IVDs.

5. **"Class C medical device"** a medical device with moderate to low risk to public health and risk low to personal i.e. Testing for compatibility for transfusion, transplantation, cell administration, excluding high risk blood grouping; tests for Infectious disease / Sexually transmitted infections agents' / cancer biomarkers/Companion diagnostics / genetic testing / TORCH (toxoplasmosis, rubella cytomegalovirus, herpes simplex, and HIV) screening / congenital disorders / monitoring high risk medicines/substances e.g. blood glucose / most self-test IVDs.

6. **"Class D medical device"** a medical device with high risk to public health and personnel. e.g. Screening for transmissible agents and for high-risk blood grouping for transfusion, transplantation, cell administration; life-threatening transmissible agents: Screening where possible high risk of propagation, and detection of infectious load where monitoring determines patient management e.g. Blood groups ABO, Rh, Kidd, Duffy, Kell; HIV1 and 2, HTLV I/II, Hepatitis B and C, Chagas, screening blood for syphilis.

7. **"Competent regulatory authority"** means any organization that has a legal authority or power to perform a designated regulatory function for authorization of a medical product.

8. **"Critical complaint"** complaints related to defective/dangerous/potentially life-threatening medicines that predictably or probably could result in serious health risk/adverse events or even deaths. Examples: wrong product for label and contents), correct product but wrong strength, with serious medical consequences, wrong active ingredient, mix-ups of some products, among others.

9. **"Emergency Situation or state"** means unexpected factors including pandemics, emergency disaster, wars, among others, that make it impossible for the Authority to conduct on- site inspections either in a particular country or all countries. Late planning for inspection or limited resources shall not be considered an emergency situation.

10. **"Good Manufacturing Practice"** means the part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate for the intended use and as required by the marketing authorization. GMP standards are directly aimed primarily at diminishing the list inherent in any pharmaceutical production that cannot be prevented completely through the testing of the final product.

11. **"Information sharing**" is defined as exchange of data between individuals or entities outside the traditional organisational boundaries, to achieve a common goal in terms of better policies and deliver better services that otherwise would not be possible without the exchange of data. This may mean that one party is disclosing information while the other is collecting the information or both parties are mutually disclosing and collecting information.

12. **"In-vitro Diagnostics"** means a device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

13. **"Major complaint"** complaints that could cause illness or mistreatment but are not critical. Examples: Mislabeling such as wrong or missing text or figures, missing or incorrect information such as leaflets or inserts, chemical/physical contamination, on-compliance with specification.

14. **"Manufacture"** all operations that involve preparation, processing, filling, transforming, packaging, and repackaging and labelling of medical products.

15. **"Manufacturer"** a manufacturer is a person or a firm that is engaged in the manufacture of medicinal products. It involves operations such as production, packaging, repackaging, labelling and relabelling of pharmaceuticals.

16. **"Marketing authorization"** approval from the authority 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.

17. **"Marketing authorization holder"** a person granted with a marketing Authorization of a product by an NRA.

18. **"Medical Devices or Devices"** means, an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is –

    i. Recognized in the Official National Formulary, or Pharmacopoeia or any supplement to them;

    ii. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals or;

    iii. Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principle intended purposes.

19. **"Medical products"** means medicines, vaccines, and diagnostics and medical devices.

20. **"Memoranda of Understanding"** a memorandum of understanding (MOU or MoU) is a formal agreement between two or more parties. Companies and organizations can use MOUs to establish official partnerships. MOUs are not legally binding but they carry a degree of seriousness and mutual respect, stronger than a gentlemen's agreement.

21. **"Minor Complaint"** complaints which may note pose a significant hazard to health, complaints due to secondary packing materials, shortage complaints and damage of containers.

22. **"Mutual Recognition Agreement"** is the reciprocal adoption or acceptance of regulatory decisions or outcomes in other Partner States as valid in the form of a legal basis – law or regulations or agreements.

23. **"Notified Body"** means an organization that has been designated by European member states to assess the conformity of products before being placed on the European Union (EU) market with the applicable essential technical requirements which are published in EU Directives or Regulations.

24. **"Orphan medicine"** a medicine for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition that is rare (affecting not more than five in 10,000 people in the European Union) or where the medicine is unlikely to generate sufficient profit to justify research and development costs**.**

25. **"Quality Audit"** means inspection of medical devices and in-vitro diagnostics manufacturing facilities for the purpose of establishing compliance to ISO 13485:2016.

26. **"Quality System"** the sum of all that is necessary to implement an organization's quality policy and meet quality objectives. It includes organizational structure, responsibilities, procedures, systems, processes and resources. Typically, these features will be addressed in different kinds of documents as the quality manual and documented procedures.

27. **"Pharmaceutical product"** means 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.

28. **"Site master file"** means a document containing specific information about the activities undertaken in the pharmaceutical manufacturing site and is usually prepared by the manufacturer.

29. **"Stringent Regulatory Authority(SRA)/ WHO Listed Authorities (WLAs)"** a regulatory Authority which is a member of the International Conference on Harmonisation (ICH) or an ICH observer, or is associated with an ICH member through a legally-binding, mutual recognition agreement.

30. **"Virtual inspection"** means inspections that are performed off-site through the use of enhanced communication and information technology to fulfil a legal requirement of an on-site inspection. The only difference from on-site inspection is that the inspector is not physically present at the inspection sit

CHAPTER ONE: INTRODUCTION

1.0 Background

National Regulatory Authorities (NRA), worldwide, use systems for the authorization and post-marketing surveillance of medical products that depend upon the assessment of submitted dossiers, and the inspection of Finished Pharmaceutical Products (FPP) and Active Pharmaceutical Products (APIs) manufacturers, Quality Audits of medical devices manufacturers and Quality Control Laboratories (QCLs) in the development, manufacture and distribution of the product. These inspections and quality audits are performed for dossier data verification and to provide evidence that the FPP, APIs and Medical devices manufacturers, QCLs are in compliance with the relevant good practice (GxP) guidelines and requirements.

The performance of on-site inspection of manufacturing facilities as well as the supply and distribution chain outside the Rwanda FDA's domestic territory is a resource-intensive activity and one that often lies on the critical path to regulatory decision-making. Furthermore, the hosting of multiple regulatory inspections and audits is also a significant overhead for the sites inspected that adds to the cost of producing the products. Even the best resourced NMRAs face resource limitations and therefore it is regulatory best practice to use quality risk management in prioritizing inspection activities. In order to best use the limited inspection resources and minimize multiple and repeated inspections, it is therefore good practice for national authorities to leverage available and reliable evidence of compliance and noncompliance with good practice requirements as part of their risk-based inspection planning process, such that there is no on-site inspection without a well-founded cause.

Verification and confirmation of GMP Compliance of a manufacturer of pharmaceutical products, and Compliance to ISO 13485/ 2016 of Medical devices in a foreign country may be based on the assessment of evidence of GMP and ISO 13485/ 2016 compliance that includes a recent inspection of the manufacturer by a competent regulatory agency and other internationally recognized institutions.

During the COVID-19 pandemic, Rwanda FDA like other regulatory authorities limited unnecessary contact by only conducting prioritized domestic and foreign facility inspections that were deemed mission-critical and not impacted by travel restrictions resulting from the public health emergency.

On-site Quality Audit or GMP inspection is regarded as the best way for determining compliance of manufacturing facilities to applicable standards. However, when on-site GMP inspection and Quality audit are not feasible, other alternative inspection and assessment such as virtual inspection and desk assessment may be applicable.

Desk assessment could be the preferred alternative for establishing compliance of manufacturing facilities to applicable standards in lieu of on-site Audits. However, according to criteria, not all medicines or medical devices manufacturing sites are eligible. Hence, the need for Rwanda FDA to develop guidelines that allow alternative assessment methods such as virtual inspections to allow

processing of GMP and quality audit applications and ultimately ensure availability of quality, safe and efficacious medicines and medical devices to the public.

Therefore, Rwanda FDA has developed these guidelines to describe various virtual interactive tools we may request to use to conduct an evaluation.

These guidelines are intended for overseas manufacturers who have applied for GMP inspection and quality audit in Rwanda FDA but do not meet the criteria for desk review and shall form the short term basis for decision making in the course of emergency states. The requirements set forth in these guidelines should be considered as minimum and they are not meant to replace other legal controls, but rather compliment them.

1.1 Aim and objectives of the guidelines

These guidelines aim at providing an approach for use by Rwanda FDA in order to assess quality audit and GMP compliance using other pathways rather than onsite inspection and desk assessment thus reducing the necessity for duplication of inspections or the delay of product registration while relying on authentic and reliable documentary evidence from other regulatory authorities.

The objective of this document is to:

i. ensure that a standardized procedure is followed for facilitating granting of temporary waiver for on-site GMP inspection and Quality Audit in emergency situations as observed during the COVID-19 pandemic.

ii. ensure a standardized procedure is followed during the planning, preparation and conducting of virtual inspections and the selection of manufacturing sites eligible for virtual inspection and temporary waivers.

1.2 Scope of the guidelines

These guidelines are applicable for facilities that have submitted new and renewal applications for GMP inspection or quality audit but do not meet criteria for desk review.

The guideline also includes the information and evidence required to undertake a virtual inspection / quality audit or provide a waiver and excludes the process of on-site inspection and GMP desk assessment.

CHAPTER 2: CONSIDERATION AND CRITERIA FOR TEMPORARY WAIVER OF ON-SITE GMP INSPECTION AND QUALITY AUDIT

There shall be no applications for temporary waiver of on-site GMP inspection and quality audit during state of emergency / force majeure, instead already submitted applications shall be used to make informed decisions.

During emergencies, decision on temporary waiver to conduct on-site GMP inspection and quality audit for new and renewal applications should base on the following: -

2.1 New GMP and quality audit applications

Criteria for new applications shall depend on the type of product, importance of the product(s) in public health, inspection history by other NMRAs and acceptance of data in the product dossier.

The evidence required for temporary waiver of each type of facility are mentioned below:

2.1.1 Type of products

i. **Medical Devices and IVDs:** On-site quality audit of manufacturing facilities for Class B medical devices and IVDs which are of low risk may be temporarily waived for a period not exceeding one year.

ii. **Medicines:** On-site GMP inspection of low risk pharmaceutical dosage forms such as those administered orally or topically may be temporarily waived for a period that does not exceed one year.

2.1.2 Products of public health importance

i. **Medical Devices:** On-site Quality audit of some manufacturing facilities for Class C and D medical devices may be temporarily waived for a period that does not exceed one year for public interest during an emergency.

ii. **Medicines:** On-site GMP inspection of facilities that manufacture medicines of public health importance may be temporarily waived for a period that does not exceed one year for public interest during an emergency.

2.1.3 On-site audit history by other regulatory authorities

Before any decision for temporary waiver of on-site quality audit and GMP inspection is made, history of valid on-site GMP inspection and quality audit approval by other NMRAs and Notified Bodies shall be sought.

2.1.4 Acceptance of information in the product dossier

Notwithstanding the above criteria, facilities which will be considered for temporary waiver of on-site GMP inspection and quality audit shall have in advance submitted application dossiers and their information assessed and accepted within Rwanda FDA.

2.2 Renewal Applications

Decision for temporary waiver of on-site GMP inspection and Quality audit for renewal applications shall depend on inspection history of the manufacturing facilities and market complaints records.

2.2.1 On-site audit history by the Authority

Facilities which complied and are due for renewal within one year shall qualify for a temporary waiver of on-site GMP inspection and quality audit for a period not exceeding one year.

2.2.2 Market Complaints

Facilities for which Rwanda FDA has recorded critical complaints from the market with regards to quality, safety and effectiveness of products, shall not be considered for temporary waiver of on-site GMP inspection and quality audit. Whereas, facilities recorded with major and minor complaints shall be considered for temporary waiver of on-site GMP inspection and quality audit for a period not exceeding one year.

2.2.3 Communication

The Authority should officially communicate with an applicant who has been granted a temporary waiver of on-site GMP inspection and Quality audit for close follow-up.

CHAPTER 3: CONSIDERATION FOR GMP AND QUALITY AUDIT VIRTUAL INSPECTION

Rwanda FDA has adopted measures that could help to prevent disruption of medical products supply during public emergency situations that may arise. Such measures include desk review and virtual inspection.

Therefore, this Chapter describes briefly but clearly the criteria, application procedures and communication with regard to virtual inspection. After inspection, the compliance with GMP or quality audit is confirmed, the facilities shall be issued with GMP or quality audit compliance certificates with a validity period of three years.

3.1 Criteria for Virtual Inspection

The criteria of selection of applicants for virtual inspections shall be as follows:

a) The applicants that cannot be inspected physically and not meet the requirement for GMP or quality audit desk review.

b) All applications for GMP Inspection and quality audit for manufacturing facilities that manufacture medical products that are deemed critical by the Authority shall qualify for virtual inspection.

c) Applications that have been declared force majeure on physical inspection resulting from a public health emergency.

3.2 Application procedures

There shall not be applications for virtual inspection, instead already submitted applications shall be considered by the Authority.

3.3 Communication

Applicants will be informed in writing by the authority about the plan to conduct virtual inspection.

3.4 Planning a virtual inspection/ audit

The following steps will be taken when planning for a virtual inspection/ audit

3.4.1 Selecting and Notifying the Facility

Once a facility is selected for virtual inspection or audit the following steps will be taken;

a) Notification for the facility and applicant (when appropriate) will be done formally. The

notification will indicate the name and address of the facility to be inspected, scope of inspection, the number of days of inspection and the names of Rwanda FDA inspectors, if known.

b) Following the manufacturing site's agreement to be inspected virtually, the Authority will contact the facility to confirm the point of contact for the virtual inspection/ audit to facilitate planning and determine a facility's ability to transfer records and perform remote interactions with Rwanda FDA staff.

c) The Authority will identify the Rwanda FDA lead for the virtual inspection/ audit and this will be communicated to the facilities.

d) The Authority will also work with facilities to procure information necessary to plan and coordinate the activities for a virtual inspection/ audit.

3.4.2 Preparing for a Virtual Inspection

Once the facility confirms its willingness and ability to participate in a virtual inspection/ audit. The Authority will schedule a brief virtual meeting to discuss logistics, responsibilities, and expectations. Discussion topics may include, but are not limited to, the following:

a) Objectives and scope of virtual inspection.

b) Introduction of the Rwanda FDA inspectorate team and the lead inspector

c) Identification of the facility point of contact and all other participants (e.g., monitor, remote ancillary operations).

d) Schedule of virtual inspections and the anticipated duration of the virtual inspection.

e) Rwanda FDA's expectations during the livestreaming walkthroughs of the facility.

f) Agreeing on time zone differences and translation services in case the spoken or written language is not among the officially recognized languages in Rwanda (English, French and Kinyarwanda).

g) Virtual inspections of manufacturing operations or livestream assessment of data will occur during the facility's normal business hours.

h) Methods for sharing requested information, including sharing documents and the use of video-streaming technology.

i) Technological and tools to be used for virtual interactive during evaluation of the facility.

j) Check of the internet connection throughout the facility to verify that the signal strength is adequate to support livestreaming video and audio during the actual remote interactive evaluation.

3.4.3 Pre-Testing IT systems and inspection site selection

Once everything is in place, pre-testing of IT and connection is recommended e.g. one week before inspection. The test should include any remote sites of the facility. The feasibility study should include testing of the following elements:

a) Security/Access to the Online Portal

b) Telephone or Video Conference Capacity

c) Screen-Sharing Capability

d) Wi-Fi Signal Strength

e) Computer Hardware and Connectivity

3.4.4 Conducting Virtual Inspection

Facilities are expected to cooperate with the same level of transparency as they would during an onsite inspection. All appropriate staff are expected to be available at scheduled times for interviews and other virtual interactions and the facility to be operational to the extent possible for the Authority to evaluate areas and operations of interest (e.g., manufacturing, laboratory, packaging, among others.

As part of a virtual inspection, the Authority may:

a) Request and review documents, records, and other information (electronic systems).

b) Use livestream and/or pre-recorded video to examine facilities, operations, data and other information.

c) Through the facility's point of contact, schedule interviews and meetings to address any questions or concerns.

d) Evaluate a facility's corrective and preventive actions

e) Provide verbal updates to the facility on observations and outstanding issues, whenever feasible.

Rwanda FDA should terminate the virtual interactive evaluation and instead perform on-site

inspection or use other available assessment tools where the facility is unable to provide satisfactory evidence for virtual inspection.

3.4.5 Technological Requirements

The quality equipment of the online connection (e.g., connectivity, image quality) should be adequate for the Authority to remotely review, observe, examine, and evaluate the information requested.

Rwanda FDA will use its own IT platforms and equipment (online application for teleconference) to host virtual inspections and audits.

3.4.6 Virtual evaluation of documents and records

During the virtual inspection or audit, the authority will expect the following from the facilities;

a) Requested documents and other information should be provided within a reasonable timeframe, similar to requests for documents or other information made during an inspection.

b) Requested documents to be provided in electronic format or accessible by screen sharing during a live interaction so that the documents can be assessed efficiently. For electronic documents and other information, facilities should identify any limitations and ensure that encrypted and password-protected files can be accessed by the Authority.

c) Documents submitted during a virtual inspection should be in English, French or Kinyarwanda.

d) Documents provided in paper format should be scanned as searchable Portable Document Format (PDF) files whenever possible.

CHAPTER 4: RESPONSIBILITIES OF THE APPLICANT

The main responsibilities of an applicant for virtual inspection and temporary waiver are listed below:

4.1 **Submission of the application dossier**

The manufacturer must submit an application dossier to the Authority on the following address:

Director General
Rwanda Food and Drugs Authority
Nyarutarama Plaza, Rwanda
KG 9 Avenue, Kigali
P.O. Box 1948, Kigali, Rwanda.
E-mail : info@rwandafda.gov.rw

4.2 **Requirements for GMP**

Ensuring that all below required documents for GMP application are submitted:

a) Application letter addressed to DG of Rwanda FDA

b) Fill and sign the application form available on: (www.rwandafda.gov.rw/web/guidelines/Guidelines_on_Good_Manufacturing_Practice_for_Finished_Pharmaceutical_Products.pdf)

c) Proof of payment of prescribed fees

d) The Site Master File (Refer to the 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 of the premises issued by the competent regulatory authority in the country of origin.

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) manufactured on-site and List of products intended for supply in Rwanda. The lists should include proprietary names and international non-proprietary names (INN).

h) Copy of the recent GMP inspection report done by the competent regulatory authority in the country of origin and recent GMP inspection report from regional or international bodies if available with a certified translated copy where this is not in English or French or Kinyarwanda.

i) A copy of any warning letter or equivalent regulatory action issued by any authority to which the site provides or has applied to provide the product.

j) Corrective and preventive action (CAPA) and proof of CAPA implementation related to the inspection report(observations/deficiencies).

k) The most recent product quality review(s) (PQR)(s) of the concerned product(s).

l) A confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the product(s) has been performed and all matters dealt with.

m) Quality Manual/Laboratory Manual or equivalent.

n) The completed batch manufacturing/packaging record(s) including the analytical part for the most recently released batch of the relevant product(s).

o) A list of any recalls or any Market complaints registers in the last three years.

p) Aseptic validation report (Required for products applied for that are not terminally sterilized).

q) Contract or agreement between the FPP or API manufacturer and the outsourced testing laboratory or sterilization institution (for Outsourced testing laboratory; and Outsourced sterilization).

4.3 **Application Fees**

Remitting all application fees at the time of lodging an application for virtual inspection or temporary waiver.

4.4 Applications for Renewal

Submitting applications for renewal of a GMP Certificate at least six months prior to the expiry of the current Certificate.

4.5 **Submission of additional information**

Promptly submitting any additional information that may be requested by Rwanda FDA during an assessment. Failure to provide required documents within the specified time, depending on additional information requested, may result in the application being rejected.

ENDORSEMENT OF THE GUIDELINES

	Author	Checked by		Approved by
Title	Division manager	Head of Department	Quality Assurance Analyst	Director General
Names	Dr. Marylin M. MURINDAHABI	Dr Eric NYIRIMIGABO	Théogène NDAYAMBAJE	Dr Emile BIENVENU
Signature				
Date	22/09/2022	23/09/2022	22/09/2022	23/09/2022

RWANDA FOOD AND DRUGS AUTHORITY • RWANDA FDA