RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINE ON QUALIFICATIONS OF GMP INSPECTORS

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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,

Badly manufactured Pharmaceutical products effects are one of the public health concerns not only to our country but all over the world. It is in this context that the Rwanda Food and Drugs Authority intends to put in place guidelines that provide guidance on good practices for desk assessment for compliance with good manufacturing practices, good laboratory practices and good clinical practices for marketing authorisation of products to ensure that manufactured medicines do not constitute harmful effects to people's health that leads to losses of life.

It is expected that these guidelines will offer a clear understanding to manufacturers and other persons concerned by the guidelines during the evaluation process, they will protect consumers and Pharmaceutical manufacturing industry, thus promoting health protection, business as well as the national economy as a whole.

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ABBREVIATIONS AND ACRONYMS

GMP: Good Manufacturing Practices

NMRA: National Medicine Regulatory Authority

Rwanda FDA: Rwanda Food and Drugs Authority

API: Active Pharmaceutical Ingredients

HVAC: Heating, Ventilation and Air Conditioning

DEFINITIONS

- **GMP Inspector** means a GMP Inspector is an officer appointed by the NMRA of Partner states in accordance with national regulations and the provisions of the NMRA to conduct an inspection or assessment in order to verify GMP compliance of a manufacturing site on behalf of Rwanda FDA.
- **Lead GMP inspector** is a Senior GMP Inspector who is charged with the responsibility for leading a GMP inspection team to undertake inspection of a specified pharmaceutical manufacturing site(s).
- **Re- qualification** implies validation of the GMP inspector after 24 months' absence from conducting GMP inspections to ensure the officer possesses the knowledge and skills to carry out GMP inspections
- **Senior GMP inspector** is an officer who by virtue of experience and competence is appointed as such to conduct GMP inspections and train junior officers in inspections after evaluation by the NMRA as by the criteria outlined in the assessment form.
- **Specialized GMP inspector** is a GMP inspector who possesses specialized knowledge and experience in conducting GMP inspections for specialized areas e.g Microbiology, HVAC, Biologicals, API
- **Audit** A Systematic and independent examination to determine whether quality activities and related results comply with the planned arrangement and whether these arrangements are implemented effectively and are suitable to achieve the objectives.
- **Inspection** is the examination of a product design, product, service, system, process and premises in order to determine their conformity with requirements. NOTE: Inspection of system and processes includes personnel, facilities, technology and methodology.
- **The inspector** The inspector is the person who represents Rwanda FDA, and is the first, and often the only, point of contact between the institution and the importing community.

1. INTRODUCTION

Rwanda Food and Drugs Authority was established by the law Nº 003/2018 of 09/02/2018 determining its mission, organization and functioning. The mandate of the Authority 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 & tobacco products.

Rwanda FDA is mandated to conduct inspection among other regulatory functions for facilities dealing with regulated products,This is to ensure adherence by manufacturers, importers, exporters, contracted research organizations and other Rwanda FDA licensee to regulatory provisions. Inspection involves a sequential analysis of production and control activities on the basis of the guidelines issued by Rwanda FDA .

Considering the paramount importance of the management of inspection services, these procedures establish the requirements concerning experience, training, assessment and qualifications of inspectors. Inspectors should be well trained in all the relevant topics according to their specific role or the sector at which they work and in the way of conducting an inspection (inspection methodology).

SCOPE.

This document will be applied by Rwanda FDA to identify the competence requirements for inspectors to conduct inspection. It will also be used to identify the training needs of inspectors as per their respective role .

1.1 GENERAL REQUIREMENTS

Rwanda FDA shall appoint inspectors to inspect the local and foreign premises of regulated products. All the inspectors shall be competent to carry out their assigned duties and receive appropriate training where necessary. The Authority shall provide sufficient resources at all levels to implement competence requirements.

Rwanda FDA shall use the report on observations of all areas within the scope of the inspection to make a judgment on the competence of the inspector. Thus each inspector must be able to assess each section of targeted inspection.

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The inspectors should be aware of and maintain confidentiality whenever they gain access to confidential information as a result of inspections according to Rwanda FDA regulations.

The training of inspectors shall regularly be assessed within requirements of the applicable quality system of the Inspectorate and appropriate action taken by the authority to maintain and improve inspection skills. Information on the relevant experience, training and qualifications of individual inspectors must be documented and these records must be kept up-to-date.

1.3 Qualities of an INSPECTOR

Objectivity and professional integrity, competence in technical matters and inspection skills shall be the main features of inspectors. The inspector shall have a high personal integrity, maturity, honesty, be open-minded, understanding of complexity, possess sound judgment, assertiveness, analytical skills and tenacity and have the ability to perceive situations in a realistic way.

During an inspection, the inspector shall help in creating an open atmosphere and in this context inspector shall answer questions or provide clarification but avoid entering into the role of a consultant. inspector shall demonstrate competence in clearly and fluently expressing concepts and ideas orally and in writing in English and/or other languages defined by the Authority.

The inspector shall also possess the following attributes:

• Awareness of the probable methods of using forged or false documents for transactions of regulated products and skill in determining the genuineness of documents presented for examination
• Responsible conduct which commands respect willingness to accept challenges
• Ability to assess facts quickly and take rational and sound decisions without delay
• Ability to assess character and honesty of persons being interviewed
• Commitment to hard work and work extra time where necessary

- Result based oriented
- be capable of exercising confidentiality of information obtained in the course of performing inspection
- must be impartial and objective to the audit conclusion.
- Inspectors must declare conflicts of interest

2. CATEGORIZATION OF INSPECTORS

Inspectors in Rwanda FDA shall be categorized into three levels i.e. level I, II and III for the purpose of assigning responsibilities and also identifying their training needs.

The categorization will be done by Rwanda FDA based on the criteria set in this document. The three levels are defined below:

Level I – Entry Level (Junior Inspector)

This is a career entry level. The individual who operates at this level is at a junior or more established stage in their own professional career but is likely to be inexperienced in inspection or is new to the authority.

Inspectors with limited experience require significant support and close supervision to attain the necessary skills. They also need to get specific trainings related to conducting of inspection of different facilities.

Level II – Experienced level (Senior level)

This is an experienced inspector level. The inspector has demonstrated that he/she is competent to work independently and without supervision and that he/she has the necessary technical and organizational skills to inspect different premises and regulated products at national and regional level. Level II inspectors shall continue to develop in the job to enable them to take on more complex applications as their training and competence develops. They shall continue to develop their competence through training and mentorship by level III inspectors.

Level III Inspectors – Expert level

Level III consists of more experienced inspectors who are expected to make an advanced contribution to the inspection and may be recognized as an expert or specialised in a particular field, based on increased breadth or depth of skills. They should have knowledge and personal skills appropriate to mentoring and development of less experienced inspectors. Expert inspector should be able to inspect a wide range of facility premise, including those with complex issues, to ensure product compliance with regulatory requirements. The inspector should have continuing knowledge of the broader regulatory environments and processes following the best international practices.

2.1 Criteria for categorization of Inspectors

The following criteria will be used to categorize the inspectors into different levels:

a) Scientific Knowledge and Skills – The knowledge and skills required to achieve the objectives for the various conduct of inspection which are gained through education, training and experience.
b) Regulatory Knowledge and Experience – The regulatory knowledge and experience required to achieve the inspection objectives through training and experience.
c) Work complexity and consistency in conducting inspection – an inspector shall have demonstrated attitude, aptitude and consistency in preparation, conducting of an inspection, writing inspection report including complying with the set timelines.
d) Social skills and attunement to internal and external context – The inspector shall be aware of conducting of inspection with regards to national and international situations.
e) Language requirements – Should have a good command of English language and French language

2.2 EDUCATION AND TRAINING

The inspector education should be relevant to the assigned duties, the knowledge of national legislation as well as systems for applications for marketing authorisation and control of regulated products is compulsory. The inspectors shall be trained to the extent necessary to ensure their competence in skills required for planning, carrying out and reporting inspections.

The training and experience should be documented individually and evaluated within the requirements of the applicable quality system of Rwanda FDA.

2.3 QUALIFICATION OF INSPECTORS

2.3.1 GMP INSPECTORS

GMP Inspectors for pharmaceutical products and medical devices shall normally be pharmacists, medical and Veterinary doctors, biomedical engineer, chemists, biotechnologists and any other relevant qualification.

GMP Inspectors for food products should preferably be food scientist, food Biotechnologists, nutritionists, pharmacists, chemists, animal production, veterinary doctors and any other relevant qualification.

GMP inspectors shall be trained in drug, medical devices control affairs, food control affairs and in GMP inspectorate functions. Moreover, in order to be appointed a GMP inspector by Rwanda FDA, the candidate shall demonstrate their knowledge and skills in the relevant pharmaceutical field and food sector including:

• Good Manufacturing Practice
• Food and Pharmaceutical technology,
• Microbiology, process and ventilation engineering, analytical instrumentation, computer systems process validation, the statistical aspects of quality control.
• Interrelation of inspection, sampling and analysis, licensing
• Marketing and manufacturing authorization systems and their relationships
• Auditing/inspection techniques
• Training in inspection technique, acquired by attending relevant courses and/or by accompanying and/or be guided by qualified GMP inspectors during inspections
• Training in administration procedures required for managing an inspection, such as planning, organizing, communicating or providing feedback to inspectee
• Training in evaluation of findings and reporting
• Good Distribution Practices
• medicine and food products legislations at National and International levels
• Communication skills, oral and written
• Organization of the national medicine and food sector regulator
• The general principles of Quality Management Systems (ISO 9000: etc.)
• Knowledge of and training in working according to relevant Rwanda FDA SOPs for inspections
• Structure and principles of operation of commercial organizations
• Judiciary procedures
- Training in proper food protection principles, personal hygiene and good sanitary practices

IN-SERVICE TRAINING

After recruitment and in addition to their basic training, new inspectors should be trained by senior inspectors. The theory of inspection should be explained and the practice should be shown in the field, so that concrete examples of the meaning and of the goals of inspections are given and can be discussed.

New inspectors should participate, but only as observers, in on the spot inspections carried out during their initial training. Training of inspectors should be a combination of theoretical and practical training. It should cover both technical and non-technical aspects.

Prior to assuming responsibility for performing GMP inspections, the new inspector should have gained experience by participation as a team member in inspections led by senior inspectors. Preferably, the inspector should start with national GMP inspections as a member of a team and then deal progressively with more complex GMP inspections to be able to act as a team leader and/or reporting inspector in international inspections

This should consist of six phases:

1. **Initially** the trainee is trained in the basic principles of GMP and good inspection techniques
2. In addition, the trainee inspector should have assessed at least ten (10) dossiers prior to qualification as a GMP inspector
3. The trainee inspector would participate in a GMP inspection with experienced inspector as an observer in at least three inspections.
4. **Secondly,** the trainee inspector would participate in inspections as a junior member of the team (at least six inspections).
5. **Thirdly,** the trainee inspector would participate in inspections as a coinspector under supervision of a qualified lead inspector (at least three inspections). After assessment and satisfactory performance, the trainee qualifies as a GMP inspector.
6. **Finally,** the GMP inspector would participate in inspections as a co-inspector in at least twenty inspections at national, regional or international level taking into consideration of different dosage forms and expertise acquired to become a lead GMP inspector after assessment of satisfactory performance.

At all stages, the performance of the trainee should be assessed. This should be recorded within the requirements of the applicable quality system of the Rwanda FDA GMP Inspectorates Besides this and where needed, training courses in auditing techniques and communication, reporting, language, legal matters and management should be organized by RWANDA FDA

OTHER INSPECTORS

PORT OF ENTRY INSPECTORS

POE inspectors shall preferably be pharmacists, chemist, biotechnologists, food scientists, nutritionists and any other relevant qualification,

Moreover, in order to be appointed a POE inspector, the candidate shall demonstrate their knowledge and skills in the relevant pharmaceutical field and food sector including In **:**

• Good Manufacturing Practice

• Food and Pharmaceutical technology,

• Microbiology, process and ventilation engineering, analytical instrumentation, computer systems process validation, the statistical aspects of quality control.

• Interrelation of inspection, sampling and analysis, licensing

• Marketing and manufacturing authorization systems and their relationships

• Auditing/inspection techniques

• Training in inspection technique, acquired by attending relevant courses and/or by accompanying and/or be guided by qualified GMP inspectors during inspections

• Training in administration procedures required for managing an inspection, such as planning, organizing, communicating or providing feedback to inspectee

• Training in evaluation of findings and reporting

• Good Distribution Practices

• medicine and food products legislations at National and International levels

• Communication skills, oral and written

• Organization of the national medicine and food sector regulator

• The general principles of Quality Management Systems (ISO 9000: etc.)

• Knowledge of and training in working according to relevant Rwanda FDA SOPs for inspections

• Structure and principles of operation of commercial organizations

• Judiciary procedures

- Training in proper food protection principles, personal hygiene and good sanitary practices

Technical Training of POE

The technical training which should be undertaken by a PoE inspector should cover:

- Inspection program: uniformity of inspection (annex), overview of sequence of events ,notification of consignment,decision to inspect, official release, conditional release, arrange inspection, conduct inspection
- Registration process of importers and industries
- Priorities and scope of imported food (to determine which food to inspect compared to resource budget : Risk management, inspection and sampling frequency
- Conduct visual inspection: to allow full examination of the consignment (check documentation, labelling and general condition of consignment(packaging)
- Methods for sampling and laboratory analysis, procedures and actions (to confirm if it meets standard requirements
- Have knowledge on the standards and regulations of the b imported products

- Basic of communication system (information flow)
- Food technology (food preservation techniques and procedures, food microbiology,)
- Food hygiene and safety
- Administrative training (barrier operations)
- Legal authority (to have confidence that he or she has the legal right to conduct the activity)
- Data collection, Development and maintenance of data system (be able to retrieve results of previous inspection)

PROFILE OF INSPECTOR

The inspector is the person who represents Rwanda FDA and is the first, and often the only, point of contact between the institution and the importing community. So the inspector should be able to present a professional and confident image to the clients of Rwanda FDA, whether those clients be importers or their agents, or officials of Customs, Quarantine or other government agencies which have jurisdiction at the country's border.

PERSONAL QUALITIES

Choosing inspection staff with personal integrity, the ability to effectively deal with people and a good technical background is essential in providing the inspection programme with a solid base.

An inspector must be beyond corruptible influences. The most desirable personality is a strong character, prepared to remain firm where difficult and unpalatable decisions must be made, yet flexible enough to assist or advise importers where necessary without jeopardising the programme. An inflexible "got you" personality can be as damaging for the programme as a weak ineffective individual.

Education background of the inspector,administration,liaison skill and ability to conduct inspection and handle the broad range of activities required of POE inspector should also be taken into account

2.5 CONTINUOUS TRAINING

Considering the dynamic nature of manufacturing technologies, the ever more frequent utilization of automatic and computerized systems both in production and quality control of medicinal products, inspectors should also receive continuous training. This could be reached through their participation in courses, seminars, scientific meetings and conferences organized by either Rwanda FDA or by national, regional or international scientific

organizations. When appropriate, joint inspections or training visits with other inspectors of the EAC NMRA or other DRAs may be a useful training method. GMP Training in form of courses, symposiums, conferences, or any other mode the NMRA deem suitable) should be arranged by Rwanda FDA on annual basis.

2.6 MANAGEMENT CAPABILITIES

The inspector should through suitable means demonstrate their knowledge and capability of using the necessary management skills required in execution of an inspection, i.e. planning, announcing, conducting and reporting an inspection.

3. References

1.September, V. (2014). Compendium of Good Manufacturing Practices Gmp Technical Documents for Harmonization of Medicines Regulation in the East African Community. September.

2.Weeks, D. P. C. C. L. E. Y. N. to K. in 20. (2015). Doc. No. TFDA/DBS/QM/G/001 TANZANIA FOOD AND DRUGS AUTHORITY. Dk, 53(9), 1689–1699. https://doi.org/10.1017/CBO9781107415324.004

3. WHO-inspection. (2002). 0011-Annex 7 Guidelines on pre-approval inspections. World Health Organization WHO Technical Report Series, 902, 94–100.