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REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDANCE ON QUALIFICATION AND EXPERIENCE REQUIREMENTS AND RESPONSIBILITIES FOR KEY PERSONNEL OF LICENSED MANUFACTURERS OF MEDICAL PRODUCTS AND HEALTH TECHNOLOGIES KENYA

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1. ABBREVIATIONS AND ACRONYMS

API	-	Active Pharmaceutical Ingredient
BMGF	-	Bill and Melinda Gates Foundation
BMR	-	Batch Manufacturing Record
EAC	-	East African Community
EAC-MRH	-	East African Community Medicines Regulatory Harmonization
EAC-NMRA	-	East African Community National Medicines Regulatory Authority
EMA	-	European Pharmaceutical products Agency
EU	-	European Union
FEAPM	-	Federation of East African Pharmaceutical Manufacturers Harmonization
FPP	-	Finished Pharmaceutical Product
GCP	-	Good Clinical Practice
GLP	-	Good Laboratory Practice
GMP	-	Good Manufacturing Practice
ICH	-	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
MA	-	Marketing Authorization
NEPAD	-	New Partnership for African Development
NMRA	-	National Medicines Regulatory Authority
PIC/S	-	Pharmaceutical Inspection Convention Scheme
PPB	-	Pharmacy and Poisons Board
TWG	-	Technical Working Group
WHO	-	World Health Organization
QA	-	Quality Assurance
HVAC	-	Heating Ventilation and Air Conditioning
QC	-	Quality Control
QRM	-	Quality Risk Management
SOP	-	Standard Operating Procedure
NRAs	-	National Regulatory Authority

2. GLOSSARY

The definitions given below apply to the terms used in this guide. They may have different meanings in other contexts.

GMP Inspector is an officer appointed by the Pharmacy and Poisons board in accordance with national regulations and the provisions of the Pharmacy and Poisons Board to conduct an inspection or assessment in order to verify GMP compliance of a manufacturing site on behalf of the Pharmacy and Poisons Board.

Lead GMP inspector is a Senior GMP Inspector who is charged with the responsibility of 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 Pharmacy and Poisons Board 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

1. Scope and objective of the guidance

1.1. This guidance represents the current PPB's requirement on key personnel involved in batch production and control, batch certification and on eventual batch release by licensed manufacturers of human or veterinary products[1] meant for domestic and export markets.

1.2. The principles of this guidance also apply to investigational medicinal products (IMP) for human and veterinary use in accordance with legal provisions that may be reviewed from time to time.

1.3. The basic arrangements for batch release for a product are defined by its Marketing Authorization (MA). Nothing in this guideline should be taken as overriding those arrangements.

2. Legal basis

2.1. The legal basis for identification of a pharmaceutical manufacturer's key personnel including the Authorized Person is in the current Pharmacy and Poisons Board Act (Cap 244); The Act empowers The Pharmacy and Poisons Board (PPB) to adopt the Guidelines on Good Manufacturing Practices (GMP) wherein the Key Personnel is specified.

2.2. The World Health Organization (WHO) GMP guidelines adopted by Kenya specifies key personnel to include the heads of production, the head(s) of quality unit(s) and the authorized person. The quality unit(s) typically comprise the quality assurance and quality control functions. In some cases, these could be combined in one department. The authorized person may also be responsible for one or more of these quality unit(s). Normally, key posts should be occupied by full-time personnel.

[1] Products; include medicinal products and Health Technologies for human and veterinary use

The heads of production and quality unit(s) should be independent of each other. In large organizations, it may be necessary to delegate some of the functions; however, the responsibility cannot be delegated.

2.3. The composition and responsibilities of Key Personnel shall be as specified in the current WHO GMP guidelines on key personnel.

3. Background

3.1. WHO Guide to Good Manufacturing Practice for Pharmaceutical Products require that products are not sold or supplied before an Authorized Person has certified that each production batch has been produced and controlled in accordance with the requirements of the marketing authorization and any other regulations relevant to the production, control and release of the pharmaceutical products.

3.2. In addition, WHO GMP guidelines require that personnel must have the necessary qualifications and practical experience to carry out their responsibilities.

3.3. Authorized Persons and other key personnel should be suitably qualified, experienced and competent for the types of manufacturing operations undertaken by the manufacturer for whom they work for.

3.4. Manufacturers are responsible for providing training for all personnel whose activities could affect the quality of the product. Authorized persons must ensure that training programmes as well as continuing professional development (CPD) is part of the organization's culture.

3.5. Kenyan Licensed manufacturers shall ensure that an Authorized Person is employed to be responsible for ensuring and certifying that:

3.5.1. each batch of the pharmaceutical products has been manufactured and checked in accordance with the GMP Guide; and

3.5.2. the registrable particulars of each batch of the pharmaceutical products correspond exactly with the registered particulars of the products.

4. Identification

4.1. For the purpose of a Kenyan Pharmaceutical Industry, Key personnel shall include:

a) Head of Quality Unit (HQU),

b) Head of Quality Assurance (HQA),

c) Head of Quality Control (HQC) and the

d) Head of Production (HPDN).

4.2. The HQU shall be recognised as the Authorized Person (AP) and the Company Pharmacist (CP). His name shall be entered in the register of APs in accordance to applicable regulations.

4.3. The separate Quality Assurance and the Quality Control units/departments that shall collectively be referred to as the Quality Unit (QU) to be headed by HQU.

4.4. Key personnel shall be employed on full-time basis and shall be independent of each other.

4.5. Under normal circumstances, depending on the size of the manufacturing facilities.

5. Differential requirements

5.1. For large-sized pharmaceutical manufacturing facilities, the HQU shall double as a Company Pharmacist and shall act as an Authorized Person. It could be necessary to delegate some of the functions of the HQU to the QA head; however, the responsibility would not be delegated;

5.2. For mid-sized pharmaceutical manufacturing facilities, the head of Quality Assurance may act as the company pharmacist and as an Authorized Person with an independent head of quality control headed by a head quality control;

5.3. For small manufacturing facilities, there could be one Quality Unit combining both quality assurance and quality control functions. In this case the head Quality Unit shall also act as the Authorized Person if they meet the requirement.

5.4. If, under provision 5.3, the HQU does not meet the requirements of an Authorized person, the company shall be required to contract the services of any of the registered APs in accordance with current licensure requirement.

5.5. In whatever case, the heads of production and the head (s) of quality unit(s) shall be independent of each other. In large-sized organizations, it may be necessary to delegate some of the functions; however, the responsibility cannot be delegated.

6. Qualification of the Head Quality Unit (HQU)

6.1. The Head of Quality Unit (authorized Person) shall be a duly Registered Pharmacist in Kenya in accordance to the current guidelines for registration as a pharmacist in Kenya.

6.2. In addition to course work, the HQU shall have acquired practical experience during at least 6 years at one or more companies authorized to manufacture pharmaceutical products in the Kenya either as a HQA, HQC or as a HPDN.

6.3. During the period specified under provision 6.2, the person formally heading QC and QA shall have been involved in qualitative analysis of pharmaceutical products, quantitative analysis of active substances and testing and checking necessary to ensure the quality of pharmaceutical products.

6.4. In order to gain such experience while working either as HQA, HQC or HPDN, a preparatory period may be required, during

which they should perform their duties under professional guidance.

6.5. All HQU in Kenya involved in the certification, or confirmation of a batch before it is released should have detailed knowledge of the steps for which they are taking responsibility. The HQU should be able to prove their continuous training regarding the product type, production processes, technical advances and changes to GMP.

7. Responsibilities of the Authorized Person (Head Quality Unit; HQU)

7.1. Whereas the product marketing authorization holder (MAH) is recognised to bear the ultimate responsibility for the safety, quality and efficacy and the overall performance of products over its lifetime, the HQU (Authorized Person) is responsible for ensuring that each individual batch has been manufactured, controlled and checked in compliance with applicable Laws of Kenya, marketing authorization requirements, standards of Good Manufacturing Practice (GMP) and with pharmacovigilance requirements.

7.2. The HQU (Authorized Person), without prejudice to his/her relationship with the manufacturing facility or with the MAH, is generally responsible for compliance with technical or regulatory requirements related to the quality of finished products and the approval/certification of the release of the finished product batch for sale or supply.

7.3. The Authorized Person is responsible for controlled batch release to ensure that each batch of a product has been manufactured and checked in accordance with the requirements of its MA, principles and guidelines of GMP as well as in accordance with any other relevant legal requirements. Controlled batch release ensures that the HQU involved in the certification or confirmation as well as any relevant records are

readily identifiable for cases where product quality defect have been reported and needs to be investigated or when a batch needs to recalled.

7.4. Batches of products should only be released for sale or supply to the market after certification by the HQU, and should remain at the site of manufacture or be shipped under quarantine to another site which has been approved by the Pharmacy and Poisons Board for that purpose. No batch of product is to be released for sale or supply prior to certification by the authorized person(s).

7.5. While batch certification precedes batch release and shall be performed by the AP, batch release need not necessarily be performed by the HQU. No matter who performs batch release, the following should be considered:

7.5.1. The checking of the manufacture and testing of the batch in accordance with defined release procedures.

7.5.2. The certification of the finished product by the HQU to demonstrate that the batch is in compliance with GMP and the marketing authorization. This represents the "Quality Release Certification" of the batch.

7.5.3. The transfer for local sale/supply, and/or export of the finished batch of product following batch certification by the HQU. For cases where batch certification and batch transfer for local or export occur in different locations, a written contract detailing the responsibilities and activities should be documented and availed to PPB inspectors.

7.6. During controlled batch release, the HQU shall ensure that:

7.6.1. Each batch of product has been manufactured and checked in compliance with Kenyan laws and in accordance with the requirements of the marketing authorization;

7.6.2. Where a domestic manufacturer has engaged several sites involved in the various stages of manufacture, importation, testing and storage of a batch before it undergoes certification, regardless of how many sites are involved, the HQU performing certification of the finished product must ensure that all necessary steps have been completed under accepted (pharmaceutical) quality systems to assure compliance of the batch with GMP, Marketing Authorization and pharmacovigilance requirements.

7.6.3. Consideration is given to applicable requirements required by Kenyan Law.

7.6.4. All sites, activities and corresponding authorized persons involved in certification or confirmation as well as all the relevant records are readily identifiable in the event that any quality defects reported require investigation.

7.7. In the case of products imported into Kenya;

7.7.1. Each batch of pharmaceutical product, has undergone all the tests or checks necessary to ensure the quality of pharmaceutical products comply with the requirements of the marketing authorization and Pharmacovigilance requirements.

7.7.2. To accomplish this responsibility the HQU ensures that a batch of finished pharmaceutical product has undergone in exporting country a full qualitative analysis, a quantitative analysis in accordance with marketing authorization requirements.

7.7.3. The batches of pharmaceuticals products imported into Kenya as finished pharmaceutical products from sites that have been approved by the Pharmacy and Poisons Board are currently exempt from tests and controls.

7.7.4. Each batch of product, where appropriate arrangements have been made by the exporting country to ensure that the manufacturer of the product applies standards of good manufacturing practice at least equivalent to WHO GMP guidelines, and that the controls referred to above have been indeed carried out in the exporting country. In this case, the manufacturer in Kenya may be exempt from carrying out those controls.

7.8. In all incidences and especially where the products are released for sale, the HQU must certify in a register or equivalent document, provided for that purpose, that each production batch satisfies the provisions of the marketing authorization and pharmacovigilance requirements. The said register or equivalent document, in whatever form and format, must be kept up to date as operations are carried out and must remain at the disposal of the Pharmacy and Poisons Board inspectors for at least five years.

7.9. The following further HQU responsibilities may be delegated to appropriately qualified and trained personnel.[2]Ensuring that:

7.9.1. The entire supply chain of the active substance and pharmaceutical product is documented and available for PPB inspectors including manufacturing sites of the starting materials and packaging materials for the pharmaceutical product and any other materials deemed critical through a risk assessment of the manufacturing process.

7.9.2. All sites of manufacture and analysis are compliant with the terms of Kenyan and export marketing authorization as well as to the marketing authorization to which the pharmaceutical product is exported.

[2]

7.9.3. All manufacturing activities and testing activities are consistent with those described in the marketing authorizations.

7.9.4. Any regulatory post-marketing commitments relating to manufacture or testing of the product have been addressed. On-going stability data continues to support certification

7.9.5. Any on-going complaints, investigations or recalls do not negate the conditions for certification of the batch in question.

7.9.6. The required technical agreements are in place.

7.9.7. In the case of parallel importation and parallel distribution any repackaging operation carried out on a batch which has already been released must be approved by the Pharmacy and Poisons Board or the National Regulatory Authority of the intended market.

7.9.8. The repackaging of parallel imported batch has been performed in accordance with the relevant authorization pertaining to the repackaged product and with GMP.

7.9.9. Prior to certification of a repacked batch, the batch complies with national requirements for parallel importation and distribution.

8. Qualification of the Head Quality Assurance (HQA)

8.1. The Head of Quality assurance shall be a duly Registered Pharmacist in Kenya in accordance to the Pharmacy and Poisons Act, Cap 244.

8.2. In addition to course work, the HQA shall have acquired practical experience for at least 3 years at one or more companies authorized to manufacture Medical Products and Health Technologies products in Kenya in the areas of Quality Assurance, Quality Control, and/or Production. During the

period, the person shall have been involved in or shall have supervised qualitative analysis of pharmaceutical products, quantitative analysis of active substances and testing and ensuring the quality of MPHT products.

8.3. In addition to such experience while working in the areas of Quality Assurance, Quality Control, and/or Production, an orientation period may be required, during which they should perform their duties under professional guidance.

8.4. The scientific education and practical experience should be such as to enable the HQA exercise independent professional judgement, based on the application of scientific principles and understanding to the practical problems encountered in the production and QC of MPHT products.

8.5. In mid-sized pharmaceutical manufacturing facilities where the head of Quality Assurance may act as the company pharmacist and as an Authorized Person, with an independent quality control headed by a head quality control, the head quality control shall be answerable to the Head Quality Unit.

8.6. In small manufacturing facilities where there could be one Quality Unit combining both quality assurance and quality control functions, the Quality Unit shall be headed by the quality assurance head meeting the qualification above.

8.7. All HQA in Kenya involved in the certification, or confirmation of a batch before it is released should have detailed knowledge of the steps for which they are taking responsibility. The HQA should be able to prove their continuous training regarding the product type, production processes, technical advances and changes to GMP.

9. Responsibilities of the Head Quality assurance (HQA)

9.1. The head of Quality Assurance shall have the following responsibilities:

9.1.1. approve or reject starting materials, packaging materials, and intermediate, bulk and finished products in relation to their specifications;

9.1.2. evaluate batch records;

9.1.3. ensure that all necessary testing is carried out

9.1.4. approve sampling instructions, specifications, test methods and other QC procedures

9.1.5. approve and monitor analysis carried out under contract;

9.1.6. check the maintenance of the department, premises and equipment;

9.1.7. ensure that the appropriate validations, including those of analytical procedures, and calibrations of control equipment are carried out;

9.1.8. ensure that the required initial and continuing training of quality unit personnel is carried out and adapted according to need;

9.1.9. establish, implement and maintain the quality system;

9.1.10. supervise the regular internal audits or self-inspections;

9.1.11. participate in external audit (vendor audit);

9.1.12. participate in validation programmes.

9.2. For small manufacturing facilities;

9.2.1. The HQA (company's Authorized Person) shall be responsible for ensuring that each individual batch has been manufactured, controlled and checked in compliance with applicable Laws of Kenya, marketing authorization requirements, standards of Good Manufacturing Practice (GMP) and with pharmacovigilance requirements. This however, does not remove the ultimate responsibility for the safety, quality and efficacy and the overall performance of a

pharmaceutical products over its lifetime from the marketing authorizations holder (MAH).

9.2.2. The HQA, who supervises the quality unit comprising the quality assurance and quality control units, shall be responsible for all the functions of the HQU.

10. Qualification of the Head of Production (HPDN)

10.1. The head of production responsible for supervising the production of MPHT shall be a duly registered Pharmacist in Kenya in accordance to Pharmacy and Poisons Act, Cap 244 Laws of Kenya.

10.2. The HPDN shall have at least 3 years practical experience in the manufacture and QA of pharmaceutical products. In order to gain such experience, a preparatory period may be required, during which they shall perform their duties under professional guidance.

10.3. The scientific education and practical experience of HPDN should be such as to enable them to exercise independent professional judgement, based on the application of scientific principles and understanding to the practical problems encountered in the manufacture of products.

11. Responsibilities of the Head of production (HPDN)

11.1. The head of production shall have the following responsibilities:

1.1.1. ensure proper production planning and forecasting for the department

1.1.2. ensure that products are produced and stored in accordance with the appropriate documentation in order to obtain the required quality;

1.1.3. approve the instructions relating to production operations, including the in-process controls, and to ensure their strict implementation;

1.1.4. ensure that the production records are evaluated and signed by a designated person;

1.1.5. check the maintenance of the department; premises and equipment.

1.1.6. ensure that the appropriate process validations and calibrations of control equipment are performed, recorded and reports made available.

1.1.7. ensure that the required initial and continuing training of production personnel is carried out and adapted according to need.

2. Qualification of the Head of Quality Control (HQC)

2.1. The HQC responsible for supervising the Quality Control function should possess the qualifications of a scientific education and practical experience.

2.2. The HQC shall be in possession of a degree certificate awarded on completion of a university course of study, extending over a period of at least four years of theoretical and practical study in a scientific discipline in the following:

2.2.1. Pharmacy;

2.2.2. Analytical chemistry;

2.2.3. biochemistry;

2.2.4. chemical engineering;

2.2.5. microbiology;

2.2.6. pharmaceutical sciences and technology;

2.2.7. pharmacology and toxicology;

2.2.8. other related sciences.

2.3. The HQC shall have adequate practical experience in the quality control of MPHT. In order to gain such experience, a preparatory period may be required, during which they should perform their duties under professional guidance.

2.4. To gain such experience, the officer shall have worked as an analyst for at least 3 years and as supervisor for at least 2 years reporting to a HQC.

2.5. The scientific education and practical experience should be such as to enable the HQC exercise independent professional judgement, based on the application of scientific principles and understanding to the practical problems encountered in Quality Control of MPHT.

2.6. The HQC shall be registered by the Board.

3. Responsibilities of Heads of Quality Control (HQC)

3.1. The head of Quality Control shall have the following responsibilities:

3.1.1. Approve or reject starting materials, packaging materials, and intermediate, bulk and finished products in relation to their specifications;

3.1.2. ensure that all necessary testing is carried out;

3.1.3. approve sampling instructions, specifications, test methods and other QC procedures;

3.1.4. approve and monitor analysis carried out under contract;

3.1.5. check and maintain the department; premises and equipment;

3.1.6. ensure that the appropriate validations, including those of analytical procedures and calibrations of control equipment are carried out;

3.1.7. ensure that the required initial and continuing training of quality control personnel is carried out and adapted according to need;

3.1.8. establish, implement and maintain the quality control system;

3.1.9. participate in regular internal audits or self-inspections;

3.1.10. participate in external audit (vendor audit);

3.1.11. participate in validation programmes.

3.1.12. establish, validate and implement all QC procedures;

3.1.13. evaluate, maintain and store reference standards for substances;

3.1.14. ensure the correct labelling of containers of materials and products;

3.1.15. ensure that the stability of the active pharmaceutical ingredients and products is monitored;

3.1.16. participate in the investigation of complaints related to the quality of the product;

3.1.17. participate in environmental monitoring;

3.1.18. participate in quality risk management programs.

4. Jointly exercised responsibilities

4.1. The heads of the production and the quality unit(s) generally have some shared or jointly exercised responsibilities relating to quality including but not limited to:

4.1.1. authorization of written procedures and other documents, including amendments;

4.1.2. monitoring and control of the manufacturing environment and plant hygiene;

4.1.3. supervise process validation and calibration of analytical apparatus;

4.1.4. training, including the application and principles of QA;

4.1.5. approval and monitoring of suppliers of materials;

4.1.6. approval and monitoring of contract manufacturers;

4.1.7. designation and monitoring of storage conditions for materials and products;

4.1.8. oversee performance and evaluation of in-process controls;

4.1.9. retention of QA, QC and production records

4.1.10. monitoring of compliance with GMP requirements;

4.1.11. inspection, investigation and taking of samples in order to monitor factors that may affect product quality.

Reference documents

The following Guidance contain further requirements for the tasks to be fulfilled by a HQU,HQA, HQC and HPDN as the Key Personnel:

Key personnel	**reference document**
The Head Production	*WHO good manufacturing practices for pharmaceutical products: main principles*
The head Quality Assurance	*WHO good manufacturing practices for pharmaceutical products: main principles*
Head Quality Control	*WHO good manufacturing practices for pharmaceutical products: main principles*
Head Quality Unit	*a) WHO good manufacturing practices for pharmaceutical products: main principles* *b) EU GMP Guide to Good Manufacturing Practices* *c) Annex 16 to the EU Guide to Good Manufacturing Practice Certification by a Qualified Person*

REFERENCES

1. WHO Technical Report Series 986, Annex 2
2. EAC Compendium for Good Manufacturing Practices.

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