HPT/ISE/GMP/GUD/006
Revision. 03

REPUBLIC OF KENYA

**MINISTRY OF HEALTH**

**PHARMACY AND POISONS BOARD**

# GUIDELINES FOR ESTABLISHING MANUFACTURING FACILITIES FOR HEALTH PRODUCTS & TECHNOLOGIES IN KENYA

**FEBRUARY, 2026**

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## ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| **HPTs** | Health Products and Technologies |
| **ICT** | Information Communication Technology |
| **PIC/S** | Pharmaceutical Inspection Co-operation Scheme |
| **PRIMS** | Pharmaceutical Regulatory Information Management System |
| **PPB** | Pharmacy and Poisons Board |
| **WHO** | World Health Organization |
| **QAO** | Quality Assurance Officer |

## GLOSSARY OF TERMS

**Applicant** means a person, organization, company, or entity seeking approval to set up a manufacturing facility in Kenya.

**Board** means the Pharmacy and Poisons Board appointed under the provisions of section 3 of the Cap 244.

**Health Products and technologies (HPT)** This includes any product that is used in treatment, diagnosis or to prevent a disease or alter physiology in a human or in animals**.**

**Local Technical Representatives** An entity bearing a wholesale dealers license in Kenya appointed to represent a third party in Kenya for purposes of engagement with PPB.

**ACKNOWLEDGEMENT**

The Pharmacy and Poisons Board (PPB) is grateful to all the stakeholders and staff who contributed to the successful review of this guideline.

**PREFACE**

With increased influx of applications for setting up manufacturing facilities in Kenya, and given the responsibility to regulate the manufacture and trade of Health Products and Technologies, the Pharmacy and Poisons Board has developed this guidance notes for the industry in Kenya.

The primary purpose of this guidance is to promote the establishment and operation of manufacturing facilities that adhere to the highest standards of quality, safety, and efficiency. By sharing best practices, regulatory requirements, and industry insights, we aim to facilitate the creation of manufacturing facilities that can reliably produce health products and technologies that meet the needs of patients, healthcare providers, and the broader healthcare ecosystem.

This guidance is intended to facilitate the setting up of manufacturing facilities in Kenya fit for manufacture of quality health products and technologies that meet international standards as well as protecting personnel working in these premises. This guidance is intended to guide on establishment of manufacturing facilities for health products and technologies as well as ease of doing business.

Over the years, HPTs manufacturing has evolved so much that it is important for Pharmacy and Poisons Board to establish a guidance document to ensure that the development and maintenance of new and existing HPTs manufacturing facilities are done according to current international standards.

Taking note that Health Products & Technologies manufacturing premises often require substantial resources to construct and maintain, standardization in the construction of HPTs manufacturing is important for improving the health of the public in Kenya and in the region. This guidance therefore, is meant to act as reference to ensure appropriate planning, development and upgrading of the HPTs manufacturing facilities in Kenya.

We hope that this guidance will serve as a valuable resource for all stakeholders committed to advancing healthcare through the establishment

of manufacturing facilities. By working together to uphold the highest standards and embrace innovation, we can collectively contribute to better health outcomes for individuals and communities.

**DR. AHMED I. MOHAMED**
**CHIEF EXECUTIVE OFFICER**

## 1.0 INTRODUCTION

### 1.1 Background

The pharmaceutical and biopharmaceutical industries are dedicated to the production of life-saving medicines, vaccines, and therapies, making it vital that every aspect of the manufacturing process adheres to the highest standards of safety, quality, and efficacy. Good Manufacturing Practices (GMP) represent a set of rigorous guidelines and regulations that have been established to ensure that pharmaceutical products are consistently produced and controlled in a manner that meets predetermined quality standards.

One of the foundational elements in the successful implementation of GMP is the manufacturing facility itself. The design, construction, and operation of such facilities are pivotal in maintaining the integrity of the production process and the quality of the final products. A well-designed and maintained facility provides the optimal environment for the production of pharmaceuticals, biologics, and medical devices, safeguarding against contamination and deviations that could compromise the safety and effectiveness of the end products. The "Guidelines for Establishment of Manufacturing Facilities in GMP" have been developed to address the critical aspects of setting up, maintaining, and operating GMP-compliant manufacturing facilities. These guidelines serve as a comprehensive resource, offering insights into the considerations, best practices, and regulatory requirements that must be adhered to during the planning, construction, validation, and operation of GMP manufacturing facilities.

This document is the result of collaborative efforts from experts in the pharmaceutical, biopharmaceutical, and medical device industries, as well as regulatory authorities and other stakeholders. It is designed to be a living reference point, continually updated to reflect evolving industry standards and regulations. These guidelines not only offer a roadmap for manufacturers but also provide regulatory authorities with a framework to assess and approve facilities that meet GMP requirements.

The significance of the establishment and operation of GMP-compliant manufacturing facilities cannot be overstated. These facilities are at the very heart of the pharmaceutical manufacturing process, and they must conform to the highest standards of quality, safety, and compliance. The guidelines outlined in this document serve as a common language for manufacturers, regulators, and all parties involved in the design and operation of these facilities. Their comprehensive nature ensures that the facilities established are not just in compliance with GMP but also adaptable to changes in technology, regulation, and industry best practices.

As the pharmaceutical and biopharmaceutical sectors continue to innovate and advance, these guidelines play a vital role in ensuring that manufacturing facilities remain in step with industry changes. By adhering to these guidelines, manufacturers demonstrate a commitment to providing patients with safe, effective, and consistently high-quality therapeutic products.

We encourage manufacturing companies, regulatory authorities, and other stakeholders to embrace these guidelines as a benchmark for excellence in the establishment and operation of GMP-compliant manufacturing facilities. Together, we can maintain the highest standards of quality, safety, and efficacy in the production of pharmaceuticals, biologics, and medical devices, while advancing the collective goal of improving public health and well-being.

This document reflects our shared dedication to upholding the principles of GMP and ensuring that every manufacturing facility continues to be a bastion of safety, quality, and innovation in the pharmaceutical and biopharmaceutical industries.

### 1.2 Legal Framework

The Pharmacy and Poisons Act Cap 244 of the Laws of Kenya states that every person who is granted a manufacturing license is mandated to comply with good manufacturing practices. Additionally, a marketing authorization is granted upon confirming the site of manufacture complies with Good Manufacturing Practices. To ensure that this requirement is met the PPB exercises regulatory oversight over manufacturers of Health Products and

Technologies in Kenya and performs periodic GMP inspections for all manufacturers of products marketed in Kenya whether locally produced or imported.

### 1.3 Scope

This guideline applies to;

a) Individuals or companies interested in investing in and establishing health product manufacturing facilities in Kenya.
b) Manufacturers and industry professionals involved in the day-to-day operations of the manufacturing facilities including production managers, quality control personnel.
c) Regulatory authorities responsible for overseeing and regulating health product manufacturing end ensuring compliance with relevant laws, standards and regulations.
d) Financial institutions that may provide funding or financial support to investors and entrepreneurs involved in manufacturing of HPTs.
e) Environmental and sustainability agencies overseeing environmental regulations and sustainability practices, ensuring that manufacturing facilities adhere to responsible and eco-friendly standards.

## 2.0 ESTABLISHING MANUFACTURING FACILITIES FOR HEALTH PRODUCTS AND TECHNOLOGIES

Establishing manufacturing facilities for health products and technologies in Kenya holds immense potential for advancing healthcare and promoting economic development. Kenya, like many other developing nations, faces health challenges that can be mitigated through the local production of health products and technologies.

Kenya's healthcare landscape has long grappled with issues such as limited access to quality medical products, especially in rural areas. By establishing manufacturing facilities, the country can address these challenges by producing a range of health products locally. This not only reduces dependence on imports but also ensures a more reliable and cost-effective supply chain. The key considerations and benefits associated with this endeavor are as follows:

a) One crucial aspect of this initiative is regulatory compliance. A robust regulatory framework ensures that health products meet quality standards and adhere to safety protocols. Collaborating with regulatory bodies is essential to streamline approval processes and foster a conducive environment for manufacturing.
b) Selecting an appropriate site and developing the necessary infrastructure are pivotal steps. Accessibility, utilities, and proximity to suppliers and markets must be carefully considered. Moreover, incorporating eco-friendly practices and ensuring compliance with environmental regulations reflects a commitment to sustainability.
c) Quality control and assurance are paramount to the success of health product manufacturing. Strict adherence to international quality standards, coupled with well-documented quality assurance protocols, instills confidence in both consumers and regulatory bodies.

In conclusion, establishing manufacturing facilities for health products and technologies in Kenya is a multifaceted endeavor with the potential to bring about transformative changes. From improving healthcare access to fostering

economic growth, these facilities can play a pivotal role in shaping a healthier and more prosperous future for the nation.

Through careful planning, regulatory adherence, and collaboration, Kenya can unlock the full potential of local health product manufacturing, positively impacting the lives of its citizens and contributing to the nation's overall development.

### 2.1 Useful guidance documents

Persons or agencies intending to set up manufacturing facilities of HPTs in Kenya, must apply to the Pharmacy and Poisons Board for approval in the form and format provided **(Annexes I & II)** Their knowledge and acquaintance to Kenya legal requirements and guidelines related to HPTs manufacturing in Kenya is a useful starting point.

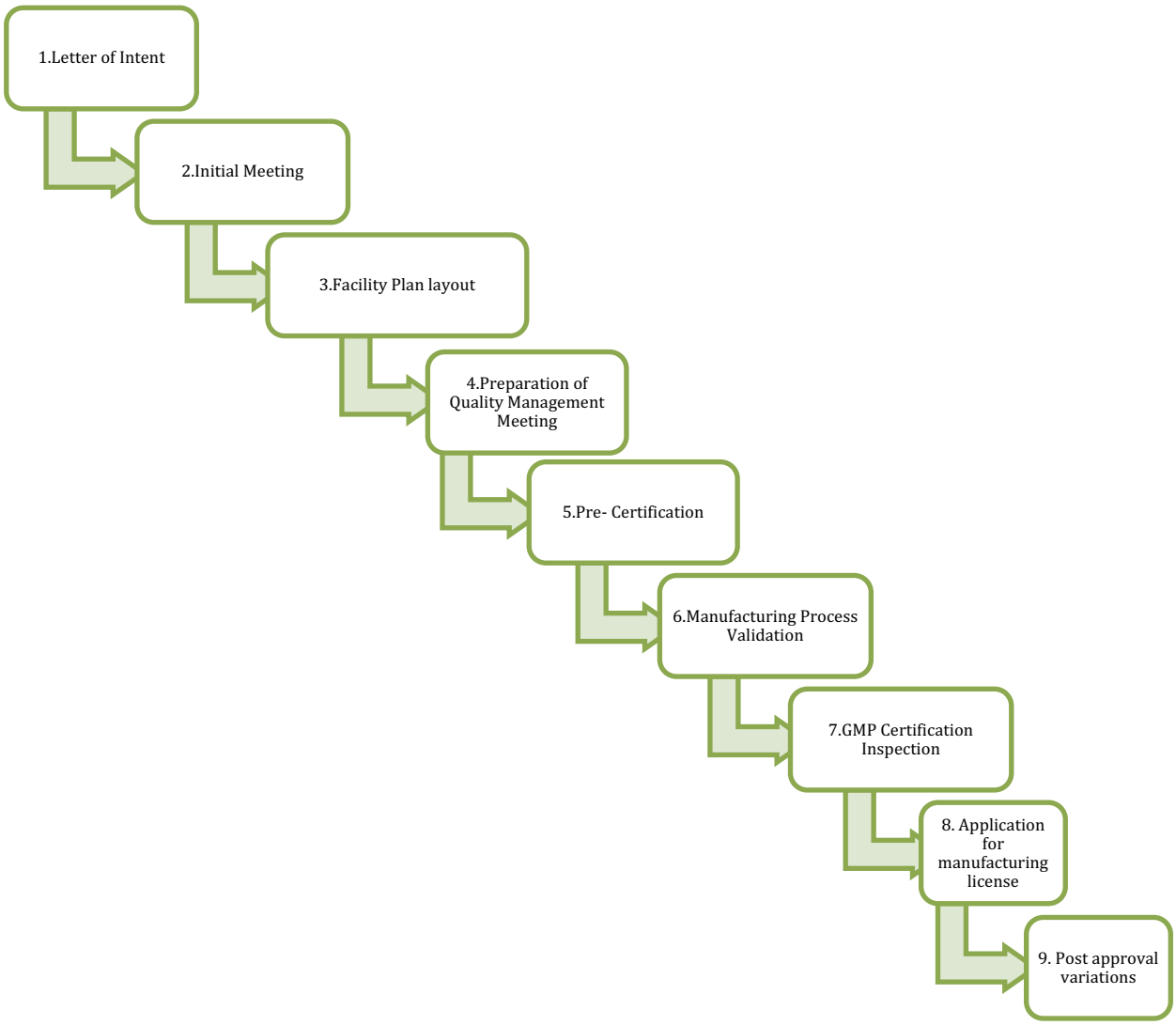
This guide explains the useful documents needed for the application procedure as follows:

a) Submission of letter of intent
b) Initial PPB meeting with the applicant
c) Preparation of Quality Management System
d) Pre-certification inspection
e) Post licensure

## 3.0 APPLICATION PROCEDURE

The figure below provides the highlights of the application process.

***Figure 1: General Process Flow Chart for the Manufacturing Facility Set Up***




### 3.1 Submission of Letter of intent

An applicant shall submit a letter of Intent to set up a HPT manufacturing facility. The Letter should contain such information as contained in Annex 1 below. (Letter of Intent). The Letter of intent is meant to arrange a meeting with the relevant PPB Department before the commencement of the manufacturing facility construction. The meeting will discuss highlights of the proposed manufacturing facility as discussed under section 3.2 below.

Only applicants whose application forms have been received shall be allowed to proceed as in Figure 1 above representing general setup process. Any other arrangements will not be admissible.

### 3.2 Initial PPB meeting with the applicant

During the initial meeting, the company is expected to make a presentation of the company and the layouts of the new facility. The company team should preferably constitute persons that are technically conversant with the project. No less than two senior GMP inspectors shall represent the Board in the meeting. During the inaugural meeting, the applicant will be required to make a concise presentation on but not limited to;

a) Background
b) Information of the product(s) proposed to be manufactured,
c) Concept design report/notes

The applicant will be required to submit the following documents:

a) Certified copies of the memorandum and articles of association.
b) An environment impact assessment report from National Environment Management Authority (NEMA).
c) Where appropriate, clearance from the Radiation Protection Board.
d) As may be applicable, Authorization from the Kenya Investment Authority and county governments.
e) Company Profile
f) Architectural layout plan of the site
g) A clear, defined facility layout plan
h) Proposed manufacturing process flow
i) Approval or no-objection letter from applicable proximal government
j) Installations whose approval may be required for establishment of your proximal facility would be required. These could include Kenya Airports Authority and Ministry of Internal Security (MIS).

The documents will be reviewed with the view of assessing the suitability of the layout in the manufacture of the HPTs. An assessment will also be made

to determine the suitability of the proposed establishment in providing sufficient protection to the environment and personnel involved in production.

The facility layout must be an integrated design that satisfies the following:

a) Process requirements
b) Personnel flows
c) Material flows (product, component and raw material movements)
d) Equipment layout requirements
e) Operational access requirements
f) Maintenance access requirements

If necessary, additional information may be requested for review alongside the above documents. After satisfactory review of the preliminary documentation, the company will be given approval-for execution and to establish a Quality Management System appropriate for the manufacture of HPTs. This shall be in the form an “approved for execution” rubber stamp, date and sign of a layout plan.

Unforeseen minor changes that do not result in significant change in the layout plan may be acceptable during construction. The Pharmacy and Poisons Board shall be notified of any such deviations in writing. Final approval of the plan shall be made after construction and commissioning of the plant. This shall be in the form of an “Approved” rubber stamp, sign and date of the final layout plan.

A deviation from an approved for execution plan shall have to be pre-approved by PPB. This shall require a submission of a new layout, which should be re-presented from stage 3 in the flow chart above. Depending on the extent of deviation, a presentation by the company may be waived for the approval of the updated version.

Following the company’s presentation, PPB’s GMP inspectors will assess the suitability of the proposed location for setting up of the manufacturing facility and the layouts. This assessment may constitute an onsite inspection which shall be considered with reference to activities to be undertaken in the

proposed site against all the neighboring facilities, activities and human settlement among other considerations.

On conclusion of document review and approval of the layouts by the Board, a Letter of No Objection for Commencement of construction, qualifications of equipment and development of Quality Management System including documentation preparation shall be issued as per Annex 2.

### 3.3 Preparation of Quality Management System

The facility will proceed to begin construction of the facility, undertake qualifications of equipment and development of Quality Management System including documentation preparation.

Preliminary inspections may be carried out at various stages of construction and setting up the site and reports prepared for each of the steps. These may include:

a) Site visits before and during construction of premises

b) Site visit upon completion of construction.

### 3.4 Pre-certification inspection

A Pre-Certification inspection will be conducted once the company indicates to have completed construction, validation/qualification and preparation of quality management system. At this point the company would have commissioned the facility and submitted a formal application for GMP inspection of the applicable areas and a license to manufacture HPTs.

Having paid the prescribed fee, the application should be made on the PRIMS (www.prims.pharmacyboardkenya.org). An Inspection shall be carried out in-line with WHO Good Manufacturing Practice Guidelines and other guidelines recognised by the PPB.

A letter recognizing the applicant as a manufacturer and indicating readiness of the facility to begin manufacturing activities (manufacture process validation batches) shall be issued. This letter may be used to apply for provisional manufacturing license.

### 3.5 GMP Certification Inspection

A GMP Certification inspection will be conducted in-line with WHO Good Manufacturing Practice Guidelines and other guidelines recognised by the PPB once the company indicates to have completed process validation batches in view of full certification. **These batches are not for commercial purposes unless otherwise approved by the PPB.**

Applicants may get more information and answers by contacting;

| | |
|---|---|
| Department | GMP Division, Pharmacy and Poisons Board of Kenya |
| Telephone | +254709770100/200/202/207 |
| Email | gmp@ppb.go.ke |
| Postal Address | P.O. Box 27663-00506 Nairobi, Kenya |

### 3.6 Application of manufacturing license

The valid GMP certificate issued by the Board shall serve as a prerequisite document that the manufacturer may use when applying for a manufacturing license. The Pharmacy Practice Directorate shall review the GMP certificate, together with other supporting documents as per Guidelines for Registration and Licensing of Premises No. PRA/LPP/GPP/GUD/060, to determine eligibility for the grant or renewal of a manufacturing license.

### 3.7 Post approval variations

#### 3.7.1 Post approval variations to GMP Certificate

Manufacturers intending to implement changes affecting the scope or conditions of an existing GMP certificate must obtain prior approval from The Board where applicable.

The following steps shall be followed:

1. **Identification and Classification of the Proposed Change**

   The applicant will be required to:

   a) Clearly define the proposed amendment (e.g., facility modification, addition of equipment, process change, expansion of manufacturing areas, addition of dosage form).

b) Conduct and document a Quality Risk Management (QRM) assessment to determine the impact of the change on product quality, safety, and compliance.
c) Classify the proposed amendment (major, minor, or administrative) in accordance with PPB's published requirements (described below).

**2. Preparation of the amendment application**

The applicant must submit a complete amendment dossier, which should include:

a) A formal cover letter describing the proposed change and justification
b) A completed amendment application form (annex 3)
c) Updated Site Master File (where applicable)
d) Revised facility layout drawings (if relevant)
e) Equipment qualification and/or process validation reports (if applicable)
f) Updated Standard Operating Procedures (SOPs), where affected
g) Change control documentation
h) Risk assessment report
i) Proof of payment of applicable fees

Incomplete submissions may delay processing.

**3. Submission of Application**

The applicant should submit the complete application through the designated submission channel (electronic portal or physical submission, as applicable).

No change requiring prior approval should be implemented before receiving formal authorization from Pharmacy and Poisons Board.

**4. Review and inspection**

The Board will conduct an administrative and technical review of the submitted documentation.

For major amendments, the Board may conduct a GMP inspection.

Applicants must facilitate such inspections and address any findings through documented corrective and preventive actions (CAPAs) within the stipulated timelines.

**5. Regulatory decision**

The Board will communicate its decision in writing. Where the amendment is approved:

a) An updated GMP certificate may be issued, where applicable.
b) The approved scope of manufacturing activities will be reflected in the certificate.

**6. Communication with the Licensing Department**

Where the approved amendment affects the manufacturing licence, the applicant will be required to submit the updated GMP approval to the Licensing Department to ensure alignment of licence records.

Applicants are responsible for ensuring that the manufacturing licence and GMP certificate remain consistent and up to date.

### 3.7.2 Timelines and Classification of Post-Approval Amendments to a GMP Certificate

Applicants must classify proposed changes prior to submission. The level of review, documentation required, and the need for inspection will depend on the category of amendment.

To ensure regulatory harmonisation and predictability, timelines for post-approval amendments to a GMP Certificate shall align, where applicable, with the Licensing Department's post-approval amendment timeline of thirty-one (31) calendar days from receipt of a complete application.

The review timeline shall commence only upon:

a) Receipt of a complete application; and
b) Confirmation of payment of the applicable fees.

Incomplete applications will not be accepted for technical review, and the review clock will not start until all deficiencies have been addressed.

**1. Major amendments**

**Definition:**

Changes that may significantly impact product quality, safety, compliance status, or the scope of the GMP certificate. Prior approval by the NRA is mandatory before implementation.

Examples (non-exhaustive):

a) Addition of new manufacturing block or facility expansion
b) Site relocation
c) Addition of a new dosage form or new manufacturing line
d) Significant modification of cleanroom classification
e) Significant process change
f) Major equipment replacement affecting critical process steps
g) Introduction of new sterilization systems
h) Change of manufacturing site
i) Significant changes to HVAC systems affecting classified areas

Requirements:

a) Full amendment application dossier
b) Comprehensive Quality Risk Assessment
c) Updated Site Master File (where applicable)
d) Validation and qualification reports
e) Possible GMP inspection prior to approval

Review Timeline:

a) Administrative screening: Within 5 calendar days
b) Technical review: Within 31 calendar days from confirmation of completeness
c) Where inspection is required, the timeline may be extended depending on inspection scheduling and closure of findings.

If an inspection is required:

a) Inspection findings must be addressed within timelines communicated by the Board.
b) Final approval will be issued upon satisfactory closure of all critical and major deficiencies.

**2. Minor amendments**

Definition:

Changes with limited potential impact on product quality or GMP compliance. Prior notification and/or approval may be required as specified by the Board.

Examples (non-exhaustive):

a) Replacement of equipment with equivalent specifications
b) Minor layout adjustments not affecting material or personnel flow
c) Administrative changes in key personnel
d) Updates to non-critical SOPs
e) Installation of additional non-critical utilities
f) Limited process adjustments not affecting critical parameters.

Requirements:

a) Amendment application form
b) Supporting documentation
c) Risk assessment summary
d) Inspection may not be required

Review Timeline:

a) Administrative screening: Within 5 calendar days
b) Technical review and decision: Within 31 calendar days from receipt of a complete application

Inspection is generally not required unless deemed necessary by the Board.

**3. Administrative amendments**

Definition:

Changes that do not affect manufacturing operations, quality systems, or compliance status.

Examples (non-exhaustive):

a) Change of company name (without change in legal entity)
b) Change of physical address (without relocation of manufacturing site)
c) Update of contact details
d) Correction of typographical errors

Requirements:

a) Formal notification letter

b) Supporting documentary evidence (where applicable)
c) Payment of applicable administrative fee

Review Timeline:

a) Administrative review and decision: Within 14 calendar days from receipt of a complete application

### 3.7.3 Harmonisation with Manufacturing Licence Amendments

Where a proposed change affects both the GMP Certificate and the Manufacturing Licence:

a) Applicants shall first obtain GMP approval (where required);
b) The approved GMP amendment shall then be submitted to the Licensing Department to enable issuance or variation of the Manufacturing Licence;
c) The Licensing Department's 31-day timeline shall apply upon receipt of the complete application and GMP approval.

Applicants are responsible for ensuring that the GMP Certificate and Manufacturing Licence remain consistent at all times.

**Important Regulatory Note**

Applicants shall not implement any Major amendment prior to receiving written approval from The Board.

Failure to notify or obtain approval for applicable changes may result in regulatory action, including suspension or withdrawal of the GMP certificate

## 4.0 REFERENCES


1. 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
2. https://www.who.int/publications/m/item/trs986-annex2

## 5.0 REVISION HISTORY

| Revision No: | Date | Author | Section(s) revised | Description of change |
|---|---|---|---|---|
| 1 | 10/04/2023 | QAO | Title of the document | Changed from "Guidance notes for establishing medical products and health technologies manufacturing facilities in Kenya" to "Guidelines for establishing manufacturing facilities for health products & technologies in Kenya". |
| | | | Content | Guideline revised to reflect updated process steps and compliance requirements. |
| | | | Annex I | Deleted Product Classification application form. |
| | | | Annex III | Deleted PPB setup inspection report. |
| | | | Annex IV | Deleted Assessment of plant layout application. |
| | | | Annex V | Deleted Application for pre-certification of GMP inspection. |
| 2 | 25/09/2025 | QAO | Section 3.0 | Updated General Process Flow Chart to incorporate manufacturing license application and post-approval variations procedures. |
| | | | Section 3.6 | Added Application of manufacturing license section to detail submission requirements. |
| | | | Section 3.7 | Introduced step-by-step process for manufacturers intending to implement changes affecting the scope & conditions of existing GMP certificate; classification of Post Approval Amendments to GMP certificate included. |

| | | | | |
|---|---|---|---|---|
| | | | Section 3.8 | List of contributors updated. |
| | | | Annexes | Application form for post-approval variations introduced. |
| 3 | 29/01/2026 | QAO | Section 3.7 | Updated Post Approval Variations to GMP Certificate to capture stepwise implementation procedure. |
| | | | Section 3.7.2 | Introduced timelines and classification of post-approval amendments to a GMP certificate. |
| | | | Section 3.7.2 | Harmonization of post-approval amendments of GMP Certificate with manufacturing license introduced. |
| | | | Annex 3 | Application form for post-approval variations updated to categorize major, minor, and administrative changes. |

## 6.0 CONTRIBUTORS/REVIEWERS

| | | |
|---|---|---|
| 1. | Dr. Ahmed Mohamed | Chief Executive Officer |
| 2. | Dr. Dominic Kariuki | Deputy Director, Inspectorate, Surveillance and Enforcement |
| 3. | Dr. Sichei Cheworei | CPRO, Regulatory Inspections |
| 4. | Dr. James Owuor | Head, GMP Division |
| 5. | Dr. Emmanuel Devi | GMP Division |
| 6. | Dr. Sharon Kipkosgei | GMP Division |
| 7. | Dr. Dan Moin | GMP Division |

## 7.0 ANNEXES

### Annex 1: Letter of Intent to set up Pharmaceutical Manufacturing Facility

REPUBLIC OF KENYA

**MINISTRY OF HEALTH**
**PHARMACY AND POISONS BOARD**

| **Part I: Applicant Details** | |
|---|---|
| Company name: | Click here to enter text. |
| Official Address: | Click here to enter text. |
| Name and address of applicant to whom correspondence should be addressed to: | |
| *(Name of applicant)*<br>*(Applicant's correspondence address)* | |
| Contact phone no.: | Click here to enter text. |
| Contact fax no.: | Click here to enter text. |
| Email address of applicant: | Click here to enter text. |

| **Part II: Product/s Details** | | |
|---|---|---|
| *Category* | *Dosage Form* | *Active ingredients* |
| | | |
| | | |
| | | |
| | | |

| **Part III: Manufacturing Details** | |
|---|---|
| Manufacturing facility address: | Click here to enter text. |
| Packaging facility address:<br>(*if applicable*) | Click here to enter text. |

| **Part IV: Applicant's Declaration** | |
|---|---|
| With this application, I hereby declare that;<br>☐the above particulars are, to the best of my knowledge and belief, correct.<br>☐ understand the purpose of this application | |
| Signature (applicant) and company stamp | |
| Name: | Click here to enter text. |
| Title / Position: | Click here to enter text. |

| | |
|---|---|
| Date: | Click here to enter a date. |
| **Part V: For Office Use Only** | |
| Officer in charge: | Click here to enter text. |
| Date of meeting: | Click here to enter a date. |
| Date of correspondence: | Click here to enter a date. |

| **Part VI: Reminder (*for applicant's reference*)** | | |
|---|---|---|
| The following information must be prepared prior to meeting with the Pharmacy and Poisons Board. | | |
| No. | Checklist for Presentation | ☒ |
| 1. | Presentation slide | ☐ |
| | Company's background | ☐ |
| | Product/s information; type and source, name of active ingredient | ☐ |
| | Facility layout plan; personnel and material flow (starting to finished products | ☐ |
| 2. | Own laptop (compatible with VGA/HDMA cable connector) | ☐ |

**Annex 2: Letter of No Objection for Commencement of Construction**

**PPB REFERENCE NUMBER** **DATE**

COMPANY NAME
PHYSICAL ADDRESS
POSTAL ADDRESS
LOCALITY
KENYA

**RE: NO OBJECTION TO EXECUTION OF PROPOSED LAYOUT PLAN**

Following proposed layout presentation made on……., You are hereby recognised as a potential manufacturer of HPTs.

You may proceed with construction, equipment installation, qualification and, establishment of Pharmaceutical Quality Management System as stipulated in the "*Guidance for establishing pharmaceutical manufacturing facilities for health products and technologies in Kenya*"

Meanwhile you are required to submit your final Layout plan encompassing any recommendations made and any minor, but essential modifications made in the course of construction for approval and filing.

Note that this phase should be guided by applicable WHO GMP guidelines (and where applicable other internationally recognized GMP guidelines) relevant to; the Location, suitability of the Design, Construction, Adaptation and Maintenance of the Premises used for manufacture, quality control, packaging and release of pharmaceuticals as well as to the establishment of applicable Pharmaceutical Quality System.

In addition, you are required to adhere to applicable Kenyan Law and to requirements set by other government agencies and, where applicable obtain clearance.

**Deputy Director;**
**Inspectorate & Enforcement**

**Annex 3: Application form for post approval variations**


**MINISTRY OF HEALTH**
**PHARMACY AND POISONS BOARD**

| **Part I: Applicant Details** | |
|---|---|
| Name of manufacturer | Click here to enter text. |
| Physical Address of Manufacturing Site | Click here to enter text. |
| Manufacturing License Number | Click here to enter text. |
| PPB GMP Certificate Number | Click here to enter text. |
| Contact Person (Name and Title) | Click here to enter text. |
| Contact Details (Telephone and Email) | Click here to enter text. |
| **Part II: Variation(s) Applied For** | |
| **Please tick and complete the relevant section(s). Multiple variations may be applied for in a single application if related.** | |
| **Major changes** | a) **Layout and Premises**<br>☐ Addition of new manufacturing block or facility expansion<br>☐ Reduction of existing premises<br>☐ Modification of existing premises<br>☐ Site relocation<br>☐ Change of manufacturing site<br>☐ Significant modification of cleanroom classification<br><br>b) **Production Lines**<br>☐ Addition of a new dosage form or new manufacturing line |

| | |
|---|---|
| | ☐ Removal/discontinuation of production line(s)<br><br>c) **Production Categories**<br>☐ Addition of product category(ies)<br>☐ Removal of product category(ies)<br><br>d) **Manufacturing activities**<br>☐Addition of new manufacturing activity (e.g. processing operations, batch certification, packaging, quality control testing)<br>☐ Discontinuation of new manufacturing activity (e.g. processing operations, batch certification, packaging, quality control testing)<br><br>e) **Major equipment**<br>☐ Installation of new major equipment affecting critical process steps<br>☐ Replacement/deinstallation of major equipment affecting critical process steps<br>☐Relocation of existing major equipment to a new site<br>☐ Significant changes to HVAC systems affecting classified areas<br><br>f) **Key personnel**<br>☐ Change in Head of Quality Unit<br>☐ Change in Head of Quality Assurance<br>☐ Change in Head of Quality Control<br>☐ Change in Head of Production<br>☐ Change in Authorised Person(s)<br><br>g) **Process steps**<br>☐ Significant process change<br>☐ Introduction of new sterilization systems<br><br>Please write a brief description of the requested change and the proposed date of change: |

| | |
|---|---|
| **Minor amendments** | ☐ Replacement of equipment with equivalent specifications<br>☐ Minor layout adjustments not affecting material or personnel flow<br>☐ Administrative changes in key personnel<br>☐ Updates to non-critical SOPs<br>☐ Installation of additional non-critical utilities<br>☐ Limited process adjustments not affecting critical parameters.<br><br>Please write a brief description of the requested change and the proposed date of change: |
| **Administrative amendments** | ☐ Change of company name (without change in legal entity)<br>☐ Change of physical address (without relocation of manufacturing site)<br>☐ Update of contact details<br>☐ Correction of typographical errors<br><br>Please write a brief description of the requested change and the proposed date of change: |

**Part III: Summary of variation applied**

| **Current Status** | **Proposed Change** | **Classification (Minor, Major or Administrative)** |
|---|---|---|
| | | |

**Part IV: Supporting Documentation where applicable**

1. Cover letter with summary of variation(s) requested
2. Revised facility layout/site master file
3. Updated organizational chart, educational/experience qualification (for personnel changes)

4. Equipment qualification documents
5. Other supporting documents

**Part V: Declaration**

I, the undersigned, hereby declare that the information provided in this application is true, accurate, and complete to the best of my knowledge.

Name:

Designation:

Signature:

Date:

**Part VI: For official use only (PPB)**

Date of receipt:

Application type: ☐ Complete ☐ Incomplete

Comments:

Reviewed by:

Date:

END OF DOCUMENT

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