FOOD AND DRUGS AUTHORITY

20th September 2024
FDA/MFD/GDL-03/03
Governing Board/ CEO, Food and Drugs Authority

Guidelines on Approval of Qualified Person for the Pharmaceutical Manufacturing Facility

Draft written by Inspectorate Directorate	NA
Draft reviewed by DCEO TOD	NA
Start of public consultation	NA
Adopted by FDA Governing Board	3rd September 2024
Final Quality Assurance Review	13th September 2024
Approved by CEO	17th September 2024
Date of coming into effect	23rd September 2024

This guideline replaces guideline for selection of authorized person in the pharmaceutical and chemical industry (FDA/DRI/DED/GL-SAP/2013/01)

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Document Revision History

Date of Revision	Version Number	Changes made and/or reasons for revision
2013	01	Initial issue
2013	02	Inclusion of Section 4
20/09/2024	02	i. General review in line with the current organogram ii. Review to guideline to conform to current format for guidelines. iii. Inclusion of sections 3.4, 3.5, 3.6, 4, Annex 1

Table of Contents

Document Revision History *2*

Acknowledgements *4*

Executive summary *4*

1. INTRODUCTION (BACKGROUND) *4*

1.1 Legal Basis **4**

1.2 Scope **5**

2 DEFINITIONS AND ABBREVIATIONS *5*

2.1 Definitions *5*

2.2 Abbreviations 5

3 REQUIREMENTS *5*

3.1 General Information **5**

3.2 Educational Requirements **6**

3.3 Experience Requirements for applicants already in industry **6**

3.4 Applicants in industry and without requisite number of years of experience, and appropriate knowledge **7**

3.5 Renewal of Approval. **7**

3.5 Sanctions: Revocation/Cancellation of QP Certification **7**

3.6 Duties of a Qualified Person **8**

4 TRAINING PROGRAMME *9*

4.1 Goal *9*

4.2 Objectives **9**

4.3 Training **9**

4.4 Evaluation of Training **13**

5.0 FEES *13*

Annex 1 ..... *14*

Acknowledgements

This guideline was developed based on the Ireland's Health Products Regulatory Authority's Guide to Attainment of Qualified Person Status in Ireland: Educational Requirements, Training and Licensing as well as Joint Professional Bodies (JPB) (the Royal Pharmaceutical Society, the Royal Society of Biology, and the Royal Society of Chemistry) study guide on Qualified Persons involved in the manufacture of pharmaceuticals.

Executive summary

The FDA's guideline for approval of Qualified Person (QP) for the Pharmaceutical Manufacturing Industry is developed to define the necessary requirements for the attainment of qualified person for a pharmaceutical manufacturing company. This guideline stipulates FDA's current educational requirements, training, and experience to becoming a QP. It also defines the process followed by the FDA in the approval of QP candidates.

The duties of a QP are outlined in this guideline. It further provides information for the renewal, suspension, or revocation of a QP's licence.

1. INTRODUCTION (BACKGROUND)

The use of QP in the pharmaceutical industry has become a general principle recognized by industry players and National Regulatory Authorities (NRA). Qualified Persons are essential in the quality assurance (QA) and Quality control (QC) of medicines as such they ensure not only the adherence to GMP but are also responsible for the batch release of medicines. The Qualified Persons is usually required to have a good understanding of all aspects of the medicines manufacturing and supply chain.

The role of a QP is critical in ensuring compliance with Good Manufacturing Practices (GMP), safeguarding product quality, and ensuring that pharmaceuticals are safe for public consumption. The purpose of this guideline is to establish the requirements for approval as a Qualified Person in Ghana's pharmaceutical manufacturing industry, aligned with international best practices, including guidelines from the WHO and the European Union.

1.1 Legal Basis

The legal foundation for this guideline is derived from the **Public Health Act, 2012 (Act 851)**, particularly **Section 115 (1) (a) and 2**, which mandates that the manufacturing of pharmaceuticals must be supervised by a pharmacist or a QP approved by the Ghana FDA as stated below;

115 (1) "A ***person shall not manufacture a drug herbal medicinal product, cosmetics, medical device or household chemical substance for sale unless***

(a) The manufacturing operation is carried on, or is supervised by a pharmacist or a qualified person approved by the Authority as having knowledge in the article to be manufactured and

115 (2) An application for approval under subsection (1) shall be made to the Authority

and may be granted by the Authority subject to the conditions determined by the Authority".

This guideline is hereby promulgated for information, guidance and strict adherence by all concerned for approval of QP in the pharmaceutical industry.

The application process and procedure to undertake towards issuing approvals to qualified persons is thus outlined.

1.2 Scope

The object of this document is thus to propose an application format and procedure for the approval of a QP by the Food and Drugs Authority in line with the provisions of section 115 (1) and (2) of the Public Health Act, 2012, Act 851 of the Republic of Ghana.

2 DEFINITIONS AND ABBREVIATIONS

2.1 Definitions

A Qualified Person (QP) is responsible for ensuring that all products manufactured comply with GMP and other regulatory requirements before release to the market. They oversee all aspects of the manufacturing process, including testing, documentation, and batch certification.

2.2 Abbreviations

(a) **GMP** **:** Good Manufacturing Practices
(b) **MOU** **:** Memorandum of Understanding
(c) **NRA** **:** National Regulatory Authority
(d) **QA** **:** Quality Assurance
(e) **QC** **:** Quality Control
(f) **QP** **:** Qualified Person
(g) **WHO** **:** World Health Organization

3 REQUIREMENTS

3.1 General Information

3.1.1 The procedure outlined below is proposed for approval of a qualified person in the pharmaceutical manufacturing industry.

3.1.2 An application in the form of a cover letter shall be written to the FDA, Addressed to:
The Chief Executive Officer
Food and Drugs Authority
P. O. Box CT 2787
Cantonments
Accra

3.1.3 Applicant shall submit, as an attachment to the cover letter and form, the following documentations

(a) Curriculum vitae of the applicant
(b) Certificates of relevant trainings and qualifications

3.1.4 An application for approval as a qualified person for the pharmaceutical manufacturing facility can be submitted at any of the offices of the FDA (as per Annex 1).

3.1.5 An assessment of the application shall be made by designated officers of the Manufacturing Facilities Department of the FDA.

3.2 Educational Requirements

To be approved as a QP, candidates must meet specific educational criteria and other relevant criteria. The following are the different pathways to becoming a QP in Ghana:

3.2.1 Route 1: A candidate must hold a recognized pharmacy degree from an accredited institution in Ghana or internationally. If the degree is obtained outside Ghana, the candidate must provide proof of recognition by the appropriate Ghanaian regulatory authority.

3.2.2 Route 2: A candidate must possess a bachelor's or master's degree in relevant scientific disciplines such as Pharmacy, Pharmaceutical Sciences, Chemistry, Biology, or Biochemistry, and have completed a post-graduate course that satisfies GMP educational requirements.

3.2.3 Route 3: If a candidate was already performing the duties of a QP before the implementation of this regulation, they can apply for QP status under the transitional arrangements, provided they have been nominated by a pharmaceutical manufacturing company and can demonstrate competence.

3.2.4 Route 4: A candidate who has completed a QP eligibility course in another recognized jurisdiction and satisfies requirements of this guideline may also apply.

3.3 Experience Requirements for applicants already in industry

An applicant already in the industry seeking for certification as a Qualified Person (QP) is required to satisfy the following requirements**:**

i. Must be nominated or appointed by his/her employer (pharmaceutical manufacturing company)
ii. Bachelor's or master's degree in a relevant field (e.g. Pharmacy, Pharmaceutical Sciences, Chemistry, Biology or Biochemistry)
iii. Minimum of 3-5 years of experience in pharmaceutical manufacturing, quality control, or regulatory affairs.

3.4 Applicants in industry and without requisite number of years of experience, and appropriate knowledge

3.4.1 QP certification from a recognised authority (e.g. Institute of Quality Assurance, Pharmaceutical Quality Group) may be considered for applicants already in industry without the requisite years of experience.

3.4.2 All other applicants without the requisite number of years of experience shall be required to undergo a training (see proposed training in **section 4.0**) organized by the FDA Ghana and shall pass a written exam at the end of the training to qualify for approval as a QP.

3.4.3 A written response shall be sent to the applicant stating the outcome of the assessment whilst communicating the training date where applicable (see **section 4.0** for proposed training modules). Otherwise, the response shall be an **approval letter** issued to the applicant (already in the industry) whose application has been evaluated and found to have met the requirements as a QP.

3.4.4 Applicants who are listed to undergo training shall pay a training fee as per **section 5.0** of this document.

3.4.5 Applicants undergoing training shall pass an exam conducted by the Authority to qualify for approval as a QP.

3.4.6 A certificate shall be issued to participants who have undergone training with the FDA. The certificate shall indicate that participants have completed a Qualified Person Training Course organized by the FDA.

3.4.7 The approval as a QP shall be subject to renewal **every three (3) years.**

3.5 Renewal of Approval.

3.5.1 An application for renewal as a QP shall be made in the same format as initial application (see **3.1**)

3.5.2 An application for renewal shall be accompanied by attachments of current certificate of the QP obtained as part of their continual professional development. This shall serve as a way of evidence that the knowledge and experience of the QP is up to date.

3.5 Sanctions: Revocation/Cancellation of QP Certification

The Authority shall cancel, suspend or revoke an approval of a qualified person if;

(i) The QP operations/decisions is/are found to pose a risk or affect the quality and/or safety of batch releases of medicines under his/her control.

(ii) A QP fails on two occasions to adhere to warnings/directives issued by the Authority to the facility or the QP. In the case of the directives issued to the manufacturing facility, there shall be adequate evidence that the QP was duly

notified at a good time but failed to take steps to see to the enforcement of the directive/warning.

(iii) Any of the conditions under which the approval issued, no longer exist.

(iv) The documented information on which the approval was given is later found to be false.

(v) The circumstances under which the approval was given no longer exist.

(vi) The Management of a Manufacturing facility in which the affected qualified person works shall ensure that the QP seizes to play that role.

(vii) Irrespective of the above sanctions, the authority may also decide to impose an administrative fine on QPs whose operations/decisions is/are found to pose a risk or affect the quality and/or safety of batch release of medicines under his/her control in accordance with the approved fees and charges Act applicable by the FDA.

(viii) Other penalties as provided for in **section 129** of the **Public Health Act, 2012, Act 851,** related to contraventions to the provisions of this guideline may also be imposed.

3.5.1 Where the approval is suspended, withdrawn, or cancelled, the Authority shall issue a notice to the QP and management of the Manufacturing facility in which the QP works.

3.6 Duties of a Qualified Person

(a) Ensure that the batch of the medicinal product is compliant with the marketing authorization requirements.
(b) Verify that the GMP guidelines have been strictly followed during production.
(c) Certify that all quality control (QC) checks and tests have been performed according to validated methods.
(d) Ensure that any deviations, changes, or non-compliances identified during manufacturing or packaging have been adequately resolved before batch release.
(e) Oversee documentation to ensure it is complete, accurate, and endorsed by qualified personnel, including calibration, maintenance, and environmental monitoring records.
(f) Ensure that batch records have been reviewed and found to be satisfactory.
(g) All necessary manufacturing packaging and associated documentation have been completed and endorsed by a suitably qualified staff.
(h) All relevant factors have been considered including any not specifically associated with the output batch directly under review (e.g. Calibration and maintenance records, environmental monitoring).

Failure to comply with these responsibilities may lead to the revocation of QP approval and legal action under the provisions of the Public Health Act, 2012 (Act 851).

4 TRAINING PROGRAMME

The FDA mandates comprehensive training for QP candidates. This training shall cover all relevant aspects of the pharmaceutical quality management system, ensuring that candidates gain the necessary skills for batch certification.

4.1 Goal

To provide comprehensive training for the certification of a QP towards ensuring a better collaborative regulatory environment within the pharmaceutical industry.

4.2 Objectives

(i) Provide qualified applicants with the requisite foundation knowledge in pharmaceutical manufacturing industry.

(ii) Provide applicants with an understanding of the additional areas of professional development required by QP.

(iii) Provide applicants with knowledge of the regulatory requirements and processes of pharmaceutical regulation in Ghana

4.3 Training

Based on the responsibilities of a qualified person, the knowledge areas in **Table 1 (below)** shall be addressed in the training program.

Table 1. Knowledge areas and corresponding content.

Knowledge areas	**Content**
Quality Management System (QMS) principles.	Overview of QMS: Definition, importance, and benefits of implementing a QMS in pharmaceutical manufacturing. GMP Requirements: How QMS ensures compliance with GMP guidelines. Components of QMS: Organizational structure, documentation, risk management, continuous improvement, and change control. CAPA (Corrective and Preventive Action): Understanding root cause analysis, corrective actions for identified issues, and preventive measures. Internal Audits: The role of internal audits in maintaining the QMS. Regulatory Audits: Preparing for and managing regulatory inspections (e.g., FDA, WHO).

	QMS in Batch Release: How the QMS integrates with batch certification and product release.
Validation of processes and methods.	Process Validation: Phases of process validation (prospective, concurrent, and retrospective). Key stages of process validation: Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). Analytical Method Validation: Principles of validation: accuracy, precision, specificity, linearity, and robustness. Guidelines on method validation from regulatory authorities (e.g., FDA, ICH, WHO). Cleaning Validation: Importance of cleaning validation in preventing cross-contamination. Techniques for validating cleaning processes, including sampling methods (swab or rinse). Ongoing Process Verification (OPV): Monitoring validated processes to ensure consistent quality over time.
Stability testing	Purpose of Stability Testing: To assess how the quality of a drug varies with time under different environmental conditions (temperature, humidity, etc.). ICH Stability Guidelines (Q1A-Q1F): International standards for designing and conducting stability studies. Types of Stability Studies: Real-time, accelerated, intermediate, and long-term studies. Stability Testing Protocols: Selection of batches, storage conditions, frequency of testing, and evaluation parameters (physical, chemical, microbiological). Data Analysis and Interpretation: Understanding trends in stability data and their implications on product quality. Shelf-life Determination: Using stability data to establish expiration dates and recommended storage conditions.

Pharmaceutical microbiology	Microbial Contamination: Common sources of microbial contamination in pharmaceutical manufacturing. Sterility Testing: Methods for testing sterility in pharmaceuticals (e.g., membrane filtration, direct inoculation). Environmental Monitoring: Monitoring air, surfaces, and personnel to detect contamination in manufacturing environments. Microbiological Control in Cleanrooms: Best practices for cleanroom maintenance and personnel hygiene to prevent contamination. Endotoxin Testing: Methods for detecting bacterial endotoxins (e.g., LAL test). Bioburden Testing: Techniques for measuring the microbial load on raw materials, equipment, and finished products. Water Quality: Microbiological considerations for water used in pharmaceutical production, including testing for total microbial count and endotoxins.
Regulatory compliance	Ghana FDA Regulations: Overview of the FDA regulations in Ghana, particularly concerning the approval of QPs, GMP guidelines, and product registration. International Regulatory Frameworks: WHO GMP guidelines. EU Guidelines. Product Registration: Processes for registering pharmaceutical products, including dossier preparation, submission, and approval timelines. Pharmacovigilance: Importance of monitoring adverse drug reactions (ADRs) post-market, and the QP's role in ensuring product safety. Good Documentation Practices (GDP): Best practices for record-keeping, ensuring traceability, and maintaining accurate batch records. Handling Recalls and Regulatory Inspections: QP's role in product recalls and how to prepare for and manage regulatory inspections.

Pharmaceutical warehousing and packaging	Good Storage Practices (GSP): Best practices for storing raw materials, intermediates, and finished products, with a focus on temperature control, humidity, and segregation. Packaging Materials: Understanding the role of packaging in protecting product quality, tamper-evidence, and regulatory requirements for labeling. Warehouse Management Systems (WMS): The use of computerized systems to manage inventory, ensure proper stock rotation (e.g., FIFO or FEFO), and track product movement. Controlled Substances Handling: Special handling requirements for controlled drugs and hazardous materials. Packaging Validation: Ensuring that packaging materials and processes are validated to prevent degradation and contamination.
Sampling, Analysis and Testing of Pharmaceuticals	Sampling Techniques: Proper methods for sampling raw materials, intermediates, and finished products, including random and stratified sampling. Analytical Testing: Overview of common pharmaceutical testing methods, such as High-Performance Liquid Chromatography (HPLC), Gas Chromatography (GC), and UV-Vis Spectroscopy. Physical Testing: Techniques for testing the physical properties of drugs (e.g., tablet hardness, dissolution, disintegration). Microbiological Testing: Testing for sterility, bioburden, and endotoxins, as well as determining acceptable microbial limits. Product Release Testing: Final quality checks before batch release, including potency, purity, and stability tests. Laboratory Data Integrity: Best practices for maintaining data accuracy and integrity, including electronic records management and audit trails.

4.4 Evaluation of Training

(i) Participants shall be examined on each training module.

(ii) There shall be an evaluation of the entire training program by the participants.

(iii) Successful candidates after evaluation and examination shall be certified as QPs.

(iv) Certified QPs must undergo continuous professional development (CPD) to maintain their approval status.

5.0 FEES

(i) Applicants shortlisted for training shall be required to pay an approved fee determined by the FDA

Annex 1

OFFICE	ADDRESS	CONTACT
Head Office	No. 17 Indian Ocean Street, Nelson Mandela Avenue, Shiashie P.O, Box CT 2783 Accra. GPS: GA–237–7316	03022 35100
Western Regional Office	Adjacent Fidelity Bank, Ghana Post Building, Takoradi Harbour P. O. Box MC 2129, Takoradi GPS: WS-406-1927	031 202 7558, 0544 338 829
Volta Regional Office	GWCL Building (Same Building with Cool FM) Private Mail Bag, Ho GPS: VH–0016–3748	03620 26659, 0244399632, 0247 978 956
Upper West Regional Office	Controller Block, Ministries, P. O. Box 291 Wa. GPS: SW–022–9492	03920-20111, 0244 470 413
Upper East Regional Office	Regional Administration Building, P. O. Box 612, Bolgatanga GPS: UB-0034-4017	0247 717 744
Northern Regional Office	Regional Administration Building, P. O. Box TL 1763, Tamale GPS: NT–0066–3381	03672024935
Eastern Regional Office	Hospital Road, Opposite Assemblies of God Church, P. O. Box KF 2431, Koforidua GPS: EN-011-2579	0277 705 752

Central Regional Office	UCC Credit Union Building Adjacent, CEDECOM Building, Pedu Junction P. O. Box CC 1373, Cape Coast GPS: CC-097-0402	033090110, 0245839521, 0504422905
Bono Regional Office	House No. 61A, Nkwabeng Extention, Sunyani. Near St. Mary's School. Opposite Goode Goode Spot. Postal address PMB, Sunyani GPS: BS-0054-2542	0352028791, 0265062697
Ashanti Regional Office	Regional Coordinating Council (RCC), next to Electoral Commission's Office P. O. Box ST 402, Kumasi GPS: AK-133-7324	0302-203-6027/70, 0507-187-420/1/2