# ICTQual AB

## Qualification Specification

# ICTQual AB Level 3 Certificate in Quality Control Pharmaceutical

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# ICTQual AB's

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# Qualification Specification about

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## About ICTQual AB's

ICTQual AB is a distinguished awarding body based in the United Kingdom, dedicated to fostering excellence in education, training, and skills development. Committed to global standards, ICTQual AB's provides internationally recognized qualifications that empower individuals and organizations to thrive in an increasingly competitive world. Their offerings span diverse industries, including technical fields, health and safety, management, and more, ensuring relevance and adaptability to modern workforce needs.

ICTQual AB's delivers high-quality educational solutions through a network of Approved Training Centres worldwide. Their robust standards and innovative teaching methodologies equip learners with practical knowledge and skills for personal and professional growth. With a mission to inspire lifelong learning and drive positive change, ICTQual AB's continuously evolves its programs to stay ahead of industry trends and technological advancements.

## Course Overview

This certificate offers foundational training in the principles, standards, and procedures relevant to pharmaceutical quality control. It provides learners with comprehensive knowledge of regulatory requirements, quality control testing, documentation practices, and Good Manufacturing Practices (GMP) essential for maintaining product safety, efficacy, and compliance in the pharmaceutical sector. The qualification emphasizes analytical and inspection techniques used throughout the drug manufacturing lifecycle, equipping learners to meet the rigorous demands of quality assurance in pharmaceutical environments. Learners will explore the key components of quality systems, product evaluation techniques, sampling protocols, and laboratory operations. The course ensures that participants understand the link between regulatory frameworks, laboratory practices, and production quality in the pharmaceutical industry. Emphasis is placed on maintaining data integrity, observing safety protocols, and aligning with both national and international quality expectations.

**Course Aim:**

The aim of this course is to develop a skilled workforce capable of performing essential quality control operations in the pharmaceutical industry. It intends to empower learners with the technical knowledge and practical skills necessary to contribute to the assurance of product quality and compliance throughout pharmaceutical production and distribution processes. By completing this course, participants will be able to identify non-conformities, ensure batch consistency, support laboratory activities, and participate in continuous improvement within quality systems.

**For Whom This Course is For:**

- Entry-level professionals aspiring to enter the pharmaceutical quality control field.
- Laboratory assistants and production staff seeking formal recognition of their quality control knowledge.
- School leavers and college graduates aiming to build foundational competencies in pharmaceutical sciences.
- Quality inspectors and compliance staff in need of technical enhancement or formal certification.
- Individuals transitioning from general manufacturing to regulated pharmaceutical environments.

This course is ideal for those wishing to understand and support the critical role of quality control in ensuring safe, compliant, and effective pharmaceutical products. It offers the necessary preparation to pursue further development in quality assurance, laboratory operations, or regulatory compliance roles within the pharmaceutical industry.

## Certification Framework

| Qualification title | ICTQual AB Level 3 Certificate in Quality Control Pharmaceutical |
|---|---|
| **Course ID** | QC0029 |
| **Grading Type** | Pass / Fail |
| **Competency Evaluation** | Coursework / Assignments / Verifiable Experience |
| **Assessment** | The assessment and verification process for ICTQual AB's qualifications involves two key stages:<br>**Internal Assessment and Verification:**<br>✓ Conducted by the staff at the Approved Training Centre (ATC) to ensure learners meet the required standards through continuous assessments.<br>✓ Internal Quality Assurance (IQA) is carried out by the centre's IQA staff to validate the assessment process.<br>**External Quality Assurance:**<br>✓ Managed by ICTQual AB's verifiers, who periodically review the centre's assessment and IQA processes.<br>Verifies that assessments are conducted to the required standards and ensures consistency across centres |

## Entry Requirements

To enrol in ICTQual AB Level 3 Certificate in Quality Control Pharmaceutical, applicants must meet the following entry requirements:

- **Educational Background:** A minimum of a high school diploma (Matric or equivalent) is required. Applicants with a background in science, especially in biology or chemistry, will be given preference.
- **Basic Scientific Understanding:** Learners should have a foundational understanding of scientific concepts related to pharmaceutical production, quality assurance, or laboratory work.
- **English Language Proficiency:** Since the course materials and assessments are provided in English, students must have a basic to intermediate level of English proficiency to follow the instructions and complete assignments effectively.
- **Work Experience (Optional):** While not mandatory, prior experience in the pharmaceutical, healthcare, or laboratory sectors will be considered an advantage and may enhance the learner's understanding of course content.
- **Computer Literacy:** Basic computer skills are essential as the course may be delivered online or involve digital resources. Learners should be comfortable using email, PDF files, and web browsers for study and communication purposes.

These entry requirements are designed to ensure that learners can successfully engage with the course content and build a strong foundation in pharmaceutical quality control practices. If you meet these criteria, you are ready to take the first step toward a successful career in the pharmaceutical industry.

## Qualification Structure

This qualification comprises 3 mandatory units. Candidates must successfully complete all mandatory units to achieve the qualification.

| **Mandatory Units** | |
|---|---|
| **Unit Ref#** | **Unit Title** |
| QC0029-01 | Fundamentals of Pharmaceutical Quality Control |
| QC0029-02 | Introduction to Good Manufacturing Practices (GMP) |
| QC0029-03 | Pharmaceutical Sampling and Analytical Techniques |

## Centre Requirements

To ensure quality training delivery, centres must adhere to the following standards:

**1. Centre Approval**

- ✓ Centres must be formally approved by ICTQual AB's before delivering this qualification.
- ✓ Approval involves a review of facilities, policies, and staff qualifications.

**2. Qualified Staff**

- ✓ **Tutors:** must possess relevant qualifications in pharmaceutical sciences, quality control, or a related field at Level 5 or above.
- ✓ **Assessors:** Must hold a recognized assessor qualification (e.g., CAVA, AVRA) or equivalent)
- ✓ **Internal Quality Assurers (IQAs):** Must hold a recognized IQA qualification (e.g. Level 4 Award in the IQA and Level 4 Certificate in Leading the IQA) and experience to oversee assessment standards.

**3. Learning Facilities**

**Centre must offer:**

- ✓ Private study areas and internet-enabled workspaces (for blended or physical delivery)
- ✓ Academic and pastoral support for learners
- ✓ Administrative support must be available to manage enrolment, tracking, and learner queries efficiently

**4. Health and Safety Compliance**

- ✓ All training facilities must comply with health and safety regulations.
- ✓ Centres must conduct regular risk assessments for practical activities.

**5. Learning Resources**

- ✓ **Course Materials:** Approved textbooks, study guides, and digital content must align with the qualification standards.

- ✓ **Assessment Tools:** Templates and guidelines must be provided to ensure standardized evaluation processes.
- ✓ **E-Learning Support:** Centres offering online or blended learning must implement an effective Learning Management System (LMS).

**6. Assessment and Quality Assurance**

- ✓ Centres must ensure assessments meet ICTQual AB's competency standards.
- ✓ Internal quality assurance (IQA) must be conducted to maintain consistency.
- ✓ External verifiers from ICTQual AB's will review assessment and training practices.

**7. Learning Support**

- ✓ **Qualification Guidance:** Support for coursework and assignments.
- ✓ **Career Pathway Assistance:** Information on progression opportunities in sustainability and energy sectors.
- ✓ **Accessibility Support:** Accommodations for learners with disabilities or language barriers.

**8. Policies and Compliance**

Centres must uphold the following policies in accordance with ICTQual AB's standards:

- ✓ Equality, Diversity, and Inclusion Policy.
- ✓ Health and Safety Policy.
- ✓ Safeguarding and Learner Protection Policy.
- ✓ Complaints and Appeals Procedure.
- ✓ Data Protection and Confidentiality Policy.

**9. Reporting Requirements**

- Centres must provide ICTQual AB's with regular reports on learner registrations, progress, and certification outcomes.
- Assessment records must be maintained for external auditing and quality assurance purposes.

## Support for Candidates

Centres should ensure that materials developed to support candidates:

- ✓ Facilitate tracking of achievements as candidate's progress through the learning outcomes and assessment criteria.
- ✓ Include information on how and where ICTQual AB's policies and procedures can be accessed.
- ✓ Provide mechanisms for Internal and External Quality Assurance staff to verify and authenticate evidence effectively.

This approach ensures transparency, supports candidates' learning journeys, and upholds quality assurance standards.

## Assessment

This qualification is competence-based, requiring candidates to demonstrate proficiency as defined in the qualification units. The assessment evaluates the candidate's skills, knowledge, and understanding against the set standards. Key details include:

1. **Assessment Process:**

   - ✓ Must be conducted by an experienced and qualified assessor.
   - ✓ Candidates compile a portfolio of evidence that satisfies all learning outcomes and assessment criteria for each unit.

2. **Types of Evidence:**

   - ✓ Observation reports by the assessor.
   - ✓ Assignments, projects, or reports.
   - ✓ Professional discussions.
   - ✓ Witness testimonies.
   - ✓ Candidate-produced work.
   - ✓ Worksheets.
   - ✓ Records of oral and written questioning.
   - ✓ Recognition of Prior Learning (RPL).

3. **Learning Outcomes and Assessment Criteria:**

   - ✓ **Learning Outcomes:** Define what candidates should know, understand, or accomplish upon completing the unit.
   - ✓ **Assessment Criteria:** Detail the standards candidates must meet to demonstrate that the learning outcomes have been achieved.

This framework ensures rigorous and consistent evaluation of candidates' competence in line with the qualification's objectives.

## Unit Descriptors

### QC0029-01- Fundamentals of Pharmaceutical Quality Control

This unit introduces learners to the basic ideas and practices of quality control in the pharmaceutical industry. It explains why quality control is important for making safe and effective medicines. Learners will study how quality is checked at each stage of medicine production – from raw materials to finished products. The unit also covers the use of quality standards and procedures to prevent mistakes. Topics include testing methods, record-keeping, product inspections, and dealing with problems when they happen. Learners will understand how quality control helps to protect patients and maintain trust in medicines. By the end of the unit, learners will know the key roles and responsibilities in a pharmaceutical quality control team.

| Learning Outcome: | Assessment Criteria: |
|---|---|
| **1. Understand the purpose and scope of quality control in the pharmaceutical industry.** | 1.1 Define the term 'quality control' in the context of pharmaceuticals.<br>1.2 Describe the main purpose of quality control.<br>1.3 List the key activities included in quality control procedures.<br>1.4 Explain why quality control is important for the safety of pharmaceutical products. |
| **2. Identify key components and principles of pharmaceutical quality systems.** | 2.1 Identify the key components of a pharmaceutical quality system.<br>2.2 Describe the principles of a quality system.<br>2.3 Explain the role of documentation in a quality system.<br>2.4 Give examples of how quality principles are applied in a workplace.<br>2.5 State the importance of managing quality. |
| **3. Recognize the role of quality control in ensuring product safety, efficacy, and compliance.** | 3.1 Explain how quality control ensures the safety of a product.<br>3.2 Describe how quality control checks for the efficacy of a product.<br>3.3 Recognize the importance of quality control for meeting legal compliance.<br>3.4 Link specific quality control tests to product safety and efficacy. |
| **4. Explain the differences between quality control and quality assurance.** | 4.1 Explain the main goal of quality control.<br>4.2 Describe the main goal of quality assurance.<br>4.3 Compare the activities of quality control and quality assurance.<br>4.4 Explain when quality control is performed.<br>4.5 Describe when quality assurance is performed. |

| | |
|---|---|
| **5. Demonstrate knowledge of regulatory standards related to pharmaceutical quality control.** | 5.1 List the main regulatory bodies that set standards for pharmaceuticals.<br>5.2 Explain the importance of following regulatory standards.<br>5.3 Describe the purpose of regulatory inspections.<br>5.4 Demonstrate how to find a relevant standard for a specific product. |

### QC0029-02- Introduction to Good Manufacturing Practices (GMP)

This unit gives a clear introduction to Good Manufacturing Practices (GMP), which are rules followed to make sure medicines are made in a clean and controlled way. Learners will explore the basic principles of GMP, such as hygiene, proper documentation, staff training, and equipment maintenance. The unit also explains why GMP is required by law and how it helps ensure medicine safety and quality. Through simple examples, learners will understand how to follow GMP in everyday tasks and how small errors can affect the whole production process. The unit builds the foundation for working in a regulated pharmaceutical environment and encourages responsible working habits.

| Learning Outcome: | Assessment Criteria: |
|---|---|
| 1. **Define Good Manufacturing Practices and explain their importance in pharmaceutical production.** | 1.1 Define the term 'Good Manufacturing Practices' (GMP).<br>1.2 Explain why GMP is important for pharmaceutical production.<br>1.3 Describe what GMP aims to prevent.<br>1.4 Provide examples of what GMP covers.<br>1.5 State the key principles of GMP. |
| 2. **Describe the main principles and regulatory requirements of GMP.** | 2.1 Describe the main principles of GMP.<br>2.2 Identify the regulatory body that oversees GMP.<br>2.3 Explain the purpose of GMP regulations.<br>2.4 Describe how documentation is a key part of GMP requirements. |
| 3. **Understand the responsibilities of personnel under GMP guidelines.** | 3.1 State the general responsibilities of all personnel under GMP.<br>3.2 Describe the responsibilities of production staff.<br>3.3 Explain the role of quality control personnel.<br>3.4 Recognize the importance of reporting deviations from GMP. |
| 4. **Identify key areas of GMP application including facility design, hygiene, and documentation.** | 4.1 Identify the main areas where GMP is applied.<br>4.2 Describe the GMP requirements for facility design.<br>4.3 Explain the importance of personal hygiene in GMP.<br>4.4 Describe the GMP rules for documentation and record keeping.<br>4.5 Give an example of how GMP is applied to equipment. |

5. **Apply basic GMP procedures in quality control environments.**

5.1 Follow standard operating procedures (SOPs) for a given task.
5.2 Apply correct gowning procedures for a cleanroom environment.
5.3 Perform basic cleaning and sanitation procedures.
5.4 Complete documentation accurately for a simple quality control test.

### QC0029-03- Pharmaceutical Sampling and Analytical Techniques

This unit focuses on the correct ways to collect and test samples of pharmaceutical materials and products. Learners will study different sampling methods used to check raw materials, in-process materials, and finished medicines. The unit also introduces common laboratory techniques used to examine samples, such as physical and chemical testing. Learners will learn how to prepare samples, use basic testing equipment, and follow safe working rules. The unit highlights the importance of accuracy, care, and following standard procedures when handling samples. It also covers how test results are recorded and used to make quality decisions. By the end of the unit, learners will understand how sampling and testing support quality control.

| Learning Outcome: | Assessment Criteria: |
|---|---|
| 1. **Explain the principles of sampling in pharmaceutical quality control.** | 1.1 Explain why sampling is done in pharmaceuticals.<br>1.2 Describe the principle of taking a representative sample.<br>1.3 State the importance of avoiding contamination during sampling.<br>1.4 Explain the concept of a sampling plan. |
| 2. **Identify types of pharmaceutical samples and appropriate sampling techniques.** | 2.1 Identify different types of samples (e.g., raw materials, in-process, finished product).<br>2.2 Name the appropriate sampling technique for a solid material.<br>2.3 Describe the sampling method for a liquid.<br>2.4 Explain why different samples need different techniques.<br>2.5 Identify the equipment used for specific sampling tasks. |
| 3. **Understand the procedures for handling, labelling, and storing samples.** | 3.1 Follow correct procedures for handling a newly collected sample.<br>3.2 Explain the information that must be on a sample label.<br>3.3 Describe the correct storage conditions for different types of samples.<br>3.4 Follow a chain of custody procedure for samples. |
| 4. **Apply basic analytical techniques for testing pharmaceutical products.** | 4.1 Perform a basic pH test on a liquid sample.<br>4.2 Conduct a simple visual inspection of a tablet for defects.<br>4.3 Apply a basic dissolution test method.<br>4.4 Use a balance to accurately weigh a sample.<br>4.5 Follow the steps to prepare a sample for a simple test. |

5. **Interpret test results and report findings in accordance with standard protocols.**

5.1 Record test results accurately in a data sheet.
5.2 Compare test results to specified limits.
5.3 Recognize when a result is out of specification.
5.4 Report findings to a supervisor in the correct format.

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