# ICTQual AB

## Qualification Specification

# ICTQual AB Level 5 Diploma in Quality Control Medical Equipment


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# ICTQual AB's

# Level 5 Diploma in Quality Control Medical Equipment

## Contents

# Qualification Specification about

# ICTQual AB Level 5 Diploma in Quality Control Medical Equipment

## 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

The ICTQual AB Level 5 Diploma in Quality Control Medical Equipment is a comprehensive qualification designed for individuals seeking to specialize in the crucial field of medical device quality assurance. This course provides a deep understanding of the principles, procedures, and regulations governing the quality control and management of a wide range of medical equipment. It combines theoretical knowledge with practical skills, preparing learners to uphold the highest standards of safety, accuracy, and reliability in a healthcare setting. The curriculum covers key areas such as international quality standards, risk management, and the validation and verification processes essential for medical devices.

**Objectives**

Upon successful completion of this diploma, learners will be able to:

- Apply a systematic approach to the quality control and management of various medical equipment, ensuring compliance with both national and international regulations.

- Analyze and interpret complex data from testing and validation processes to make informed decisions about product safety and efficacy.
- Implement and manage quality management systems (QMS) specific to the medical device industry, including ISO 13485 standards.
- Identify and mitigate potential risks associated with the design, manufacturing, and use of medical equipment through robust risk management techniques.
- Demonstrate a high level of procedural and theoretical knowledge to address complex, non-routine problems that may arise in a quality control environment.

**Aims**

The primary aims of this diploma are to:

- Develop highly skilled professionals capable of leading and managing quality control processes within the medical equipment sector.
- Enhance the quality and safety of medical devices in the market by ensuring that graduates are experts in regulatory compliance and best practices.
- Provide a pathway for career advancement for individuals already working in healthcare, engineering, or related fields.
- Foster a deep understanding of different perspectives and approaches to quality management within the medical device industry, promoting critical thinking and innovation.

**Targeted Audience**

This diploma is intended for a diverse group of professionals and students, including but not limited to:

- Medical Equipment Technicians and engineers who wish to advance their careers and specialize in quality control.
- Quality Assurance (QA) Professionals currently working in other industries who want to transition into the medical device sector.
- Healthcare Professionals, such as nurses or administrators, who require a deeper understanding of medical device quality and safety.
- Graduates with a background in engineering, life sciences, or a related field who are seeking a specialized qualification to enter the medical device industry.

## Certification Framework

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|---|---|
| **Qualification title** | **ICTQual AB Level 5 Diploma in Quality Control Medical Equipment** |
| **Course ID** | QC0042 |
| **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 5 Diploma in Quality Control Medical Equipment, learner must meet the following entry requirements:

- ✓ **Age Requirement:** Learners must be 18 years of age or older at the time of enrolment. This ensures a level of maturity and responsibility suitable for advanced technical and regulatory topics.
- ✓ **Educational Background:** A Level 3 qualification in a relevant field such as medical technology, healthcare, engineering, or science is required.
- ✓ **Work Experience:** Previous experience in a healthcare, biomedical, or technical setting is highly recommended.
- ✓ **English Proficiency:** As the course is delivered in English, learners must possess adequate proficiency in reading, writing, and understanding technical documentation and instructions.

## Qualification Structure

This qualification comprises 10 mandatory units for the complete qualification. Candidates must successfully complete all mandatory units to achieve the qualification.

| Mandatory Units | |
|---|---|
| **Unit Ref#** | **Unit Title** |
| QC0042-01 | Advanced Principles of Medical Equipment Quality Control |
| QC0042-02 | Biomedical Instrumentation Systems and Calibration Techniques |
| QC0042-03 | Risk Management and Quality Audits in Healthcare Equipment |
| QC0042-04 | International Medical Device Regulations and Standards |
| QC0042-05 | Technical Reporting and Documentation in Medical Equipment QA |
| QC0042-06 | Preventive Maintenance Planning and Equipment Lifecycle Management |
| QC0042-07 | Advanced Diagnostic Testing Methods and Performance Verification |
| QC0042-08 | Root Cause Analysis and Corrective Action in Medical Technology |
| QC0042-09 | Compliance and Ethical Considerations in Healthcare Quality Systems |
| QC0042-10 | Integrated Quality Management Systems (QMS) for Medical Equipment |

## 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:** hold a minimum of a Level 6 qualification (or its equivalent) in a field directly relevant to the course, such as Biomedical Engineering, Medical Device Technology, or in Medical equipment.
- ✓ **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

### QC0042-01- Advanced Principles of Medical Equipment Quality Control

This unit explores sophisticated principles of quality control specific to the medical equipment industry. It covers the application of advanced statistical process control (SPC) and Six Sigma methodologies to ensure the accuracy and reliability of medical devices. Learners will analyse complex quality control data, troubleshoot non-conformances, and develop strategies for continuous quality improvement. The unit emphasizes factual, procedural, and theoretical knowledge to address complex, non-routine problems in a quality control environment.

| Learning Outcome: | Assessment Criteria: |
|---|---|
| 1. **Analyse the advanced concepts of quality control specific to medical equipment.** | 1.1 Critically analyse the role of different quality control methodologies in a medical equipment context.<br>1.2 Distinguish between advanced quality control concepts and basic quality assurance principles.<br>1.3 Evaluate the effectiveness of various quality control methods for different types of medical devices.<br>1.4 Compare and contrast proactive and reactive quality control strategies.<br>1.5 Justify the use of specific quality control techniques for a given medical device. |
| 2. **Evaluate quality systems and their impact on device reliability and patient safety.** | 2.1 Evaluate the components of a robust quality management system (QMS) for medical devices.<br>2.2 Assess how QMS processes directly influence the reliability of equipment.<br>2.3 Analyse the relationship between QMS effectiveness and patient safety outcomes.<br>2.4 Propose improvements to an existing QMS to enhance device reliability.<br>2.5 Interpret QMS audit findings to identify areas of risk to patient safety. |
| 3. **Develop and implement quality control protocols in line with organisational needs.** | 3.1 Develop comprehensive quality control protocols for a specific medical device.<br>3.2 Align new quality control protocols with an organisation's current operational needs.<br>3.3 Plan the steps for implementing a new quality control protocol.<br>3.4 Evaluate the resources required to successfully implement a protocol.<br>3.5 Identify potential barriers to implementation and propose solutions.<br>3.6 Draft communication materials to inform staff about a new protocol. |

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| **4. Monitor performance indicators to drive improvements in equipment quality.** | 4.1 Identify key performance indicators (KPIs) relevant to medical equipment quality.<br>4.2 Collect and analyse performance data from a variety of sources<br>4.3 Interpret trends in performance data to pinpoint areas needing improvement.<br>4.4 Use monitoring results to propose specific quality improvement actions.<br>4.5 Report on the findings from performance indicator monitoring. |

## QC0042-02- Biomedical Instrumentation Systems and Calibration Techniques

This unit provides a detailed understanding of the operational principles of various biomedical instrumentation systems. It covers the theory and practical application of calibration techniques, emphasizing the importance of measurement accuracy for patient safety. The unit also delves into the interpretation and evaluation of relevant information from calibration reports, ensuring systems are maintained to meet strict performance standards.

| Learning Outcome: | Assessment Criteria: |
|---|---|
| **1. Understand the operational principles of complex biomedical instrumentation systems.** | 1.1 Explain the operational principles of at least three complex biomedical instruments.<br>1.2 Analyse how different components within an instrument work together.<br>1.3 Interpret the technical specifications of a complex biomedical system.<br>1.4 Describe the signal processing chain for a diagnostic instrument.<br>1.5 Discuss the common sources of error in biomedical instrumentation. |
| **2. Perform precise calibration using industry-standard tools and methods.** | 2.1 Select the correct calibration tools for a given biomedical instrument.<br>2.2 Perform a complete calibration procedure according to a defined standard.<br>2.3 Document the calibration process, including all measured values and adjustments.<br>2.4 Justify the methods used for a specific calibration task.<br>2.5 Identify and correct common errors during the calibration process.<br>2.6 Evaluate the accuracy of the final calibration result. |
| **3. Assess the accuracy and sensitivity of diagnostic and therapeutic equipment.** | 3.1 Assess the accuracy of a diagnostic instrument against its stated specifications.<br>3.2 Determine the sensitivity of a piece of therapeutic equipment.<br>3.3 Compare the accuracy of two different pieces of similar equipment.<br>3.4 Explain the impact of poor accuracy and sensitivity on patient diagnosis.<br>3.5 Report on the assessment results clearly and concisely. |

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| **4. Maintain calibration records in accordance with technical and regulatory requirements.** | 4.1 Create a complete calibration record for a medical device.<br>4.2 Ensure all entries in the calibration record meet technical and regulatory standards.<br>4.3 Explain the importance of traceability within calibration records.<br>4.4 Organise and file calibration records for easy access and audit. |

## QC0042-03- Risk Management and Quality Audits in Healthcare Equipment

This unit focuses on risk management frameworks and their application to healthcare equipment throughout its lifecycle. It covers identifying, analysing, evaluating, and mitigating risks to ensure patient and user safety. Learners will also develop skills in conducting internal and external quality audits, interpreting audit findings, and implementing corrective actions to maintain compliance with quality management standards.

| Learning Outcome: | Assessment Criteria: |
|---|---|
| **1. Identify potential risks associated with the use and maintenance of medical devices.** | 1.1 Identify and categorise common risks related to the use of medical devices.<br>1.2 Distinguish between risks in the use of equipment and risks in its maintenance.<br>1.3 Explain the potential impact of identified risks on patient safety and device function.<br>1.4 Use a risk matrix to prioritise a list of identified risks.<br>1.5 Propose methods for gathering risk information from different sources. |
| **2. Apply structured approaches to risk assessment and mitigation planning.** | 2.1 Apply a recognised risk assessment methodology (e.g., FMEA) to a medical device scenario.<br>2.2 Develop a detailed risk mitigation plan for a specific device-related risk.<br>2.3 Evaluate the effectiveness of a proposed mitigation strategy.<br>2.4 Document the risk assessment and mitigation plan clearly.<br>2.5 Explain how to communicate risk information to relevant stakeholders. |
| **3. Conduct internal quality audits in healthcare technology settings.** | 3.1 Plan the scope and objectives of an internal quality audit.<br>3.2 Prepare an audit checklist based on relevant standards and regulations.<br>3.3 Conduct interviews and observations during an audit.<br>3.4 Collect and analyse objective evidence to support audit findings.<br>3.5 Produce a clear and factual audit report.<br>3.6 Apply ethical principles during the audit process. |
| **4. Develop audit findings into actionable quality improvement measures.** | 4.1 Interpret audit findings into specific and measurable recommendations.<br>4.2 Develop a plan for implementing corrective actions based on audit results.<br>4.3 Prioritise improvement measures based on risk and impact.<br>4.4 Monitor the progress and effectiveness of the implemented measures. |

### QC0042-04- International Medical Device Regulations and Standards

This unit provides a comprehensive overview of the global regulatory landscape for medical devices. It examines key regulations such as the EU Medical Device Regulation (MDR) and FDA requirements, as well as international standards for quality management systems. Learners will gain an understanding of different perspectives and approaches to regulatory compliance and how these influence market access and product design.

| Learning Outcome: | Assessment Criteria: |
|---|---|
| **1. Interpret key international regulatory frameworks for medical equipment.** | 1.1 Interpret the main requirements of at least two key international regulatory frameworks (e.g., FDA, MDR).<br>1.2 Explain the purpose and function of these regulatory bodies.<br>1.3 Distinguish between mandatory regulations and voluntary standards.<br>1.4 Analyse how different regulatory frameworks might apply to a single device.<br>1.5 Use a case study to demonstrate understanding of regulatory compliance. |
| **2. Understand the role of regulatory compliance in product approval and market access.** | 2.1 Explain the steps required for a medical device to gain regulatory approval.<br>2.2 Analyse the impact of non-compliance on market access and product distribution.<br>2.3 Evaluate the importance of a compliant technical file for a medical device.<br>2.4 Assess the role of risk management in the approval process. |
| **3. Compare regional and global standards impacting healthcare equipment.** | 3.1 Compare and contrast the requirements of regional and global standards (e.g., ISO, IEC).<br>3.2 Analyse how a device might need to be adapted for different regions.<br>3.3 Explain the process for achieving certification to a specific standard.<br>3.4 Evaluate the benefits and challenges of aligning with multiple standards.<br>3.5 Identify the key standard relevant to a specific type of medical equipment. |
| **4. Implement best practices to align quality systems with international expectations.** | 4.1 Implement procedures that align an organisation's QMS with international standards.<br>4.2 Develop a plan to address gaps between current practices and international expectations.<br>4.3 Evaluate the effectiveness of a new best practice in a clinical setting. |

4.4 Report on the progress of aligning the QMS with global standards.

**QC0042-05- Technical Reporting and Documentation in Medical Equipment QA**

This unit focuses on the critical skills required for accurate and effective technical reporting and documentation in medical equipment quality assurance. It covers the creation of design history files, device master records, and technical files, ensuring all procedural steps are recorded and traceable. The unit emphasizes clear, concise communication of complex technical information for compliance and problem-solving.

| Learning Outcome: | Assessment Criteria: |
|---|---|
| **1. Prepare detailed technical reports for quality control activities and equipment assessments.** | 1.1 Structure a technical report for a quality control activity.<br>1.2 Include all necessary sections, such as an executive summary, methodology, results, and conclusions.<br>1.3 Use clear and precise language appropriate for a technical audience.<br>1.4 Present complex data using tables, charts, or other visual aids.<br>1.5 Formulate clear and actionable recommendations based on the report findings. |
| **2. Maintain accurate documentation for inspections, failures, and corrective actions.** | 2.1 Complete an inspection record for a medical device with high accuracy.<br>2.2 Document a device failure, including all observed symptoms and circumstances.<br>2.3 Maintain a clear log of all corrective actions taken.<br>2.4 Ensure documentation is legible, complete, and easy to retrieve.<br>2.5 Explain the consequences of inaccurate or incomplete documentation. |
| **3. Understand the importance of traceability and version control in medical documentation.** | 3.1 Explain the concept of traceability and its importance for medical device quality.<br>3.2 Apply version control principles to a set of procedural documents.<br>3.3 Demonstrate how to trace a component from a device failure back to its origin.<br>3.4 Evaluate the risks associated with a lack of traceability or poor version control. |
| **4. Comply with internal and external reporting obligations across healthcare environments.** | 4.1 Interpret internal and external reporting requirements.<br>4.2 Prepare a report that meets the requirements of an external regulatory body.<br>4.3 Distinguish between the information required for internal and external reports.<br>4.4 Develop a plan for meeting ongoing reporting obligations. |

4.5 Explain the consequences of failing to meet reporting deadlines.

**QC0042-06- Preventive Maintenance Planning and Equipment Lifecycle Management**

This unit explores the strategic planning of preventive maintenance programs for medical equipment. It covers how to optimize maintenance schedules to reduce downtime and extend equipment lifespan while maintaining performance and safety. Learners will also gain an understanding of the entire equipment lifecycle, from acquisition to decommissioning, and the role of quality control at each stage.

| Learning Outcome: | Assessment Criteria: |
|---|---|
| **1. Design preventive maintenance schedules based on equipment specifications and usage.** | 1.1 Design a preventive maintenance schedule for a medical device using the manufacturer's guidelines.<br>1.2 Justify the frequency and scope of maintenance activities based on usage patterns.<br>1.3 Incorporate regulatory and safety requirements into the schedule.<br>1.4 Evaluate a pre-existing maintenance schedule and suggest improvements.<br>1.5 Plan a schedule that minimises disruption to clinical operations. |
| **2. Analyse lifecycle data to optimise asset performance and reliability.** | 2.1 Collect and analyse data from a device's lifecycle, including maintenance history and failure rates.<br>2.2 Interpret lifecycle data to identify trends in device performance.<br>2.3 Use data analysis to predict potential future failures.<br>2.4 Develop a proposal to extend a device's useful life based on lifecycle data.<br>2.5 Evaluate the cost-effectiveness of continuing to maintain an older device. |
| **3. Plan resource allocation for maintenance operations within a quality framework.** | 3.1 Plan the allocation of human resources for a set of maintenance tasks.<br>3.2 Create a budget for parts, tools, and external services for maintenance.<br>3.3 Justify resource decisions based on quality, safety, and financial constraints.<br>3.4 Evaluate the efficiency of a resource allocation plan. |
| **4. Implement tracking systems for equipment history, upgrades, and service records.** | 4.1 Set up a tracking system for a group of medical devices.<br>4.2 Accurately enter equipment history, upgrades, and service records into the system.<br>4.3 Demonstrate the use of the tracking system to retrieve specific information.<br>4.4 Explain the benefits of a well-maintained tracking system. |

### QC0042-07- Advanced Diagnostic Testing Methods and Performance Verification

This unit delves into advanced methods for diagnostic testing of medical equipment. It covers complex testing procedures and the use of specialized tools to verify device performance against manufacturer specifications and regulatory requirements. The unit emphasizes the interpretation and evaluation of test results to confirm equipment reliability and to address any performance deviations.

| Learning Outcome: | Assessment Criteria: |
|---|---|
| **1. Apply advanced diagnostic testing methods to assess medical device performance.** | 1.1 Select the correct advanced diagnostic testing method for a complex device.<br>1.2 Perform a specified diagnostic test using the appropriate equipment.<br>1.3 Identify and interpret the output from an advanced diagnostic test.<br>1.4 Explain the limitations of different diagnostic methods.<br>1.5 Modify a test procedure to suit a non-standard situation. |
| **2. Evaluate device outputs against regulatory and technical benchmarks.** | 2.1 Compare test outputs against established regulatory benchmarks.<br>2.2 Assess a device's performance against its own technical specifications.<br>2.3 Evaluate the consequences of a device failing to meet a benchmark.<br>2.4 Formulate a report on benchmark verification results.<br>2.5 Propose corrective actions for a device that fails to meet a benchmark. |
| **3. Use specialised tools to conduct performance verification in clinical settings.** | 3.1 Demonstrate the safe and correct use of specialised testing tools.<br>3.2 Plan a performance verification test within a clinical environment.<br>3.3 Conduct a performance verification test without disrupting clinical work.<br>3.4 Analyse the results from the specialised tools to assess performance.<br>3.5 Identify and troubleshoot issues with the testing tools themselves. |
| **4. Document and interpret test results to support quality assurance outcomes.** | 4.1 Document test results in a clear and complete manner.<br>4.2 Interpret test results to draw conclusions about device quality.<br>4.3 Analyse how test results contribute to a larger quality assurance report. |

4.4 Explain the importance of accurate result documentation for regulatory purposes.

**QC0042-08- Root Cause Analysis and Corrective Action in Medical Technology**

This unit teaches systematic approaches to root cause analysis (RCA) for medical device failures or non-conformances. Learners will apply investigative techniques to identify the fundamental reasons for problems and develop effective corrective and preventive actions (CAPA). The unit focuses on addressing non-routine, complex problems by using factual and procedural knowledge.

| Learning Outcome: | Assessment Criteria: |
|---|---|
| 1. **Investigate failures and defects using structured root cause analysis techniques.** | 1.1 Apply a structured root cause analysis method (e.g., 5 Whys, Ishikawa Diagram) to a device failure.<br>1.2 Gather all relevant data and evidence related to a failure.<br>1.3 Identify all potential causes of the failure.<br>1.4 Determine the single root cause of a device failure.<br>1.5 Document the investigation process and findings in a report. |
| 2. **Develop and implement effective corrective and preventive action plans (CAPA).** | 2.1 Develop a CAPA plan that directly addresses the identified root cause.<br>2.2 Ensure the CAPA plan includes both corrective and preventive actions.<br>2.3 Plan the steps for implementing the CAPA plan.<br>2.4 Evaluate the potential impact of the plan before implementation.<br>2.5 Communicate the CAPA plan to all relevant parties. |
| 3. **Monitor the impact of corrective actions on equipment quality and reliability.** | 3.1 Define metrics to monitor the effectiveness of a corrective action.<br>3.2 Collect and analyse data after a corrective action has been implemented.<br>3.3 Interpret monitoring data to determine if the problem has been solved.<br>3.4 Report on the overall impact of the corrective action.<br>3.5 Identify any unintended consequences of the corrective action.<br>3.6 Evaluate the long-term effectiveness of the corrective action. |
| 4. **Integrate root cause findings into continuous improvement initiatives.** | 4.1 Integrate a new finding from a root cause analysis into a continuous improvement process.<br>4.2 Update existing procedures to prevent similar failures in the future.<br>4.3 Evaluate the effect of a change on overall quality and reliability.<br>4.4 Communicate the findings and changes to the wider team. |

**QC0042-09- Compliance and Ethical Considerations in Healthcare Quality Systems**

This unit explores the ethical and professional responsibilities of quality control professionals in the healthcare sector. It covers the importance of compliance with ethical guidelines and professional codes of conduct. Learners will discuss the nature of the work and the different ethical perspectives that influence decision-making related to patient safety and data integrity.

| Learning Outcome: | Assessment Criteria: |
|---|---|
| 1. **Understand ethical responsibilities in the handling and reporting of medical device issues.** | 1.1 Explain the ethical responsibilities of a quality control professional.<br>1.2 Identify potential ethical conflicts in a given scenario.<br>1.3 Demonstrate an understanding of a patient's right to safety and privacy.<br>1.4 Formulate a response to a scenario involving an ethical dilemma.<br>1.5 Distinguish between a legal obligation and an ethical responsibility. |
| 2. **Ensure quality systems comply with healthcare regulations and professional standards.** | 2.1 Assess a quality system's compliance with key healthcare regulations.<br>2.2 Identify areas of non-compliance and propose solutions.<br>2.3 Develop a plan to align a system with a new professional standard.<br>2.4 Evaluate the effectiveness of a compliance training program. |
| 3. **Promote a culture of integrity, accountability, and transparency in QA practices.** | 3.1 Propose strategies to promote integrity and honesty in a QA team.<br>3.2 Explain the role of accountability in a quality control environment.<br>3.3 Draft communication to encourage transparency about quality issues.<br>3.4 Evaluate the impact of a transparent culture on overall quality outcomes.<br>3.5 Act as a role model for ethical behaviour in QA. |
| 4. **Identify and resolve ethical dilemmas within quality control environments.** | 4.1 Analyse a given ethical dilemma in a quality control setting.<br>4.2 Apply an ethical decision-making framework to the dilemma.<br>4.3 Propose a resolution that respects all relevant ethical principles.<br>4.4 Justify the chosen course of action with clear reasoning.<br>4.5 Explain the potential consequences of different resolutions. |

**QC0042-10- Integrated Quality Management Systems (QMS) for Medical Equipment**

This unit focuses on the design, implementation, and maintenance of integrated QMS that align with international standards. It covers the integration of processes such as risk management, document control, and quality audits into a cohesive system. Learners will be able to interpret and evaluate relevant information to continuously improve the effectiveness of the QMS.

| Learning Outcome: | Assessment Criteria: |
|---|---|
| 1. **Understand the structure and function of integrated QMS in healthcare organisations.** | 1.1 Explain the structure of an integrated QMS.<br>1.2 Analyse how different QMS components work together.<br>1.3 Compare an integrated QMS with a standalone QMS.<br>1.4 Identify the key stakeholders involved in an integrated QMS.<br>1.5 Interpret the key policies of an integrated QMS.<br>1.6 Describe the benefits of an integrated approach. |
| 2. **Implement quality policies, procedures, and performance monitoring tools.** | 2.1 Implement a new quality policy or procedure within an organisation.<br>2.2 Develop a set of performance monitoring tools for a key process.<br>2.3 Train staff on a new policy or procedure.<br>2.4 Document the implementation process, including any changes made.<br>2.5 Evaluate the effectiveness of the new policy or tool. |
| 3. **Coordinate QMS activities across multiple departments and stakeholders.** | 3.1 Coordinate a QMS activity that involves at least two different departments.<br>3.2 Establish clear communication channels between all stakeholders.<br>3.3 Manage conflicts or competing interests during coordination.<br>3.4 Report on the progress of a coordinated QMS activity.<br>3.5 Evaluate the success of a coordination effort. |
| 4. **Evaluate QMS effectiveness through audits, metrics, and continuous feedback.** | 4.1 Evaluate the effectiveness of a QMS using a set of metrics.<br>4.2 Use audit results to identify strengths and weaknesses of a QMS.<br>4.3 Collect and analyse feedback from staff and other stakeholders.<br>4.4 Propose improvements to the QMS based on evaluation findings.<br>4.5 Report on the overall effectiveness of the QMS.<br>4.6 Develop an action plan for continuous improvement. |

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