



# **QualCert Level 5 Diploma in Quality Control (QC)**

**Version 1.0 September 2024**

**QualCert Qualification number: QC01011**

***Qualification Specification***

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## ***About QualCert***

QualCert is a globally recognized awarding body based in the United Kingdom, renowned for its commitment to excellence in Quality Assurance (QA) and Quality Control (QC) education and training. Specializing in delivering high-quality qualifications, QualCert addresses the evolving needs of international learners, professionals, and industries seeking expertise in QA and QC.

Dedicated to fostering innovative and flexible learning pathways, QualCert provides learners with the skills, knowledge, and practical competencies required to excel in dynamic quality-focused professional environments. The organization adheres to international qualification frameworks and standards, ensuring its certifications are globally recognized and highly applicable across diverse sectors.

The vision of QualCert is to establish itself as a global benchmark in quality education and skills development within Quality Assurance and Quality Control. Its mission is to equip individuals and organizations with internationally recognized qualifications that enhance employability, professional productivity, and career progression in QA/QC disciplines.

## Course Overview

This advanced programme provides a comprehensive deep dive into the architecture of **Quality Management Systems (QMS)**. Unlike entry-level certifications, the Level 5 Diploma focuses on the "why" and "how" of systemic excellence. It integrates rigorous auditing practices with sophisticated process optimization techniques, ensuring that learners are not just following standards, but actively shaping them to drive organizational success.

### Course Aims

The primary goal of this qualification is to transform technically proficient individuals into **strategic quality leaders**. The curriculum aims to:

- **Standardize Excellence:** Align learner expertise with recognized UK industry standards and global compliance expectations.
- **Foster Critical Analysis:** Enable learners to evaluate organizational systems critically and identify latent risks before they impact the bottom line.

### Learning Objectives

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

- **Implement Advanced Methodologies:** Utilize sophisticated inspection techniques and statistical analysis to monitor and control process variability.
- **Manage Risk and Compliance:** Conduct thorough risk assessments and design robust corrective and preventive action (CAPA) plans.
- **Lead Quality Audits:** Plan and execute internal and external audits to ensure adherence to regulatory requirements and internal procedures.

### Targeted Audience

This qualification is strategically designed for ambitious professionals in sectors where precision is non-negotiable, such as **Manufacturing, Engineering, Construction, Logistics, and Production Management**.

### Ideal candidates include:

- **Aspiring Managers:** Quality technicians or coordinators looking to step into senior, supervisory, or managerial roles.
- **Current Quality Leads:** Professionals already in leadership positions who require a formal, high-level qualification to validate their expertise.

## Qualification Framework

Qualification Title	QualCert Level 5 Diploma in Quality Control (QC)
Qualification Duration	6 to 12 months
Grading Type	Pass / Fail
Competency Evaluation	Coursework / Assignments / Evidence Based

## Assessment Processes

Stage	Details
Internal Assessment and Verification	<ul style="list-style-type: none"><li>• Conducted by staff at the Approved Training Centre (ATC) to ensure qualification standards are met.</li><li>• Internal Quality Assurance (IQA) by designated centre staff to maintain assessment integrity.</li></ul>
External Quality Assurance	<ul style="list-style-type: none"><li>• Overseen by QualCert verifiers who periodically review assessment and IQA procedures.</li><li>• Ensures adherence to standards and consistency across all ATCs.</li></ul>

## Entry Requirements

**Age:** 18+

**Education:** Level 4 qualification or equivalent in a relevant subject

**English Competency:** Basic Understanding

## Qualification Structure

The QualCert Level 5 Diploma in Quality Control (QC), comprises 75 credits, with a Total Qualification Time (TQT) of 600 hours, including 360 Guided Learning Hours (GLH).

Mandatory Units				
Unit Ref No	Unit Name	Credits	GLH	TQT
QC01011-1	Strategic Quality Management and Governance	12.5	60	100
QC01011-2	Advanced Statistical Quality and Data Analytics	12.5	60	100
QC01011-3	Global Quality Standards and Compliance Systems	12.5	60	100
QC01011-4	Advanced Audit and Enterprise Compliance	12.5	60	100
QC01011-5	Lean Six Sigma and Operational Excellence	12.5	60	100
QC01011-6	Quality Leadership and Performance Management	12.5	60	100

## **Centre Requirements**

Centres delivering the QualCert Level 5 Diploma in Quality Control (QC) must uphold high standards to ensure quality learning, assessment integrity, and successful learner outcomes. Centres are required to provide qualified staff, appropriate facilities, and access to the necessary resources to deliver advanced pharmaceutical training. Meeting these requirements ensures learners receive a professional, engaging, and internationally recognised educational experience.

### **Qualified and Competent Teaching Staff**

- Employ instructors with advanced qualifications and professional experience in pharmaceutical technology, quality assurance, or related fields
- Ensure staff maintain up-to-date knowledge of manufacturing practices, regulatory standards, and quality systems
- Provide ongoing professional development and training to teaching staff to maintain excellence in delivery

### **Adequate Learning Facilities and Resources**

- Provide modern classrooms, laboratories, or online learning platforms to support interactive and practical learning
- Ensure access to up-to-date pharmaceutical reference materials, case studies, and digital tools
- Maintain safe and inclusive environments suitable for laboratory work, research, and practical exercises

### **Robust Assessment and Quality Assurance Systems**

- Implement clear and consistent assessment policies aligned with qualification standards
- Maintain internal quality assurance processes to monitor teaching, assessment, and learner performance
- Regularly review assessment methods to ensure relevance and alignment with industry best practices

### **Comprehensive Learner Support**

- Provide academic guidance, technical assistance, and pastoral care to support learner success
- Ensure accessibility for learners with disabilities or specific learning needs through reasonable adjustments

- Maintain effective communication channels for feedback, queries, and learner support

### **Compliance with Regulatory, Health, and Safety Standards**

- Adhere to legal, ethical, and health and safety regulations in all teaching and practical activities
- Keep accurate learner records, attendance, and assessment documentation
- Follow data protection and confidentiality protocols to safeguard learner information

## ***Support for Candidate***

### **Supporting Materials for Candidates**

- Enable tracking of learners' progress toward achieving specified learning outcomes and assessment criteria.
- Provide clear guidance on accessing QualCert policies and procedures.
- Establish robust mechanisms for Internal and External Quality Assurance personnel to verify and authenticate evidence efficiently.

## ***Assessments Requirements***

### **Part 1: Strategic & Theoretical Assessment**

#### **1.1 Evaluative Understanding of Quality Management Systems (QMS)**

Learners must demonstrate a critical understanding of the governance frameworks that underpin quality. Assessment is typically conducted through **management reports** or **strategic case studies**.

The purpose is to ensure learners can:

- **Critically Evaluate Frameworks:** Analyze the effectiveness of different QMS models (e.g., ISO 9001, Six Sigma) within specific industrial contexts.
- **Strategic Alignment:** Explain how quality objectives integrate with broader organizational goals and financial sustainability.
- **Regulatory Leadership:** Interpret complex international standards and navigate the legal implications of non-compliance in highly regulated sectors.

#### **1.2 Quantitative Analysis and Decision Making**

Unlike Level 3's basic awareness, Level 5 requires the use of data to drive strategy.

This includes:

- **Statistical Process Control (SPC):** Demonstrating the ability to interpret control charts, calculate process capability indices ( $C_p$  and  $C_{pk}$ ), and identify trends in variability.
- **Root Cause Analysis (RCA):** Applying advanced methodologies (e.g., FMEA—Failure Mode and Effects Analysis) to identify systemic risks rather than isolated errors.
- **Evidence-Based Decision Making:** Justifying resource allocation for quality improvements based on Cost of Quality (CoQ) data.

## Part 2: Leadership & Practical Systems Assessment

### 2.1 Auditing and Systems Implementation

Learners are required to demonstrate competence in managing the audit lifecycle. This is assessed through **audit portfolios** or **simulated management reviews**.

Activities focus on:

- **Lead Auditing:** Planning, executing, and leading an internal or external audit team to evaluate system integrity.
- **Continuous Improvement Leadership:** Designing and implementing a "Plan-Do-Check-Act" (PDCA) cycle or Lean initiative to optimize a specific workplace process.
- **Risk Mitigation:** Developing comprehensive risk registers and mitigation strategies for complex supply chains or production lines.

### 2.2 Reporting, Accountability, and Governance

Documentation at Level 5 is focused on transparency, traceability, and senior-level communication.

This includes:

- **Management Reporting:** Synthesizing complex quality data into concise reports for executive stakeholders, highlighting risks and opportunities.
- **CAPA Management:** Designing and overseeing Corrective and Preventive Action (CAPA) systems that ensure long-term resolution of non-conformities.
- **Traceability Systems:** Developing protocols that ensure full end-to-end traceability of products/services, critical for safety-critical environments.

## Units – Learning Outcomes & Assessment Criteria

### Unit 01 – Strategic Quality Management and Governance

#### *Learning outcome*

*The learner will:*

#### *Assessment criterion*

*The learner can:*

**01. Evaluate the impact of governance on strategic quality.**

1.1 Explain how different organizational governance structures (such as boards or steering committees) influence the success of quality initiatives.

1.2 Evaluate the link between clear leadership accountability and the achievement of long-term quality targets.

1.3 Identify potential risks to quality that arise from poor governance and suggest ways to fix them.

1.4 Analyze a real-world case study to show how a governance decision directly improved or hindered product/service quality.

**02. Develop quality frameworks aligned with organizational goals.**

2.1 Explain how a quality framework (like a Quality Management System) supports the specific mission and vision of a business.

2.2 Design a basic quality plan that includes specific Key Performance Indicators (KPIs) tied to a company's strategic objectives.

2.3 Justify why certain quality tools were chosen to meet specific organizational needs.

2.4 Propose a method for reviewing and updating the quality framework as the business goals change over time.

**03. Analyze different schools of thought in quality management.**

3.1 Compare the core principles of major quality gurus (e.g., Deming, Juran, or Crosby) and how they differ in their approach.

	<p>3.2 Discuss the reasoning behind choosing a "Total Quality Management" (TQM) approach versus a "Compliance-based" approach.</p> <p>3.3 Apply a specific quality philosophy to solve a common operational problem in a complex work environment.</p> <p>3.4 Critique which school of thought is most effective for a modern, high-tech industry compared to a traditional manufacturing setting.</p>
<p><b>04. Assess the scope of CSR within governance contexts.</b></p>	<p>4.1 Explain the role of Corporate Social Responsibility (CSR) in modern corporate governance and quality standards.</p> <p>4.2 Evaluate how ethical sourcing and environmental impact affect the overall quality reputation of a brand.</p> <p>4.3 Review a company's CSR policy and assess how well it is integrated into their daily quality control processes.</p> <p>4.4 Suggest improvements to a governance policy to ensure it better supports social and environmental sustainability.</p>
<p><b>05. Interpret regulations to guide senior-level compliance.</b></p>	<p>5.1 Explain the difference between mandatory legal regulations and voluntary quality standards for a specific industry.</p> <p>5.2 Summarize complex regulatory updates into a clear report for senior management to use for decision-making.</p> <p>5.3 Evaluate the legal and financial consequences of non-compliance within a broadly defined professional context.</p> <p>5.4 Create a compliance roadmap that ensures an organization stays updated with changing regional or international laws.</p>

## Unit 02 – Advanced Statistical Quality and Data Analytics

### *Learning outcome*

#### *The learner will:*

### *Assessment criterion*

#### *The learner can:*

<p><b>01 Use advanced statistics to interpret quality data.</b></p>	<p>1.1: Apply advanced statistical tests to identify patterns and trends within large sets of quality data.</p> <p>1.2: Calculate and interpret process capability indices to determine if a system meets required specifications.</p> <p>1.3: Use probability distributions to predict the likelihood of product defects or service failures.</p> <p>1.4: Present data findings using appropriate charts and graphs that clearly show quality performance over time.</p>
<p><b>02 Evaluate data models for predicting quality trends.</b></p>	<p>2.1: Compare different forecasting methods to determine which is most accurate for predicting future quality issues.</p> <p>2.2: Assess the reliability of specific data models when applied to non-routine or complex business scenarios.</p> <p>2.3: Identify the variables that have the most significant impact on quality outcomes within a predictive model.</p> <p>2.4: Explain how data modeling can be used to prevent quality failures before they occur in a production or service line.</p>
<p><b>03 Apply analytical tools to solve complex quality issues.</b></p>	<p>3.1: Select the most effective software or digital tools to analyze specific types of quality-related problems.</p> <p>3.2: Use data analytics tools to perform a Root Cause Analysis (RCA) on a complex process failure.</p> <p>3.3: Troubleshoot data inconsistencies that may lead to incorrect conclusions about quality performance.</p>

	<p>3.4: Create a digital dashboard or report that tracks real-time quality metrics for a specific department.</p>
<p><b>04 Critique the reasoning behind specific statistical methods.</b></p>	<p>4.1: Explain why a particular statistical method was chosen over another for a specific quality project.</p> <p>4.2: Evaluate the limitations of using certain statistical tests in environments with small or incomplete data sets.</p> <p>4.3: Discuss how the misuse of statistical data can lead to poor management decisions in a quality context.</p> <p>4.4: Justify the level of confidence required in statistical sampling to ensure results are representative of the whole process.</p>
<p><b>05 Justify strategic decisions using synthesized data.</b></p>	<p>5.1: Combine data from multiple sources to form a complete picture of an organization's quality status.</p> <p>5.2: Use data evidence to recommend specific changes to operational processes at a senior level.</p> <p>5.3: Evaluate the potential return on investment (ROI) for a proposed quality improvement based on data analysis.</p> <p>5.4: Defend a strategic quality plan by showing how it addresses the trends and risks identified in the data.</p>

## Unit 03 – Global Quality Standards and Compliance Systems

### *Learning outcome*

#### *The learner will:*

### *Assessment criterion*

#### *The learner can:*

<p><b>01 Analyze the influence of international frameworks on operations.</b></p>	<p>1.1: Explain how international standards (such as ISO) shape the daily operational procedures of a global business.</p> <p>1.2: Analyze the benefits of using recognized international frameworks to improve efficiency and customer trust.</p> <p>1.3: Evaluate how adopting global quality frameworks affects the internal resource planning of an organization.</p> <p>1.4: Discuss the role of international accreditation bodies in ensuring that operational quality meets global benchmarks.</p>
<p><b>02 Evaluate compliance strategies in diverse global environments.</b></p>	<p>2.1: Compare different approaches to maintaining quality compliance across countries with varying legal requirements.</p> <p>2.2: Assess the effectiveness of centralized versus decentralized compliance management systems for global firms.</p> <p>2.3: Identify the risks associated with non-compliance when operating in different international jurisdictions.</p> <p>2.4: Evaluate how cultural differences in different regions can impact the success of a global compliance strategy.</p>
<p><b>03 Harmonize global standards with local requirements.</b></p>	<p>3.1: Identify areas where international quality standards and local laws may overlap or differ.</p> <p>3.2: Develop a process to integrate global quality requirements into local site operations without breaking local rules.</p> <p>3.3: Create a checklist that ensures both global corporate standards and local health and safety laws are met simultaneously.</p> <p>3.4: Explain how to communicate global</p>

	quality expectations to local teams in a way that respects regional work practices.
<b>04 Interpret how global trade impacts quality strategy.</b>	<p>4.1: Analyze how changes in international trade agreements can force a shift in a company's quality control priorities.</p> <p>4.2: Evaluate the impact of import/export regulations on the selection of overseas suppliers and raw materials.</p> <p>4.3: Explain how global supply chain disruptions require flexible quality strategies to maintain product standards.</p> <p>4.4: Discuss how "rules of origin" and international labeling requirements influence final quality checks for exported goods.</p>
<b>05 Solve conflicts between regional and international standards.</b>	<p>5.1: Identify specific examples where regional quality expectations might contradict international best practices.</p> <p>5.2: Use a reasoned approach to decide which standard should take priority when a conflict in requirements occurs.</p> <p>5.3: Propose technical adjustments to a product or process to ensure it satisfies both regional and international auditors.</p> <p>5.4: Create a professional report that justifies the chosen solution for resolving a standard-related conflict to senior stakeholders.</p>

## Unit 04 – Advanced Audit and Enterprise Compliance

### *Learning outcome*

#### *The learner will:*

### *Assessment criterion*

#### *The learner can:*

<p><b>01 Evaluate the effectiveness of enterprise risk auditing.</b></p>	<p>1.1: Explain how enterprise risk auditing helps identify potential threats to an organization's goals.</p> <p>1.2: Evaluate how well an existing audit process uncovers hidden risks in complex departments.</p> <p>1.3: Analyze the link between regular risk audits and the overall financial stability of a business.</p> <p>1.4: Assess whether an audit provides enough evidence to satisfy senior management and external regulators.</p>
<p><b>02 Design audit plans for complex operational contexts.</b></p>	<p>2.1: Create a detailed audit schedule that covers multiple departments with different operational needs.</p> <p>2.2: Define clear objectives and scopes for an audit that target high-risk areas within a business.</p> <p>2.3: Select the appropriate resources, such as specialized staff or software, needed to conduct a thorough audit.</p> <p>2.4: Develop a communication plan to inform all relevant staff about their roles during the audit process.</p>
<p><b>03 Interpret audit findings to drive organizational change.</b></p>	<p>3.1: Identify the root causes of non-compliance found during an audit rather than just listing the symptoms.</p> <p>3.2: Categorize audit findings into "critical," "major," and "minor" to help the organization prioritize improvements.</p> <p>3.3: Suggest specific actions that management can take to fix recurring quality or safety issues.</p>

	<p>3.4: Create a follow-up system to check if the changes made after an audit have actually solved the problems.</p>
<p><b>04 Contrast different auditing methodologies and their uses.</b></p>	<p>4.1: Compare the benefits of "first-party" internal audits versus "third-party" external certification audits.</p> <p>4.2: Explain when to use a "vertical audit" (following one process) versus a "horizontal audit" (checking one requirement across all areas).</p> <p>4.3: Discuss the reasoning behind using "remote auditing" compared to "on-site" physical inspections.</p> <p>4.4: Evaluate which auditing style is most effective for a fast-changing digital environment compared to a stable factory setting.</p>
<p><b>05 Manage compliance systems within ethical boundaries.</b></p>	<p>5.1: Explain the importance of auditor independence and how to avoid "conflicts of interest" during an inspection.</p> <p>5.2: Create a code of conduct for staff to follow when reporting compliance issues or "whistleblowing."</p> <p>5.3: Evaluate how to handle sensitive data discovered during an audit while respecting privacy laws.</p> <p>5.4: Analyze a situation where ethical standards might conflict with business profits and propose a fair solution.</p>

## Unit 05 – Lean Six Sigma and Operational Excellence

### *Learning outcome*

#### *The learner will:*

### *Assessment criterion*

#### *The learner can:*

<p><b>01 Evaluate Lean Six Sigma within excellence strategies.</b></p>	<p>1.1: Explain how Lean Six Sigma principles contribute to the overall goal of achieving operational excellence.</p> <p>1.2: Evaluate the benefits of combining Lean (speed) and Six Sigma (accuracy) to improve business performance.</p> <p>1.3: Analyze how Lean Six Sigma helps an organization meet customer expectations and reduce operational costs.</p> <p>1.4: Assess the role of senior leadership in ensuring Lean Six Sigma projects align with the company's long-term strategy.</p>
<p><b>02 Apply improvement tools to reduce process waste.</b></p>	<p>2.1: Identify the "eight wastes" (DOWNTIME) in a specific work process and suggest ways to eliminate them.</p> <p>2.2: Use Value Stream Mapping (VSM) to distinguish between value-added and non-value-added activities in a process.</p> <p>2.3: Apply the 5S methodology to organize a workspace for maximum efficiency and reduced errors.</p> <p>2.4: Demonstrate how "Kaizen" (continuous improvement) events can be used to solve small, frequent process problems.</p>
<p><b>03 Analyze how culture affects methodology implementation.</b></p>	<p>3.1: Discuss how staff resistance to change can impact the success of a Lean Six Sigma rollout.</p> <p>3.2: Evaluate the importance of "employee buy-in" when moving from traditional working styles to a Lean culture.</p> <p>3.3: Analyze how different management styles can either support or hinder the adoption of operational excellence.</p>

	<p>3.4: Suggest methods for training and motivating teams to take ownership of quality improvement in their daily tasks.</p>
<p><b>04 Critique the selection of specific improvement tools.</b></p>	<p>4.1: Explain why a specific tool (e.g., Fishbone Diagram or 5 Whys) was chosen to solve a particular quality issue.</p> <p>4.2: Compare the effectiveness of different problem-solving tools in a complex manufacturing versus a service environment.</p> <p>4.3: Critique the limitations of using certain Lean tools if the underlying process data is inaccurate or unavailable.</p> <p>4.4: Justify the choice of using a "DMAIC" (Define, Measure, Analyze, Improve, Control) approach for a large-scale project.</p>
<p><b>05 Interpret data to measure the efficacy of interventions.</b></p>	<p>5.1: Use "Before and After" data comparisons to prove that an improvement project actually reduced waste or errors.</p> <p>5.2: Interpret Control Charts to ensure that a process remains stable and within limits after an intervention.</p> <p>5.3: Evaluate the financial impact of a Lean Six Sigma project by calculating the cost savings achieved.</p> <p>5.4: Create a final report for stakeholders that uses data to justify why a process change should be made permanent.</p>

## Unit 06 – Quality Leadership and Performance Management

### *Learning outcome*

#### *The learner will:*

### *Assessment criterion*

#### *The learner can:*

<p><b>01 Evaluate leadership styles in a quality-driven culture.</b></p>	<p>1.1: Compare different leadership styles (such as transformational or coaching) and their impact on a team's commitment to quality.</p> <p>1.2: Evaluate how a leader's behavior can encourage or discourage staff from reporting quality failures.</p> <p>1.3: Analyze the importance of "leading by example" in maintaining high standards across a department.</p> <p>1.4: Assess which leadership approach is most effective when managing a team through a high-pressure quality audit.</p>
<p><b>02 Analyze stakeholder perspectives on performance strategy.</b></p>	<p>2.1: Identify the different groups (stakeholders) who have an interest in a company's quality performance.</p> <p>2.2: Analyze how the needs of a customer might differ from the goals of a shareholder regarding quality and cost.</p> <p>2.3: Evaluate how to balance conflicting stakeholder demands when setting organizational performance targets.</p> <p>2.4: Use feedback from various stakeholders to suggest improvements to a current quality performance strategy.</p>
<p><b>03 Apply management theory to optimize team output.</b></p>	<p>3.1: Apply a recognized motivation theory (such as Maslow or Herzberg) to improve the productivity of a quality control team.</p> <p>3.2: Design a simple performance monitoring system that tracks both individual and team contributions to quality.</p> <p>3.3: Use team-building techniques to improve collaboration between different departments (e.g., Production and Quality).</p>

	<p>3.4: Explain how setting "SMART" goals can help a team stay focused on achieving specific quality milestones.</p>
<p><b>04 Manage the scope of change during quality transformations.</b></p>	<p>4.1: Explain why clearly defining the "scope" of a change project is necessary to prevent delays and confusion.</p> <p>4.2: Identify the potential risks that can occur when an organization switches to a new quality management system.</p> <p>4.3: Create a communication plan that keeps all staff informed and engaged during a major quality-related transition.</p> <p>4.4: Evaluate the success of a recent change by comparing the final results against the original project scope.</p>
<p><b>05 Develop reasoned approaches to conflict and performance.</b></p>	<p>5.1: Identify common causes of conflict within a quality team, such as disagreements over standards or workloads.</p> <p>5.2: Use a structured problem-solving approach to resolve a professional dispute between a quality inspector and a production supervisor.</p> <p>5.3: Develop a fair process for handling underperformance that focuses on support and retraining rather than just punishment.</p> <p>5.4: Justify the use of specific mediation techniques to restore a positive working environment after a team conflict.</p>




QualCert, the leading UK-based awarding body dedicated to providing a diverse range of technical and professional qualifications in the fields of occupational health and safety, quality control/quality assurance, civil/electrical/mechanical technology, ISO standards (Lead Auditors), and management courses.

At QualCert, we are committed to empowering individuals and organizations with the knowledge and skills necessary to excel in their respective industries. Whether you're looking to enhance your expertise in health and safety practices, quality management systems, or engineering technologies, our comprehensive suite of certifications caters to a wide spectrum of career paths and professional development goals.

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