QualCert Level 6 Diploma in Quality Control (QC)

Version 1.0 September 2024
QualCert Qualification number: QC01012

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

In an era of rapid technological advancement and tightening regulations, the role of Quality Control has evolved from simple "pass/fail" inspections to a sophisticated discipline involving data analytics, risk mitigation, and leadership.

This programme dives deep into the mechanics of **advanced quality assurance**, providing learners with the tools to oversee intricate process controls and audit systems. Whether in manufacturing, engineering, or service-based regulated sectors, this qualification ensures that your quality systems are both resilient and high-performing.

Course Objectives

The primary goal of this qualification is to transform practitioners into strategic quality leaders. To achieve this, the curriculum focuses on:

- **System Evaluation:** Developing the critical capacity to assess existing quality frameworks and identify systemic vulnerabilities.
- **Regulatory Mastery:** Ensuring a comprehensive understanding of legal and operational compliance within the UK and international frameworks.
- **Strategic Implementation:** Learning to deploy advanced control measures and audit cycles that align with organizational goals.
- **Data-Driven Leadership:** Utilizing statistical methods and structured problem-solving (such as Six Sigma or Lean methodologies) to influence decision-making at the executive level.

Aims

The QualCert Level 6 Diploma aims to:

- **Cultivate Expertise:** Provide an in-depth understanding of risk management and continuous improvement methodologies (e.g., PDCA, Root Cause Analysis).
- **Enhance Professional Credibility:** Establish a benchmark of excellence that signals to employers a high level of competence and dedication to industry standards.
- **Bridge Theory and Practice:** Encourage the application of academic concepts to real-world operational challenges, ensuring immediate ROI for organizations.
- **Promote Innovation:** Encourage a culture of "Quality by Design" where continuous improvement is embedded into the organizational DNA.

Qualification Framework

Qualification Title	QualCert Level 6 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	• Conducted by staff at the Approved Training Centre (ATC) to ensure qualification standards are met. • Internal Quality Assurance (IQA) by designated centre staff to maintain assessment integrity.
External Quality Assurance	• Overseen by QualCert verifiers who periodically review assessment and IQA procedures. • Ensures adherence to standards and consistency across all ATCs.

Entry Requirements

Age: 19+

Education: Level 5 qualification or equivalent

English Competency: Basic Understanding

Qualification Structure

The QualCert Level 6 Diploma in Quality Control (QC), comprises 120 credits, with a Total Qualification Time (TQT) of 1200 hours, including 600 Guided Learning Hours (GLH).

Mandatory Units				
Unit Ref No	**Unit Name**	**Credits**	**GLH**	**TQT**
QC01012-1	Quality Management Strategy and Leadership	20	100	200
QC01012-2	Quality Governance and Compliance Systems	20	100	200
QC01012-3	Data Analysis for Quality Improvement	20	100	200
QC01012-4	Risk Management and Quality Planning	20	100	200
QC01012-5	Data Analysis for Quality Improvement	20	100	200
QC01012-6	Process Optimisation and Operational Excellence	20	100	200

Centre Requirements

Centres delivering the QualCert Level 6 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 Governance & Theoretical Synthesis

1.1 Strategic Design of Quality Governance

At Level 6, learners do not just evaluate frameworks; they must justify the **architectural design** of quality systems tailored to organizational risk profiles.

- **Systems Synthesis:** Synthesize multiple international standards (e.g., ISO 9001, ISO 14001, and ISO 45001) into a single, cohesive Integrated Management System (IMS).
- **Corporate Strategy Integration:** Critically analyze the interplay between Quality Control and Corporate Social Responsibility (CSR), ESG (Environmental, Social, and Governance), and long-term financial forecasting.
- **Ethical & Legal Jurisprudence:** Evaluate the ethical implications of quality failures and navigate the complex legal precedents surrounding product liability and professional negligence in the UK.

1.2 Macro-Quantitative Intelligence

Level 6 moves beyond interpreting charts to **predictive modeling** and organizational-wide data strategy.

- **Predictive Quality Analytics:** Leverage Statistical Process Control (SPC) not just for monitoring, but for predictive modeling to prevent variance before it occurs.
- **Advanced Risk Quantification:** Utilize **Failure Mode and Effects Analysis (FMEA)** at a system-wide level, integrating RPN (Risk Priority Number) scores into the corporate risk register.
- **Cost of Quality (CoQ) Optimization:** Develop complex financial models to calculate the ROI of quality initiatives, distinguishing between prevention, appraisal, and internal/external failure costs to influence C-suite investment.

Part 2: High-Level Leadership & Systemic Innovation

2.1 Strategic Audit Management & Cultural Leadership

Competence is no longer just about leading an audit, but about managing the **audit universe** and the human element of quality.

- **Audit Universe Oversight:** Design a multi-year strategic audit programme that prioritizes high-risk operational areas based on business intelligence.
- **Change Management & Quality Culture:** Evaluate models of behavioral change (e.g., Kotter's or Lewin's) to embed a "Right First Time" culture across diverse, multi-disciplinary teams.
- **Supply Chain Ecosystem Governance:** Develop strategic frameworks for Global Supplier Quality Assurance (GSQA), ensuring compliance across complex, multi-tiered international supply chains.

2.2 Executive Reporting & Global Traceability

Communication at Level 6 is tailored for the boardroom, focusing on high-level accountability and transparency.

- **Executive Data Visualization:** Transform raw QC data into strategic "Quality Dashboards" that provide real-time visibility into organizational health for executive stakeholders.
- **Macro-CAPA Governance:** Oversee a "Systemic CAPA" framework that identifies cross-departmental trends, ensuring that corrective actions in one area do not create unintended risks in another.
- **Digital Traceability & Industry 4.0:** Design protocols for digital traceability using emerging technologies (e.g., Blockchain or IoT) to ensure end-to-end transparency in safety-critical environments.

Units – Learning Outcomes & Assessment Criteria

Unit 01 – Quality Management Strategy and Leadership

Learning outcome *The learner will:*	*Assessment criterion* *The learner can:*
01. Evaluate leadership styles that improve organizational quality performance.	1.1: Compare different leadership styles (e.g., Transformational vs. Transactional) and their impact on team quality output. 1.2: Explain how a leader's personal ethics and professional values influence the success of a Quality Management System (QMS). 1.3: Critically assess the role of senior management in providing the resources and authority needed for quality excellence. 1.4: Evaluate a real-world scenario where a specific leadership approach either improved or damaged a company's quality standards.
02. Align quality plans with the long-term goals of the business.	2.1: Analyze how a company's mission and vision statement should dictate its specific quality objectives. 2.2: Develop a quality roadmap that supports the organization's financial targets and market growth plans. 2.3: Explain how to balance the need for high-quality standards with the practical constraints of budget and time. 2.4: Demonstrate how to update a quality plan when the business changes its long-term strategic direction.
03. Create strategies to build a strong quality culture within teams.	3.1: Design a strategy to encourage staff engagement and "ownership" of quality processes at all levels of the workforce.

	3.2: Develop a communication plan that clearly explains the benefits of quality to non-technical departments. 3.3: Explain how to use rewards and recognition to reinforce a "Right First Time" attitude among employees. 3.4: Create a training framework to address resistance to change when new quality systems are introduced.
04. Analyze how global trends and technology change quality requirements.	4.1: Evaluate the impact of "Industry 4.0" (e.g., AI and automation) on traditional quality control and inspection methods. 4.2: Analyze how international trade agreements or global supply chain issues affect local quality compliance. 4.3: Critically assess the importance of environmental sustainability and "Green Quality" in modern industrial standards. 4.4: Research how emerging digital tools can be used to improve the speed and accuracy of quality reporting.
05. Develop senior-level plans to meet stakeholder quality expectations.	5.1: Identify key stakeholders (e.g., customers, regulators, investors) and categorize their specific quality requirements. 5.2: Create a "Quality Dashboard" or reporting tool designed specifically for review by senior executives and board members. 5.3: Explain the process for managing conflicting expectations between different stakeholders regarding quality vs. cost. 5.4: Propose a high-level plan for maintaining quality reputation during a major organizational crisis or change.

Unit 02 – Quality Governance and Compliance Systems	
Learning outcome ***The learner will:***	***Assessment criterion*** ***The learner can:***
01. Critique the legal and regulatory rules for quality in your industry.	1.1: Compare the specific UK and international laws that govern quality standards within your chosen sector. 1.2: Evaluate how local health, safety, and environmental regulations interact with quality control requirements. 1.3: Critically analyze the strengths and weaknesses of current industry-specific regulations in preventing product or service failure. 1.4: Explain how a change in government policy or international law can create new compliance challenges for a business.
02. Design systems that combine multiple standards like ISO into one framework.	2.1: Identify common requirements across different standards (e.g., ISO 9001 and ISO 14001) to create an Integrated Management System (IMS). 2.2: Design a single documentation structure that satisfies the needs of multiple regulatory bodies at once. 2.3: Explain how to manage resources effectively when implementing an integrated framework across different departments. 2.4: Demonstrate how an integrated system reduces paperwork and improves organizational efficiency compared to separate systems.
03. Explain the ethical and legal risks of failing to meet quality standards.	3.1: Analyze the legal consequences for a company and its directors if a product failure leads to harm or financial loss.

	3.2: Evaluate the ethical responsibility of a Quality Manager when balancing profit targets against strict safety standards. 3.3: Explain how "Whistleblowing" policies and ethical transparency help protect a company from long-term legal damage. 3.4: Assess a case study of a major quality failure and describe its impact on the company's brand reputation and stock value.
04. Use advanced methods to navigate complex and changing legal rules.	4.1: Develop a process for tracking and interpreting new updates to international quality standards (e.g., using regulatory alerts). 4.2: Propose a method for assessing the impact of new legal requirements on existing manufacturing or service processes. 4.3: Demonstrate how to use "Gap Analysis" to identify where a company's current systems do not meet new legal rules. 4.4: Create a strategy for training staff quickly when there is a major change in industry compliance laws.
05. Update company policies to stay compliant with international benchmarks.	5.1: Conduct a formal review of an existing quality policy to ensure it meets the latest international best practices. 5.2: Draft a new policy section that addresses modern challenges like data privacy (GDPR) or digital security in quality control. 5.3: Explain the process for getting "Buy-in" from senior management when significant policy changes are required for compliance.

	5.4: Design a version control and distribution system to ensure all staff are working with the most up-to-date compliance policies.

Unit 03 – Data Analysis for Quality Improvement	
Learning outcome ***The learner will:***	***Assessment criterion*** ***The learner can:***
01 Plan a long-term audit schedule based on the highest business risks.	1.1: Categorize different areas of the business by risk level (e.g., high-risk production lines vs. low-risk administration) to prioritize audit frequency. 1.2: Design an annual audit calendar that covers all critical quality standards while managing available staff and time. 1.3: Explain how to adjust an audit schedule when unexpected events occur, such as a major customer complaint or a breakdown in machinery. 1.4: Justify why certain departments or suppliers require more frequent auditing based on their past performance data.
02 Lead complex audits in environments with many different moving parts.	2.1: Demonstrate how to coordinate a multi-disciplinary audit team across different departments or geographical locations. 2.2: Apply techniques for managing "audit scope" to ensure that complex processes are reviewed thoroughly without getting distracted by minor details. 2.3: Explain how to handle difficult situations during an audit, such as uncooperative staff or conflicting evidence from different sources. 2.4: Conduct a closing meeting that clearly communicates findings to department heads in a professional and constructive manner.
03 Use audit results to find deep system failures rather than just small mistakes.	3.1: Analyze a set of audit findings to determine if errors are "one-off" human mistakes or "systemic" failures in the company's process.

		3.2: Use Root Cause Analysis (RCA) tools to trace a physical defect back to a failure in management planning or training. 3.3: Evaluate how multiple small non-conformities in different areas can combine to create a major risk for the entire organization. 3.4: Propose long-term corrective actions that fix the "root" of the problem to prevent it from ever happening again.
04	**Set high-level targets (KPIs) to measure the success of quality systems.**	4.1: Develop a set of "Key Performance Indicators" (KPIs) that measure quality from different angles (e.g., customer satisfaction, waste reduction, and audit pass rates). 4.2: Explain the difference between "leading indicators" (predicting future quality) and "lagging indicators" (measuring past results). 4.3: Create a system for collecting and verifying the accuracy of the data used to track these quality targets. 4.4: Demonstrate how to use KPI data to identify when a quality system is starting to decline before a major failure occurs.
05	**Write executive reports that show leaders how to improve the organization.**	5.1: Synthesize technical audit data into a concise summary that focuses on the information senior leaders need for decision-making. 5.2: Use professional data visualization (e.g., charts or trend lines) to clearly show quality performance over time to non-technical stakeholders. 5.3: Provide evidence-based recommendations for resource investment (e.g., new technology or more staff) based on audit and KPI results. 5.4: Draft a formal "Management Review" report that highlights both the successes of

	the quality system and the areas where the business is most vulnerable.

Unit 04 – Risk Management and Quality Planning	
Learning outcome ***The learner will:***	***Assessment criterion*** ***The learner can:***
01 Compare advanced tools for finding and assessing risk in supply chains.	1.1: Evaluate the effectiveness of different risk assessment tools (e.g., FMEA, Bowtie Analysis, or PESTLE) when applied to global supply chains. 1.2: Compare how "Quantitative" risk tools (using numbers/data) and "Qualitative" risk tools (using expert opinion) differ in their results. 1.3: Analyze how specific supply chain risks, such as raw material shortages or shipping delays, can impact the final quality of a product. 1.4: Justify the selection of a specific risk tool for a given industry scenario based on the complexity of the "interacting factors" involved.
02 Design quality plans that prevent problems before they happen in busy workplaces.	2.1: Create a "Proactive Quality Plan" that identifies potential failure points in a high-pressure production or service environment. 2.2: Design "Poka-Yoke" (error-proofing) methods to be integrated into daily workflows to prevent human error. 2.3: Explain how to set "early warning" triggers in a quality plan that alert staff before a process goes out of control. 2.4: Demonstrate how to involve floor-level staff in the planning process to ensure that prevention strategies are practical and realistic.
03 Measure how much a quality risk could cost or damage the organization.	3.1: Calculate the "Cost of Quality" (CoQ) by identifying expenses related to prevention, inspection, and both internal and external failures.

		3.2: Evaluate the potential "hidden costs" of a quality failure, such as damage to brand reputation, loss of customer trust, and future legal fees. 3.3: Use a Risk Matrix to determine the financial "Impact" versus the "Likelihood" of a specific quality threat. 3.4: Propose a budget for a quality improvement project by showing how the investment will save the company money in the long term.
04	**Build detailed risk registers that track technical and financial threats.**	4.1: Develop a comprehensive Risk Register that lists technical threats (e.g., equipment failure) alongside financial threats (e.g., rising material costs). 4.2: Assign "Risk Owners" within a register to ensure clear accountability for monitoring and managing each identified threat. 4.3: Create a scoring system within the register to prioritize which risks need immediate action and which can be monitored over time. 4.4: Demonstrate how to regularly review and update the risk register to reflect changes in the workplace or the wider market.
05	**Create backup plans to keep quality high during unexpected emergencies.**	5.1: Design a "Business Continuity Plan" specifically for the Quality Department to ensure standards are met during power outages or staff shortages. 5.2: Create a protocol for "Emergency Change Management" to ensure quality is not sacrificed when making quick decisions during a crisis. 5.3: Explain the process for identifying and approving "backup suppliers" who can meet the same quality standards as the primary source.

	5.4: Propose a method for testing or "simulating" an emergency plan to find and fix any weaknesses before a real crisis occurs.

Unit 05 – Data Analysis for Quality Improvement	
Learning outcome ***The learner will:***	***Assessment criterion*** ***The learner can:***
01 Use statistical tools to find patterns in complex sets of quality data.	1.1: Apply statistical methods (such as Mean, Median, and Standard Deviation) to identify the "average" performance and "spread" of a process. 1.2: Use Pareto Analysis to distinguish between the "vital few" problems that cause the most defects and the "trivial many." 1.3: Create Scatter Diagrams to determine if there is a relationship (correlation) between two different variables in a production process. 1.4: Interpret Control Charts to identify "special cause" variation that indicates a process is no longer stable.
02 Predict how well a process will work using capability indices (C_p and C_{pk}).	2.1: Calculate the C_p index to determine the potential capability of a process if it were perfectly centered. 2.2: Calculate the C_{pk} index to measure the actual performance of a process in relation to its specification limits. 2.3: Explain the practical difference between a process being "in control" (stable) versus being "capable" (meeting customer needs). 2.4: Use capability data to recommend whether a process needs a major redesign or just minor adjustments to stay within limits.
03 Combine different data sources into clear dashboards for senior managers.	3.1: Synthesize data from different departments (e.g., production, waste, and customer service) into a single, cohesive quality report. 3.2: Design a digital dashboard that uses "Red-Amber-Green" (RAG) status indicators to show real-time quality health.

	3.3: Explain how to choose the right type of chart (e.g., bar, line, or pie) to communicate specific quality trends to non-technical leaders. 3.4: Demonstrate how to summarize thousands of data points into a "one-page" executive overview that highlights critical risks.
04 Calculate the "Cost of Quality" to prove the value of improvement projects.	4.1: Identify and categorize "Prevention Costs" (training/planning) and "Appraisal Costs" (testing/audits) within a business case. 4.2: Measure "Failure Costs," including the price of scrap, rework, and warranty claims resulting from poor quality. 4.3: Develop a financial comparison showing how increasing spending on "Prevention" reduces the overall "Total Cost of Quality." 4.4: Present a Return on Investment (ROI) calculation for a quality improvement tool or software to justify its purchase to the finance team.
05 Evaluate the accuracy of data coming from new digital and IoT systems.	5.1: Critically assess the reliability of automated data collection (IoT) compared to traditional manual data entry. 5.2: Design a process for "Data Validation" to ensure that digital sensors are calibrated and providing truthful information. 5.3: Explain the risks of "Big Data," such as collecting too much irrelevant information (noise) that hides real quality issues. 5.4: Evaluate how "Real-Time Data" changes the speed at which a Quality Manager must make decisions in a modern workplace.

Unit 06 – Process Optimisation and Operational Excellence	
Learning outcome ***The learner will:***	***Assessment criterion*** ***The learner can:***
01 Evaluate methods like Lean and Six Sigma for improving efficiency.	1.1: Compare the core principles of Lean (waste reduction) and Six Sigma (variance reduction) to determine which is best for a specific workplace problem. 1.2: Critically analyze the "Eight Wastes" of Lean and identify which ones are most common in your current industry. 1.3: Explain how the DMAIC (Define, Measure, Analyze, Improve, Control) framework provides a structured approach to solving quality issues. 1.4: Evaluate a case study where the wrong improvement method was used and propose a more suitable alternative.
02 Lead improvement cycles (PDCA) to fix complicated or unclear processes.	2.1: Design a "Plan-Do-Check-Act" (PDCA) cycle to address a recurring quality issue in a department with many interacting factors. 2.2: Demonstrate leadership by coordinating a "Kaizen" event or a small-group improvement project to fix a specific workflow bottleneck. 2.3: Apply techniques for "Process Mapping" to visualize a complex task and identify steps that do not add value to the customer. 2.4: Evaluate the results of an improvement cycle and explain how to "Standardize" the new process so the problem does not return.
03 Use new technology to reduce waste and make operations smoother.	3.1: Propose a digital solution (e.g., automation, AI, or cloud-based tracking) to replace a slow or error-prone manual process. 3.2: Analyze how "Real-Time Monitoring" technology can reduce material waste by catching errors instantly.

	3.3: Explain the challenges of integrating new technology into existing legacy systems and how to manage the transition smoothly. 3.4: Demonstrate how digital data collection improves the speed of communication between the production floor and senior management.
04 Apply advanced practical skills to solve quality issues in unpredictable situations.	4.1: Develop a fast-response "Troubleshooting Guide" for teams to use when unexpected equipment or system failures occur. 4.2: Use advanced cognitive skills to make a high-stakes quality decision when full data is not yet available during a crisis. 4.3: Explain how to maintain "process stability" when there is a sudden change in raw material quality or a loss of key staff. 4.4: Demonstrate "Occupational Competence" by successfully resolving a quality non-conformity that involved multiple conflicting department interests.
05 Assess how improving processes helps a company stay ahead of competitors.	5.1: Evaluate the link between "Operational Excellence" and a company's ability to offer lower prices or faster delivery than its rivals. 5.2: Analyze how a reputation for "Zero Defects" can be used as a strategic marketing tool to win new business contracts. 5.3: Explain how continuous improvement makes an organization more "Agile" and better able to react to sudden market changes. 5.4: Create a presentation for stakeholders showing how process optimization directly improves the company's "Bottom Line" and long-term survival.

QualCert.

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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