

Quality Audits:

A quality audit is a systematic and independent process used to evaluate the effectiveness and conformance of a Quality Management System (QMS) against internal procedures, external standards, and regulatory requirements. A quality audit involves collecting objective audit evidence to assess whether quality objectives are being achieved.

Objectives of a Quality Audit?

A quality audit serves multiple purposes, each contributing to the overall strength and effectiveness of the QMS.

Below are the key objectives that organizations aim to achieve through quality audits.

- **Ensuring Compliance with Applicable Requirements:** Quality audits verify alignment with internal procedures, industry standards, and regulatory frameworks. Ensuring compliance with applicable requirements minimizes the risk of nonconformance and supports certification and regulatory approval.
- **Identifying Non-Conformities and Areas for Improvement:** Quality audits help detect process deviations, documentation gaps, and process inefficiencies that may impact the quality of products or services. Findings are addressed through CAPA to strengthen the QMS and reduce recurrence.
- **Verifying the Effectiveness of the Quality Management System:** Quality audits assess whether QMS processes function as intended and deliver expected outcomes. This includes evaluating performance against quality objectives, process controls, and documented procedures.
- **Supporting Continuous Improvement Initiatives:** Quality audit results support improvement strategies by highlighting recurring issues, process inefficiencies, or quality risks. Organizations can utilize this data to refine their workflows and enhance outcomes.
- **Evaluating Risk Management Practices:** Quality audits assess how well risk-based thinking is implemented within the QMS, as required by standards such as ISO 9001:2015, ISO 13485:2016, and others. Quality audits ensure that risks are identified, documented, monitored, and effectively mitigated.

Types of Quality Audits

Quality audits are typically categorized into the following types.

- **Internal Audits:** Internal audits, also known as first-party audits, are conducted by employees within the organization who are independent of the processes being audited. They evaluate compliance with internal procedures and applicable requirements and help identify areas for improvement before external assessments.
- **External Audits:** External audits are audits performed by outside entities and include second-party and third-party audits. Second-party audits are carried out by customers or stakeholders, while third-party audits are conducted by independent certification bodies.

Internal Audits

An internal audit is a systematic evaluation of an organization's QMS. An internal audit is conducted to determine whether processes comply with internal procedures and applicable requirements. Internal audit is referred to as a first-party audit or self-inspection because it is initiated and performed by the organization itself. The scope of internal audits may cover specific processes, products, departments, or the entire QMS. Internal audits assess whether documented procedures, policies, and practices align with internal quality objectives, customer requirements, and external requirements.

External Audits

An external audit is a formal, independent evaluation of an organization's QMS, performed by an outside entity. External audits may assess the entire QMS or focus on specific processes, products, or operational sites, depending on the audit scope and objectives.

- They may be categorized as a second-party or third-party audit.
- Third-party external audits are conducted by an independent organization with no direct interest in the organization's operations, such as a certification body or regulatory authority.

Scopes of Quality Audits

In the context of a quality audit, scope refers to the specific area or focus being evaluated. Based on the scope, quality audits can be categorized into three main types listed below.

- **Process Audit:** A process audit evaluates whether a specific process operates according to predefined procedures, regulatory requirements, and quality standards. A process audit focuses on reviewing inputs, controls, and outputs, and examining documents such as procedures, work instructions, training logs, and job descriptions to ensure consistency, effectiveness, and compliance.
- **Product Audit:** A product audit evaluates whether a finished product or in-process item meets defined specifications, safety standards, and customer requirements. A product audit typically involves physical inspection, functional testing, and verification activities to confirm the product meets documented performance criteria and intended outcomes.
- **System Audit:** A system audit reviews the entire QMS to determine whether all elements are effectively developed, implemented, and maintained following applicable requirements and contractual commitments. A system audit evaluates how processes interact, whether documentation aligns with regulatory and customer expectations, and how well the system supports overall quality objectives.

Key Phases of a Quality Audit Process

The key phases of a quality audit process include the steps listed below.

- **Audit Planning and Scheduling:** This phase involves defining the audit scope, objectives, and criteria, as well as selecting qualified and impartial auditors. A clear audit plan ensures that audits are risk-based, resource-efficient, and aligned with regulatory requirements and organizational priorities.
- **Audit Execution:** The execution phase includes collecting objective evidence through interviews, observations, and document reviews. The goal is to assess conformity with documented procedures and applicable requirements, and to identify nonconformities or opportunities for improvement.
- **Documentation and Reporting:** Audit findings are documented in a formal audit report, which includes identified nonconformities, observations, and examples of

positive practices. The report is shared with relevant stakeholders for review, management action, and quality improvement planning.

- **Follow-Up and Closure:** The follow-up of the audit includes implementing and verifying corrective actions to address identified findings. The audit is officially closed once all actions are confirmed effective, supporting the continual improvement of the QMS.

Post Quality Audit Activities

Post-audit activities are the actions taken after an audit to address findings, verify corrective measures, and strengthen the quality management system.

Below are listed common post-audit activities.

- **Audit Report Distribution:** Final audit reports are shared with relevant stakeholders, such as department heads, quality leadership, or external parties, when required. Proper distribution ensures visibility, transparency, and accountability of the audit results.
- **Management Review:** Audit results and trends are discussed during management review meetings to evaluate systemic risks and overall quality performance. These reviews support strategic decision-making and demonstrate leadership engagement in continuous improvement.
- **Corrective Action Implementation:** Identified nonconformities are addressed through documented corrective actions to prevent recurrence. Responsibilities, deadlines, and action plans are clearly defined to ensure accountability.
- **Updating Procedures or Documentation:** Relevant SOPs, work instructions, or QMS documentation are revised if the audit reveals gaps or outdated materials. Updates ensure continued accuracy, compliance, and operational clarity.
- **Corrective Action Verification:** The quality or audit team confirms that the implemented corrective actions have been properly implemented and are effective in addressing the identified issues. Verification activities may include reviewing updated procedures, conducting interviews, or analysing process performance data to ensure sustained improvement.
- **Closing Nonconformance Records:** Nonconformity records are officially closed once corrective actions are implemented, verified, and documented. Closure indicates audit resolution and compliance with requirements.

- **Audit Record Archiving:** All audit-related documentation, including checklists, reports, and CAPA logs, is archived according to the organization's document retention policies. Proper archiving ensures traceability and supports future audits and regulatory inspections by providing accessible, verifiable evidence of past audit activities and corrective actions.
- **Audit Effectiveness Assessment:** An audit evaluation is conducted to determine whether the audit process and corrective actions achieved the intended improvements. This analysis helps enhance future audit planning and execution.
- **Trend Analysis of Audit Findings:** Audit data is analyzed over time to identify recurring issues, systemic weaknesses, or emerging risks. These insights support proactive risk management and continuous quality improvement.
- **Employee Feedback and Lessons Learned:** Feedback from auditors and auditees is collected to improve audit methodology, communication, and efficiency. Lessons learned are incorporated into future audit cycles to enhance performance.
- **Training and Competency Refreshers:** Targeted training is conducted to address knowledge gaps or reinforce regulatory and procedural expectations revealed during the audit. Such training ensures workforce readiness and compliance.
- **Integration into Risk Management Processes:** Audit results are incorporated into the organization's risk register or risk-based thinking strategy. Incorporating audit results into risk management ensures that nonconformities inform broader risk assessments and mitigation planning.
- **Supplier or Contractor Notification (if applicable):** Relevant partners are notified when audit findings affect suppliers or outsourced services. Notifying affected partners encourages joint responsibility and drives corrective actions across the supply chain.
- **Regulatory Notification (if required):** The organization may need to notify regulatory authorities such as the FDA, EMA, or notified bodies if serious compliance issues are uncovered. Transparency ensures ongoing regulatory alignment and trust.
- **Audit Program Review and Refinement:** Insights from completed audits are used to evaluate and improve the audit program's structure, scope, frequency, and auditor performance. Continuous improvement of the program ensures relevance and effectiveness.
- **Digital System Updates :** For organizations using QMS software, audit outcomes may lead to updates in digital workflows, audit templates, and document control systems.

A Quality Council is a high-level, strategic body, often composed of senior management, tasked with leading an organization's Total Quality Management (TQM) efforts, setting quality goals, and driving continuous improvement. It defines quality policies, monitors performance metrics, and fosters a culture focused on excellence.

- **Definition:** A Quality Council (QC) is a strategic, top-level committee that provides direction, resources, and oversight for an organization's quality **improvement initiatives and TQM implementation.**

Responsibilities of the Quality Council include:

- **Accreditation and Standards:** Creating mechanisms for independent, third-party assessment of products, processes, and personnel.
- **Quality Promotion:** Promoting the adoption of quality management standards and quality tools across all sectors.
- **International Recognition:** Promoting bilateral/multilateral recognition arrangements with international accreditation bodies.
- **Benchmarking:** Establishing quality improvement and benchmarking centers to share best national and international practices.
- **Training and Education:** Organizing training programs, workshops, and seminars to enhance quality awareness.
- **Strategic Direction:** Setting the quality vision, values, and policies to align with national goals, such as fostering a TQM (Total Quality Management) culture.
- **Support Initiatives:** Supporting improvement teams, reviewing progress, and overseeing recognition/reward systems for quality achievements.

Employee Involvement:

Employee involvement in Total Quality Management (TQM) means empowering all staff to contribute ideas, solve problems, and make decisions for continuous improvement, recognizing that those doing the work know best how to enhance quality, productivity, and customer satisfaction through training, teamwork, empowerment, and feedback, fostering a culture of shared goals and ownership.

Some of the important aspects of employee involvement are,

1. Employee motivation
2. Employee empowerment
3. Recognition and reward schemes
4. Teams and teamwork
5. Performance appraisal

Benefits:

- **Improved Quality & Productivity:** Employees closest to the work can find practical solutions.
- **Higher Job Satisfaction:** Increased ownership and contribution lead to better morale.
- **Stronger Commitment:** Employees feel valued and aligned with organizational goals.
- **Faster Problem Solving:** Diverse perspectives and expertise speed up issue resolution.
- **Enhanced Competitiveness:** A motivated, quality-focused workforce drives overall success.