

Quality Audit Checklist

A quality audit checklist for auditing a quality management system (QMS).

Plan the audit

- ☐ Define the audit scope, objectives and processes to cover.
- ☐ Confirm the standard and criteria to audit against.
Use the applicable standard such as ISO 9001 and your QMS documents.
- ☐ Review previous audit reports and open corrective actions.
- ☐ Prepare the audit plan and schedule with the auditee.
- ☐ Assign auditors who are independent of the area audited.
- ☐ Notify the relevant staff and confirm availability.

Quality system and documents

- ☐ Confirm the quality policy and objectives are defined and communicated.
- ☐ Verify documented procedures exist for key processes.
- ☐ Check documents are controlled, current and approved.
- ☐ Confirm obsolete documents are removed from use.
- ☐ Verify roles, responsibilities and authority are defined.
- ☐ Check the scope of the QMS matches the standard's requirements.

Process conformity

- ☐ Confirm processes are carried out as documented.
- ☐ Verify acceptance criteria and process controls are applied.
- ☐ Check measuring and monitoring equipment is calibrated.
- ☐ Confirm suppliers are approved and controlled.
- ☐ Verify nonconforming product is identified and controlled.
- ☐ Check staff are trained and competent for their tasks.

Records and evidence

- ☐ Sample records to confirm requirements are met in practice.
- ☐ Check records are complete, legible and retained as required.
- ☐ Verify traceability of materials, lots and inspections.
- ☐ Confirm calibration and training records are current.
- ☐ Review management review and internal audit records.
- ☐ Document objective evidence for each audit finding.

Findings and nonconformities

- ☐ Record each finding against the relevant requirement or clause.
- ☐ Classify nonconformities as major or minor.
- ☐ Note observations and opportunities for improvement.
- ☐ Confirm findings with the auditee to agree the facts.
- ☐ Summarize positive findings and areas of strength.
- ☐ Prepare a clear, evidence-based audit conclusion.

Report and follow-up

- ☐ Issue the audit report to the relevant stakeholders.
- ☐ Agree corrective actions with owners and due dates.
- ☐ Require root cause analysis for nonconformities.
- ☐ Verify corrective actions are implemented and effective.
- ☐ Close out findings once evidence confirms resolution.
- ☐ Feed results into the management review and next audit plan.