Quality Audit Checklist

A quality audit checklist for a QMS, with an ISO 9001:2015 clause-by-clause check (clauses 4-10) plus planning, evidence, findings and follow-up.

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.

ISO 9001:2015 Clause Check

- [ ] Clause 4, Context: QMS scope, interested parties, and processes and their interactions are defined
- [ ] Clause 5, Leadership: quality policy is communicated and roles, responsibilities and authorities are assigned
- [ ] Clause 6, Planning: risks and opportunities are addressed and measurable quality objectives are set
- [ ] Clause 7, Support: resources, competence records, awareness and control of documented information are in place
- [ ] Clause 8, Operation: requirements are reviewed and design, purchasing, production and nonconforming outputs are controlled
- [ ] Clause 9, Performance evaluation: monitoring, customer satisfaction, internal audits and management review are carried out
- [ ] Clause 10, Improvement: nonconformities get corrective action with root-cause analysis, and continual improvement is evident

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.