QMS Audit Checklist

Quality Management System Audit | ISO 9001:2015 Coverage

Organization:	_____	**Site / Location:**	_____
Audit Date:	_____	**Auditor Name:**	_____
Audit Type:	■ Internal ■ Supplier ■ Third Party	**Standard / Framework:**	■ ISO 9001 ■ HACCP ■ BRC ■ SQF ■ Other

How to use this checklist: Mark ■ Conforming | ■ Non-Conforming | ■ Not Applicable. Record objective evidence, observations, and corrective action references in the Notes column. All non-conformances must be formally documented with root cause analysis and a time-bound corrective action.

SECTION 1: Context and Leadership | ISO 9001:2015 Clauses 4–5

#	Audit Requirement	Status	Evidence / Notes
1	The scope of the QMS is defined, documented, and includes justification for any exclusions (Clause 4.3)	▪ C ▪ NC ▪ N/A	
2	Interested parties — customers, regulators, suppliers — and their requirements have been identified and are reviewed periodically (Clause 4.2)	▪ C ▪ NC ▪ N/A	
3	Internal and external issues relevant to the QMS purpose are identified and monitored (Clause 4.1)	▪ C ▪ NC ▪ N/A	
4	Quality policy is documented, communicated, and understood at all levels of the organization (Clause 5.2)	▪ C ▪ NC ▪ N/A	
5	Quality objectives are measurable, monitored, and aligned with the quality policy (Clause 6.2)	▪ C ▪ NC ▪ N/A	
6	Roles, responsibilities, and authorities for quality-relevant functions are defined, documented, and communicated (Clause 5.3)	▪ C ▪ NC ▪ N/A	
7	Management review records demonstrate active leadership engagement with QMS performance data (Clause 9.3)	▪ C ▪ NC ▪ N/A	
8	Top management demonstrates leadership and commitment to the QMS — not delegated entirely to quality function (Clause 5.1)	▪ C ▪ NC ▪ N/A	

SECTION 2: Risk Management and Planning | ISO 9001:2015 Clause 6

#	Audit Requirement	Status	Evidence / Notes
1	Risks and opportunities affecting the QMS have been identified, documented, and assessed (Clause 6.1)	■ C ■ NC ■ N/A	
2	Actions to address risks are planned, implemented, and their effectiveness is evaluated (Clause 6.1)	■ C ■ NC ■ N/A	
3	Changes to the QMS are planned and managed systematically — not informally implemented (Clause 6.3)	■ C ■ NC ■ N/A	
4	Quality objectives have defined timelines, responsible owners, and measurement methods (Clause 6.2)	■ C ■ NC ■ N/A	
5	Planning for achieving quality objectives is documented and resourced (Clause 6.2)	■ C ■ NC ■ N/A	

SECTION 3: Support and Resources | ISO 9001:2015 Clause 7

#	Audit Requirement	Status	Evidence / Notes
1	Competence requirements for quality-related roles are defined and training/qualification records are current (Clause 7.2)	■ C ■ NC ■ N/A	
2	Awareness of the quality policy and QMS objectives is demonstrated across all relevant personnel (Clause 7.3)	■ C ■ NC ■ N/A	
3	Documented information — documents and records — is controlled, current, and accessible (Clause 7.5)	■ C ■ NC ■ N/A	
4	Calibration and maintenance records for monitoring and measuring equipment are current (Clause 7.1.5)	■ C ■ NC ■ N/A	
5	Internal and external communications relevant to the QMS are managed systematically (Clause 7.4)	■ C ■ NC ■ N/A	
6	Infrastructure and work environment necessary for conforming product/service delivery are provided and maintained (Clause 7.1)	■ C ■ NC ■ N/A	
7	Knowledge required for QMS operation is identified, maintained, and protected (Clause 7.1.6)	■ C ■ NC ■ N/A	

SECTION 4: Operational Controls | ISO 9001:2015 Clause 8

#	Audit Requirement	Status	Evidence / Notes
1	Customer requirements — including statutory and regulatory — are reviewed and agreed before commitments are made (Clause 8.2)	■ C ■ NC ■ N/A	
2	Design and development processes (if applicable) are planned, controlled, and documented with appropriate reviews (Clause 8.3)	■ C ■ NC ■ N/A	
3	Supplier and contractor controls are defined based on risk and impact on product/service quality (Clause 8.4)	■ C ■ NC ■ N/A	
4	Production and service delivery processes are carried out under controlled conditions with documented procedures (Clause 8.5)	■ C ■ NC ■ N/A	
5	Product and service verification activities — inspections, tests — are performed at appropriate stages (Clause 8.6)	■ C ■ NC ■ N/A	
6	Non-conforming outputs are identified, segregated, and managed through a documented non-conformance process (Clause 8.7)	■ C ■ NC ■ N/A	
7	Records of product/service conformity and customer-required traceability are maintained (Clause 8.5.2)	■ C ■ NC ■ N/A	
8	Post-delivery activities are defined and fulfilled where applicable — warranty, service, recall (Clause 8.5.5)	■ C ■ NC ■ N/A	
9	Change control processes ensure changes to production or service delivery are reviewed and authorized (Clause 8.5.6)	■ C ■ NC ■ N/A	

SECTION 5: Performance Evaluation | ISO 9001:2015 Clause 9

#	Audit Requirement	Status	Evidence / Notes
1	Customer satisfaction is measured using defined methods at planned intervals and results are analyzed (Clause 9.1.2)	■ C ■ NC ■ N/A	
2	Internal QMS audit program is documented with planned schedules, scope, criteria, and methods (Clause 9.2)	■ C ■ NC ■ N/A	
3	Internal QMS audit records demonstrate auditor independence, risk-based scope, and impartial findings (Clause 9.2)	■ C ■ NC ■ N/A	
4	Key performance indicators for quality objectives are monitored, analyzed, and reported to management (Clause 9.1)	■ C ■ NC ■ N/A	
5	Management review meetings are conducted at planned intervals with all required inputs documented (Clause 9.3)	■ C ■ NC ■ N/A	
6	Management review outputs include decisions and actions related to improvement opportunities (Clause 9.3.3)	■ C ■ NC ■ N/A	
7	Analysis of quality data is being used to evaluate QMS performance and identify trends (Clause 9.1.3)	■ C ■ NC ■ N/A	
8	Internal QMS audit results are fed into the management review process — not treated as separate activities (Clause 9.3.2)	■ C ■ NC ■ N/A	

SECTION 6: Improvement and Corrective Action | ISO 9001:2015 Clause 10

#	Audit Requirement	Status	Evidence / Notes
1	Non-conformances are documented using a structured process that includes root cause analysis (Clause 10.2)	▪ C ▪ NC ▪ N/A	
2	Corrective actions are time-bound, assigned to named owners, and tracked to formal completion (Clause 10.2)	▪ C ▪ NC ▪ N/A	
3	Effectiveness of corrective actions is verified with objective evidence before they are formally closed (Clause 10.2)	▪ C ▪ NC ▪ N/A	
4	Corrective actions address root causes — not just the immediate symptom or occurrence (Clause 10.2.1)	▪ C ▪ NC ▪ N/A	
5	Similar processes and products are reviewed when a non-conformance is identified — systemic review (Clause 10.2.1)	▪ C ▪ NC ▪ N/A	
6	Continual improvement activities are planned and explicitly linked to QMS performance data (Clause 10.3)	▪ C ▪ NC ▪ N/A	
7	Lessons learned from non-conformances are applied to prevent recurrence across similar processes (Clause 10.2)	▪ C ▪ NC ▪ N/A	
8	Opportunities for improvement identified during audits are formally logged and actioned — not just noted (Clause 10.1)	▪ C ▪ NC ▪ N/A	

Audit Summary & Sign-Off

Total Items: _____ **Conforming (C):** _____ **Non-Conforming (NC):** _____ **Not Applicable:** _____

Major Non-Conformances:	Describe briefly (attach corrective action records):
	_____
	_____
	_____
Minor Non-Conformances / Observations:	_____
	_____
	_____

Lead Auditor Signature:	_____	**Date:**	_____
Management Acknowledgment:	_____	**Date:**	_____
Next Review Date:	_____	**Document Reference:**	_____

This checklist was generated by Qualsmart.ai — Tech-Enabled eQMS. It covers ISO 9001:2015 requirements and can be adapted to HACCP, BRC, SQF, and other quality management frameworks. For digital QMS audit management, corrective action tracking, and multi-site compliance programs, visit qualsmart.ai.