SANTHIA CONSULTING

Manufacturing Excellence Toolkit · ISO 9001:2015

FREE RESOURCE

ISO 9001:2015 Gap Analysis Checklist

Identify your quality gaps and build your 90-day roadmap to certification.

7	28	90 Days
ISO Clauses	Requirements	To Certification

ISO 9001:2015 Gap Analysis Checklist

■ YES	Requirement is fully met and documented
■■ PARTIAL	Requirement is partially met or informally handled
■ NO	Requirement is not currently met
— N/A	Requirement does not apply to your operation

CLAUSE 4 — Context of the Organization

REF	REQUIREMENT	STATUS	NOTES / PRIORITY
4.1	Internal & external issues relevant to the QMS have been identified and documented		
4.2	Interested parties (customers, regulators, staff) and their requirements are identified		
4.3	The scope of the QMS is defined in writing and justified		
4.4	QMS processes, their sequence, and interactions are mapped and documented		

CLAUSE 5 — Leadership

REF	REQUIREMENT	STATUS	NOTES / PRIORITY
5.1	Top management demonstrates commitment to the QMS (meetings, resources, accountability)		
5.2	A Quality Policy is documented, approved, posted, and communicated to all staff		
5.3	QMS roles, responsibilities, and authorities are defined and communicated		

CLAUSE 6 — Planning

REF	REQUIREMENT	STATUS	NOTES / PRIORITY
6.1	Risks and opportunities related to quality have been identified and addressed		
6.2	Quality objectives are documented, measurable, monitored, and communicated		
6.3	A process exists to manage planned changes to the QMS in a controlled way		

CLAUSE 7 — Support

REF	REQUIREMENT	STATUS	NOTES / PRIORITY
7.1.1	Resources needed to operate and improve the QMS are identified and provided		
7.1.5	All monitoring/measuring equipment is identified, listed, and calibrated on schedule		
7.2	Competency requirements are defined per role; training records are maintained		
7.3	All staff are aware of the Quality Policy and their contribution to quality		
7.4	Internal and external quality communications are planned and executed		
7.5.1	Required documents and records are identified for all QMS processes		
7.5.2	All documents have version numbers, approval dates, and authorized signatures		
7.5.3	Documents are controlled: access, retrieval, protection, change, retention, disposal		

CLAUSE 8 — Operation

REF	REQUIREMENT	STATUS	NOTES / PRIORITY
8.1	Operational processes are planned and executed under controlled conditions		
8.2.2	Customer and product requirements are fully determined before order acceptance		
8.2.3	Requirements are reviewed and confirmed before commitment; records are kept		
8.4.1	Externally provided goods/services are evaluated and controlled for quality		
8.4.2	Type and extent of control over each supplier is defined		
8.5.1	Production runs under documented, controlled conditions (work instructions, etc.)		
8.5.2	Products are identified and traceable throughout production (lot codes, labels)		
8.6	Products are verified against acceptance criteria before release; records kept		
8.7	Nonconforming products are identified, segregated, documented, and dispositioned		

CLAUSE 9 — Performance Evaluation

REF	REQUIREMENT	STATUS	NOTES / PRIORITY
9.1.1	Process performance, product conformance, and QMS effectiveness are monitored		
9.1.2	Customer satisfaction is monitored and analyzed at defined intervals		
9.2	Internal audits are planned and conducted; records and findings are maintained		

REF	REQUIREMENT	STATUS	NOTES / PRIORITY
9.3	Management reviews are conducted; minutes cover all required inputs		

CLAUSE 10 — Improvement

REF	REQUIREMENT	STATUS	NOTES / PRIORITY
10.2	Nonconformities are documented; root cause analysis performed; CAPAs tracked		
10.3	Continual improvement of the QMS is actively pursued and evidenced over time		

SCORING GUIDE

90–100% YES	Audit-ready. Focus on documentation polish.
75–89% YES	Strong foundation. Formalize remaining gaps.
50–74% YES	Solid progress. Prioritize Clauses 7, 8, and 10.
25–49% YES	Significant work. Start with Clause 5 (Leadership).
Under 25%	Start from zero. Focus on Clause 5 first.