



Iso 9001 Audit Checklist

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Context of the Organization

- ☐ Internal/external issues determined
- ☐ Interested parties identified
- ☐ Their requirements understood
- ☐ Scope of QMS defined
- ☐ QMS processes determined
- ☐ Process interactions defined
- ☐ Process criteria established
- ☐ Resources determined
- ☐ Responsibilities assigned
- ☐ Risks and opportunities addressed
- ☐ Process monitoring planned
- ☐ Improvement opportunities identified

Leadership

- ☐ Leadership commitment demonstrated
- ☐ Customer focus maintained
- ☐ Quality policy established
- ☐ Policy communicated/understood
- ☐ Organizational roles assigned
- ☐ Responsibilities defined
- ☐ Authorities communicated
- ☐ Management review conducted
- ☐ Customer requirements determined
- ☐ Regulatory requirements identified
- ☐ Customer satisfaction monitored
- ☐ Continual improvement promoted

Planning

- ☐ Risks and opportunities identified
- ☐ Actions planned and integrated
- ☐ Effectiveness evaluated
- ☐ Quality objectives established
- ☐ Objectives measurable/monitored
- ☐ Planning to achieve objectives
- ☐ Changes planned systematically
- ☐ Resources considered

- ☐ Responsibilities assigned
- ☐ Timeframes established
- ☐ Evaluation methods defined
- ☐ Results documented

Support

- ☐ Resources determined/provided
- ☐ People competent/available
- ☐ Infrastructure maintained
- ☐ Environment suitable
- ☐ Monitoring resources calibrated
- ☐ Organizational knowledge managed
- ☐ Competence requirements defined
- ☐ Training effective
- ☐ Awareness ensured
- ☐ Communication planned
- ☐ Documented information controlled
- ☐ External provider controlled

Operation

- ☐ Operational planning conducted
- ☐ Customer requirements determined
- ☐ Design and development controlled
- ☐ External provision controlled
- ☐ Production/service controlled
- ☐ Product/service release controlled
- ☐ Nonconforming outputs controlled
- ☐ Customer communication effective
- ☐ Contingency plans prepared
- ☐ Post-delivery activities managed
- ☐ Changes controlled
- ☐ Requirements preserved

Performance Evaluation

- ☐ Monitoring/measurement planned
- ☐ Customer satisfaction measured
- ☐ Analysis and evaluation performed
- ☐ Internal audits conducted
- ☐ Audit program implemented
- ☐ Audit results reported
- ☐ Management review scheduled
- ☐ Review inputs comprehensive
- ☐ Review outputs actionable
- ☐ Evidence of improvement
- ☐ Effectiveness evaluated

- ☐ Trends analyzed

Improvement

- ☐ Improvement opportunities identified
- ☐ Nonconformities addressed
- ☐ Corrective actions taken
- ☐ Root causes analyzed
- ☐ Action effectiveness reviewed
- ☐ Preventive actions considered
- ☐ Continual improvement demonstrated
- ☐ Customer complaints resolved
- ☐ Process improvements implemented
- ☐ Innovation encouraged
- ☐ Best practices shared
- ☐ Lessons learned captured

Document Control

- ☐ Document control procedure exists
- ☐ Documents approved before use
- ☐ Documents reviewed/updated
- ☐ Changes identified
- ☐ Current versions available
- ☐ Documents legible/identifiable
- ☐ External documents controlled
- ☐ Obsolete documents prevented
- ☐ Records controlled
- ☐ Retention times defined
- ☐ Records protected/retrievable
- ☐ Electronic media controlled

Customer Focus

- ☐ Customer requirements determined
- ☐ Regulatory requirements identified
- ☐ Product requirements defined
- ☐ Contract review conducted
- ☐ Changes communicated
- ☐ Customer property controlled
- ☐ Customer feedback obtained
- ☐ Satisfaction measured
- ☐ Complaints handled effectively
- ☐ Customer needs anticipated
- ☐ Relationships managed
- ☐ Future needs considered

Process Approach

- ☐ Processes identified
- ☐ Sequence/interaction determined
- ☐ Criteria/methods defined
- ☐ Resources available
- ☐ Responsibilities assigned
- ☐ Risks addressed
- ☐ Monitoring implemented
- ☐ Measurements analyzed
- ☐ Improvements made
- ☐ Process documentation adequate
- ☐ Process performance evaluated
- ☐ Process objectives achieved

Risk-Based Thinking

- ☐ Risk assessment conducted
- ☐ Opportunities identified
- ☐ Risk criteria established
- ☐ Risk treatment planned
- ☐ Controls implemented
- ☐ Effectiveness monitored
- ☐ Risk register maintained
- ☐ Risk communication effective
- ☐ Risk review scheduled
- ☐ Lessons learned applied
- ☐ Risk culture promoted
- ☐ Integration achieved

Measurement & Analysis

- ☐ KPIs established
- ☐ Data collection systematic
- ☐ Statistical techniques used
- ☐ Trends analyzed
- ☐ Benchmarking performed
- ☐ Root cause analysis conducted
- ☐ Data integrity ensured
- ☐ Reporting effective
- ☐ Decision-making informed
- ☐ Performance gaps identified
- ☐ Improvement actions taken
- ☐ Success measured

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