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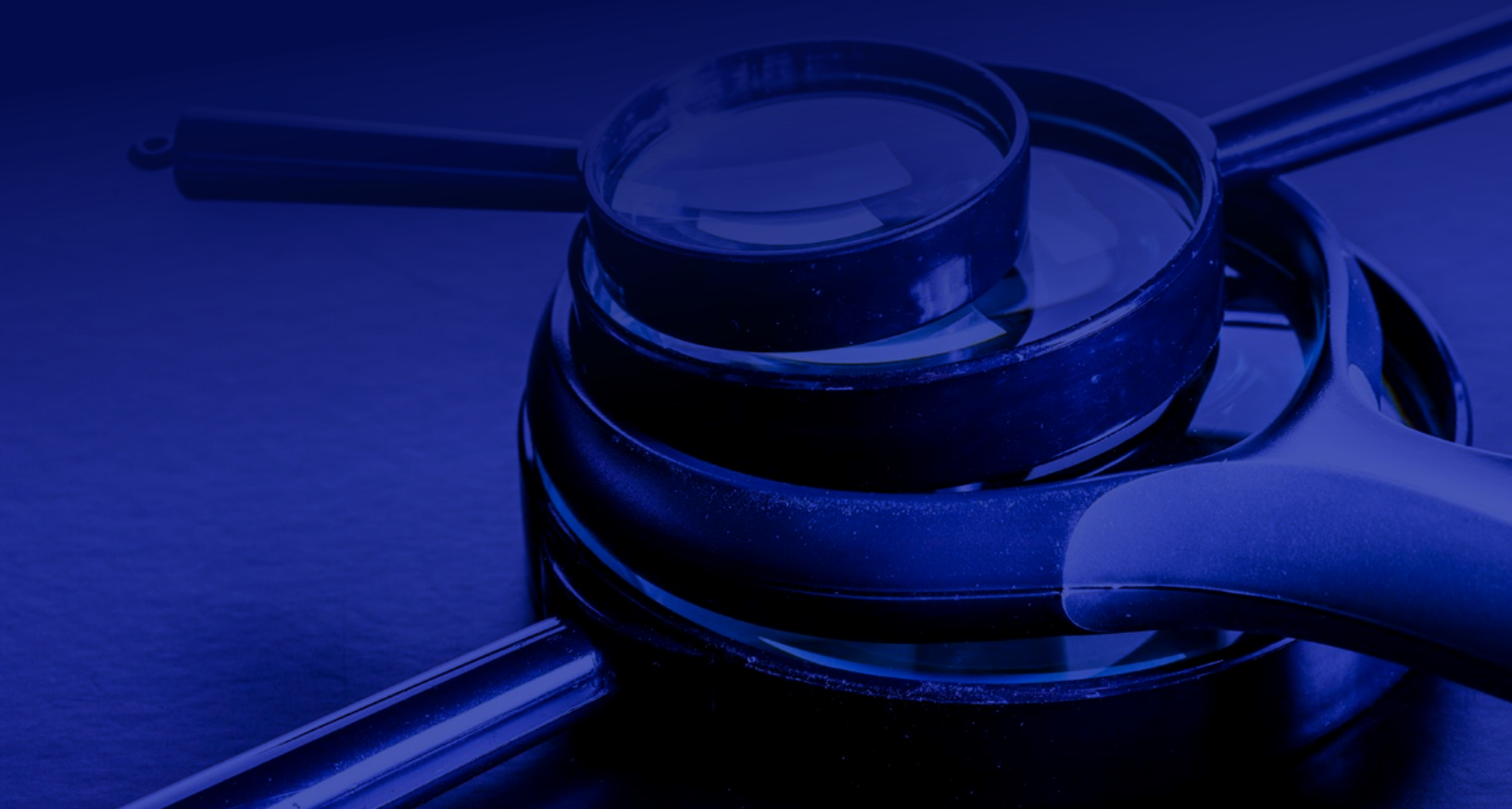
CHECKLIST

ISO 9001 Audit-Readiness Checklist



INTRODUCTION

ISO 9001 Audit-Readiness Checklist

Preparing for an ISO 9001 audit is not simply a matter of collecting documents shortly before the auditor arrives. It is an opportunity to check that your quality management system (QMS) is operating as intended: people understand their responsibilities, processes are followed consistently, records provide objective evidence, and improvement actions lead to meaningful results.

Use this checklist to assess your organization's readiness before an internal, surveillance, recertification, or certification audit.

Category 1: **Quality Management System Foundations** 02

Category 2: **Documentation and Records** 03

Category 3: **Leadership, People, and Competence** 04

Category 4: **Operational Control** 05

Category 5: **Improvement and Audit Evidence** 06

CATEGORY 1

Quality Management System Foundations

- [ ] Confirm that the scope of the QMS is current and accurately reflects the organization's sites, products, services, activities, and any justified exclusions.
- [ ] Ensure the quality policy is approved by top management, communicated throughout the organization, available to relevant interested parties, and still appropriate to business priorities.
- [ ] Review quality objectives to confirm they are measurable where practical, monitored regularly, assigned to responsible owners, and supported by action plans.
- [ ] Check that the organization has identified relevant internal and external issues that could affect the QMS, such as market conditions, regulatory changes, supply-chain risks, technology changes, or workforce capability.
- [ ] Verify that the needs and expectations of relevant interested parties—including customers, regulators, suppliers, employees, and certification bodies—have been considered.
- [ ] Ensure QMS processes are defined, including their purpose, inputs, outputs, owners, controls, measures, risks, and interactions with other processes.

CATEGORY 2

Documentation and Records

- [ ] Confirm that documented procedures, work instructions, specifications, forms, and policies are current, approved, and available at the point of use.
- [ ] Check that obsolete documents have been removed from active use or are clearly identified to prevent accidental use.
- [ ] Verify that document-control practices cover review, approval, version control, distribution, access, retention, retrieval, and disposal.
- [ ] Make sure records are legible, identifiable, protected from loss or unauthorized change, and retained for the required period.
- [ ] Review whether digital systems provide an auditable record of document revisions, approvals, training acknowledgment, deviations, corrective actions, and other quality activities.
- [ ] Prepare a clear index or central location for key audit evidence so process owners can retrieve it promptly during the audit.

CATEGORY 3

Leadership, People, and Competence

- [ ] Confirm that leadership can demonstrate accountability for the effectiveness of the QMS and active support for quality objectives.
- [ ] Ensure roles, responsibilities, authorities, and escalation paths are defined and understood across relevant functions.
- [ ] Check that employees performing work that affects quality have the appropriate education, training, skills, and experience.
- [ ] Verify that training records are complete and that competency has been assessed, not just attendance recorded.
- [ ] Confirm that employees understand the quality policy, relevant objectives, applicable procedures, and the consequences of not following established requirements.
- [ ] Speak with process owners before the audit so they are ready to explain what their process does, how it is controlled, what records it produces, and how performance is monitored.

CATEGORY 4

Operational Control

- [ ] Confirm that customer requirements, including delivery, quality, technical, contractual, regulatory, and post-delivery requirements, are reviewed before acceptance.
- [ ] Verify that changes to customer requirements, specifications, designs, processes, or production plans are assessed, authorized, communicated, and documented.
- [ ] Review supplier approval and monitoring records to ensure external providers are evaluated according to defined criteria.
- [ ] Check that purchasing requirements clearly communicate specifications, quality requirements, acceptance criteria, competency needs, and any necessary approvals.
- [ ] Ensure outsourced processes are controlled in proportion to their impact on product or service quality.
- [ ] Verify that production or service-delivery processes are performed under controlled conditions, using current instructions, appropriate equipment, competent personnel, and defined acceptance criteria.
- [ ] Confirm that inspection, testing, verification, and release activities are documented and completed before products or services are delivered.
- [ ] Check that identification and traceability requirements are met wherever they apply, including the ability to trace materials, batches, components, records, and release decisions.
- [ ] Ensure customer or supplier property is identified, protected, verified, and reported if lost, damaged, or found unsuitable for use.
- [ ] Verify that preservation controls protect products, materials, records, and data during handling, storage, packaging, transport, and delivery.

CATEGORY 5

Improvement and Audit Evidence

- [ ] Review nonconformity records to confirm issues are identified, contained, documented, and managed before unintended use or delivery occurs.
- [ ] Confirm that corrective actions address root cause rather than only the immediate symptom, and that their effectiveness has been evaluated.
- [ ] Check that internal audits have been carried out according to the audit program, by suitably independent and competent auditors.
- [ ] Ensure previous internal-audit findings, certification-body findings, customer complaints, and corrective actions are closed or have credible, documented progress plans.
- [ ] Verify that management reviews have taken place at planned intervals and include required inputs such as audit results, customer feedback, process performance, nonconformities, corrective actions, risks, opportunities, resources, and improvement opportunities.
- [ ] Review performance evidence, including KPI trends, on-time delivery, defect rates, customer satisfaction, complaint data, supplier performance, process outcomes, and progress toward quality objectives.
- [ ] Confirm that improvement opportunities are captured, prioritized, assigned, and tracked through to completion.
- [ ] Conduct a final readiness review with process owners, ensuring they can locate relevant evidence and explain how their work supports conformity, customer satisfaction, and continual improvement.

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