

ISO 9001 gap analysis checklist

ISO 9001:2026 – Quality management systems

For each requirement, record whether your organisation conforms, partly conforms or has a gap, and note the evidence (documents, records, interviews) that supports your answer. To score the results, track corrective actions and produce a report automatically, use the free online Gap Assessment at paperwingpdf.com/iso-gap-assessment/ – it runs in your browser and nothing is uploaded.

Organisation: _____ Assessed by: _____ Date: _____

4.1 Context — Internal & external issues

Identify and document internal issues (culture, performance, capabilities, values) and external issues (legal, regulatory, market, technological, competitive) that are relevant to the QMS purpose and strategic direction. Review and update at least annually or when significant change occurs. Maintain a documented context analysis (e.g. PESTLE, SWOT) that links to risk planning in clause 6.1.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

4.2 Context — Interested parties & their requirements

Identify all relevant interested parties (customers, regulators, employees, suppliers, shareholders, community). Document their specific requirements and expectations that are relevant to the QMS. Determine which requirements will be monitored and reviewed, and at what frequency. Evidence tip: maintain an interested-party register with a column for 'relevant requirements' and 'monitoring method'.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

4.3 Context — Scope of QMS

Define the QMS scope in documented form, specifying which products, services, sites, and processes are included and — where applicable — which ISO 9001:2026 clauses are excluded and the justification for each exclusion. The scope must be maintained as documented information and be available to interested parties. Ensure scope boundaries are realistic, defensible to a certification auditor, and consistent with the context analysis. Note: ISO 9001:2026 introduces a limited set of core QMS terms and definitions directly within the standard (drawn from ISO 9000) — align scope wording with this terminology rather than organisation-specific jargon.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

4.4 Context — QMS processes & their interactions

Identify all processes needed for the QMS, their sequence and interaction, required inputs and expected outputs, criteria and methods (including KPIs), resources required, responsibilities, risks and opportunities, and how changes will be managed. Maintain a process map or turtle diagrams and process interaction matrix. Ensure outsourced processes are identified and controlled. Cross-reference the new, expanded Annex A of ISO 9001:2026 (informative guidance on structure, terminology and intent) when interpreting how these requirements apply — Annex A adds no new obligations but clarifies auditor expectations.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

5.1 Leadership — Top management commitment, quality culture & ethical behaviour

Top management must demonstrate personal leadership — not merely delegate responsibility. Evidence includes: taking accountability for QMS effectiveness, ensuring the quality policy and objectives align with strategy, promoting customer focus and risk-based thinking, ensuring resources are available, communicating the importance of conformance, engaging, directing, and supporting people to contribute. New in ISO 9001:2026: leadership requirements now explicitly embed quality culture and ethical behaviour — top management must foster an environment and behavioural norms (awareness, integrity, accountability) in which quality is treated as a shared value rather than a compliance activity. Evidence: leadership walk-arounds, culture surveys, recognition schemes, and visible modelling of ethical decision-making. Tip: auditors look for direct evidence from top management, not just QA managers.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

5.1.2 Leadership — Customer focus

Top management must ensure customer and applicable regulatory requirements are determined, understood, and consistently met. Customer satisfaction is monitored and actions taken when satisfaction falls below targets. Risks to conformity of products/services and the ability to enhance customer satisfaction are identified and addressed as part of planning.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

5.2 Leadership — Quality policy

Establish a quality policy that is appropriate to the organisation's purpose and context, provides a framework for quality objectives, includes a commitment to satisfying applicable requirements and to continual improvement. The policy must be available as documented information, communicated and understood within the organisation, and available to relevant interested parties. Review and update when the context changes.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

5.3 Leadership — Roles, responsibilities & authorities

Assign, document, and communicate QMS roles and responsibilities throughout the organisation. Specifically: appoint a person (does not need to be called 'MR') to ensure QMS requirements are met and report to top management on QMS performance and improvement opportunities. All persons shall understand their QMS responsibilities. Review assignment when personnel change or structure changes.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

6.1 Planning — Determining & addressing risks

New in ISO 9001:2026: risks and opportunities are now addressed under clearly separated requirements rather than a single combined clause. For risks: identify risks to the QMS achieving its intended results and to product/service conformity. Determine actions to prevent or reduce undesired effects, integrate actions into QMS processes, and evaluate their effectiveness. Document the risk assessment methodology (e.g. risk register, FMEA, bow-tie) and risk rating criteria (likelihood × impact). Not every risk requires a formal documented treatment plan, but the approach must be proportionate and traceable to evidence.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

6.1.2 Planning — Determining & addressing opportunities

New in ISO 9001:2026: opportunities are determined and addressed through their own distinct requirement, separate from risk treatment. Identify opportunities to enhance desirable effects, achieve new outcomes, pursue improvement, or exploit favourable circumstances (new markets, technology, partnerships). Evaluate and prioritise opportunities, decide which to pursue, and integrate accepted opportunities into QMS planning and objectives (clause 6.2). Maintain a distinct opportunities log separate from the risk register so auditors can trace each opportunity from identification through to a planning or objective outcome.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

6.2 Planning — Quality objectives & plans to achieve them

Establish quality objectives that are measurable, monitored, communicated, and updated as needed. For each objective document: what will be done, what resources are required, who is responsible, when it will be completed, and how results will be evaluated. Objectives must be consistent with the quality policy and relevant to achieving product/service conformity and customer satisfaction. Maintain a documented objectives register with status and trend data.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

6.3 Planning — Planning of changes (strengthened change management)

New in ISO 9001:2026: change management requirements are reinforced beyond the 2015 edition. When changes to the QMS are needed, carry out changes in a planned manner, considering: the purpose and consequences of the change, integrity of the QMS, availability of resources, and allocation/reallocation of responsibilities. Requirements now place explicit emphasis across the full change lifecycle: planning the change, communicating it to affected interested parties, monitoring its implementation, and reviewing its outcome against intent. Document a change management process covering process changes, scope changes, and documentation changes, and retain evidence of communication and post-change review — not just the initial approval.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

7.1 Support — Resources (people, infrastructure, environment, monitoring)

Provide and maintain the resources needed: competent people, suitable infrastructure (buildings, equipment, IT), a suitable work environment (physical and psychological safety, hygiene, creativity), monitoring and measuring resources (calibrated/verified equipment), and organisational knowledge. Document the basis for resource decisions. Maintain calibration/verification records for measuring equipment, and knowledge management records.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

7.2 Support — Competence

Determine the competence needed by persons performing work affecting quality conformance. Ensure persons are competent through appropriate education, training, or experience. Where gaps exist, take actions to acquire competence and evaluate effectiveness. Maintain documented information (training matrix, CVs, qualifications, competency assessments) as evidence. Review competence after changes to processes, products, or services.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

7.3 Support — Awareness

Ensure all persons under the organisation's control are aware of: the quality policy, relevant quality objectives, their contribution to QMS effectiveness (including the benefits of improved performance), and the implications of not conforming to QMS requirements. Document the awareness programme (induction, toolbox talks, notice boards, team briefings) and retain evidence.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

7.4 Support — Communication

Determine internal and external communications relevant to the QMS: what will be communicated, when, with whom, how, and by whom. Ensure communications support QMS understanding and effectiveness. Maintain a communications plan and retain records of significant communications. For external communications involving product/service information or customer feedback, ensure accuracy and timeliness.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

7.5 Support — Documented information

Create and maintain documented information required by ISO 9001 and by the organisation. Control documented information to ensure availability, suitability, adequate protection, and version control. Control distribution, access, retrieval, and use. Control changes (version/revision control). Retain documented information as evidence of conformance. Distinguish between 'documents' (procedures, policies) and 'records' (evidence of activities performed).

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes:

8.1 Operation — Operational planning & control

Plan, implement, control, review, and maintain processes needed to meet product/service requirements. Establish criteria for processes and acceptance of products/services. Retain documented information to confirm conformance. Control planned and unintended changes and mitigate adverse effects of unintended changes. Ensure outsourced processes are controlled. Tip: work instructions, process parameters, and acceptance criteria are key audit evidence here.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes:

8.2 Operation — Requirements for products & services

Establish processes for customer communication (product info, enquiries, orders, complaints). Determine, review, and confirm requirements before accepting a commitment to supply — including: customer-stated requirements, requirements not stated but implied by use, statutory and regulatory requirements, any additional requirements the organisation considers necessary. Retain records of review results and any new requirements. Amend relevant documented information on changes.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes:

8.3 Operation — Design & development

Where design and development of products/services is within scope: establish, implement, and maintain a D&D process. Determine stages, reviews, verification, validation, and responsibilities. Control D&D inputs (functional requirements, previous designs, standards, regulatory requirements, consequences of failure). Control D&D outputs (meet inputs, adequate for production/provision, include or reference monitoring criteria, specify characteristics essential for intended use). Manage reviews, verification, and validation. Control changes and retain documented information throughout.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes:

8.4 Operation — Control of externally provided processes, products & services

Ensure that externally provided processes, products, and services conform to requirements. Determine and apply controls based on ability to meet requirements, degree of control over process, potential impact on conformance. Communicate to external providers requirements for processes, products, services, release criteria, competence of personnel, QMS requirements, and right of verification at provider's premises. Maintain a documented approved supplier list and supplier performance evaluation records.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes:

8.5 Operation — Production & service provision

Implement production and service provision under controlled conditions: documented information defining characteristics of products/services and results to be achieved; monitoring and measurement activities at appropriate stages; use of suitable infrastructure and environment; appointment of competent persons; validation of special processes (where output cannot be verified by subsequent monitoring); implementation of actions to prevent human error; implementation of release, delivery, and post-delivery activities. Maintain unique identification and traceability records where required.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes:

8.6 Operation — Release of products & services

Implement planned arrangements at appropriate stages to verify that product and service requirements have been met before release. Retain documented information as evidence of conformance with acceptance criteria, including traceability to the persons authorising release. Ensure no product or service proceeds to the customer until planned arrangements have been satisfactorily completed — unless approved by relevant authority or customer.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

8.7 Operation — Control of nonconforming outputs

Identify and control nonconforming outputs (products, services, process outputs) to prevent unintended use or delivery. Take appropriate action: correction, segregation, containment, return, suspension, inform the customer, obtain authorisation for acceptance under concession. Re-verify after correction. Retain documented information describing nonconformity and actions taken. Report nonconformity data into the corrective action process (10.2).

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

9.1 Performance — Monitoring, measurement, analysis & evaluation

Determine what needs to be monitored and measured, the methods used, when monitoring/measurement will be performed, when results will be analysed and evaluated. Evaluate the performance and effectiveness of the QMS. Monitor customer satisfaction through customer satisfaction surveys, complaints, returns, compliments, and repeat orders — at defined intervals. Analyse and evaluate data to assess conformance of products/services, degree of customer satisfaction, QMS performance and effectiveness, supplier performance, and the need for improvements.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

9.2 Performance — Internal audit

Conduct internal audits at planned intervals to determine whether the QMS conforms to the organisation's own requirements and ISO 9001 requirements, and is effectively implemented and maintained. Plan, establish, implement, and maintain an audit programme covering frequency, methods, responsibilities, planning, reporting, and records. Define audit criteria and scope. Select auditors to ensure objectivity and impartiality. Report results to relevant management. Retain audit programme and audit reports as documented information. Address any identified nonconformities without undue delay.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

9.3 Performance — Management review

Top management must review the QMS at planned intervals (at minimum annually). Inputs must include: status of actions from previous reviews; changes in external/internal issues relevant to QMS; QMS performance and effectiveness data (customer satisfaction, objectives, process performance, nonconformities, audit results, external provider performance); resource adequacy; effectiveness of risk/opportunity actions; improvement opportunities. Outputs must include: decisions on improvement opportunities, changes to the QMS, and resource needs. Retain management review records as documented information.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

10.1 Improvement — General

Determine and select improvement opportunities and implement necessary actions to meet customer requirements and enhance customer satisfaction. Include improving products/services to meet requirements and future needs, correcting, preventing, or reducing undesired effects, and improving the performance and effectiveness of the QMS. Demonstrate that improvement is systematic, data-driven, and linked to QMS performance analysis.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

10.2 Improvement — Nonconformity & corrective action

When a nonconformity occurs (including from complaints): react to the nonconformity and take action to control and correct it, deal with the consequences, evaluate the need for corrective action to eliminate the root cause, implement corrective action needed, review the effectiveness of corrective action taken, update risks/opportunities if necessary, and make changes to the QMS if required. Retain documented information including the nature of nonconformity, actions taken, and results of any corrective actions.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____

10.3 Improvement — Continual improvement

Continually improve the suitability, adequacy, and effectiveness of the QMS. Use outputs of analysis and evaluation, management review results, and improvement opportunities identified to determine whether there are needs or opportunities for improvement. Document the continual improvement approach (e.g. improvement register, PDCA cycles, Kaizen initiatives) and demonstrate measurable year-on-year improvement trends in QMS performance indicators.

☐ Conforms ☐ Partly ☐ Gap ☐ Not applicable

Evidence / notes: _____