ISO 9001:2015 GAP ANALYSIS TEMPLATE

Quality Management Systems | Downloadable Website Resource

Use this template to compare your existing quality management practices against ISO 9001:2015 requirements, identify gaps, assign responsibilities, and prepare for certification readiness.

Prepared for organizations planning ISO 9001:2015 certification, internal review, process improvement, supplier readiness checks, or management system maturity evaluation.

Pacific Certifications provides independent third-party certification services. This template is an educational reference and does not replace the ISO 9001:2015 standard or organization-specific professional implementation support.

Organization Name
Location / Site
Scope of Activities
Prepared By
Date

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How to Use This Gap Analysis Template

Review each ISO 9001:2015 clause reference and compare it with your current procedures, records, controls, performance data, and actual work practices. Mark each requirement as Conforms, Partial, Gap, or Not Applicable. For every partial or gap area, define a corrective action, responsible owner, and target date.

Suggested Status Definitions

Status	Meaning	Typical Evidence	Action Needed
Conforms	Requirement is implemented and effective.	Approved procedure, records, KPIs, review outputs, maintained controls.	Maintain and monitor.
Partial	Requirement is partly implemented but needs improvement.	Draft procedure, incomplete records, inconsistent practice.	Assign owner and close gaps.
Gap	Requirement is missing or not demonstrated.	No defined process, no evidence, unclear responsibility.	Plan and implement action.
N/A	Requirement is not applicable to the organization.	Justification in QMS scope or process records.	Document reason clearly.

Gap Analysis Summary

Clause Area	Conforms	Partial	Gap	N/A	Priority Notes
4 Context of the Organization					
5 Leadership					
6 Planning					
7 Support					
8 Operation					
9 Performance Evaluation					
10 Improvement					

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ISO 9001:2015 Clause-Wise Gap Analysis Checklist

Use the table below during review meetings, process walkthroughs, document checks, and evidence sampling. The questions are written as practical prompts and should be interpreted against the organization's scope, products, services, risks, and interested-party expectations.

Clause	Gap Analysis Prompt	Current Evidence / Records	Status	Gap / Action Required	Owner	Target Date
4.1	Has the organization identified internal and external issues that can affect the QMS and its intended results?					
4.2	Are relevant interested parties and their quality-related requirements identified, reviewed, and updated?					
4.3	Is the QMS scope defined with boundaries, applicability, products, services, locations, and exclusions where relevant?					
4.4	Are QMS processes identified with inputs, outputs, sequence, interaction, criteria, resources, responsibilities, risks, and performance indicators?					
5.1	Does top management show leadership for the QMS through accountability, customer focus, resources, and process integration?					
5.1.2	Are customer and applicable statutory/regulatory requirements determined, understood, and consistently met?					
5.2	Is the quality policy appropriate, communicated, available, and aligned with the organization's direction?					
5.3	Are roles, responsibilities, and authorities for QMS processes clearly assigned and communicated?					
6.1	Are risks and opportunities identified, planned, addressed, and evaluated for effectiveness?					
6.2	Are measurable quality objectives established at relevant functions, levels, and processes?					
6.2	Are quality objective plans defined with actions, resources, owners, timelines, and evaluation methods?					
6.3	Are changes to the QMS planned and controlled to avoid unintended consequences?					
7.1.1	Are resources available for establishing, implementing, maintaining, and improving the QMS?					

7.1.2	Are personnel resources sufficient for effective operation and control of processes?					
7.1.3	Is infrastructure such as buildings, equipment, utilities, IT, and transport maintained where needed?					
7.1.4	Is the work environment suitable for achieving conformity of products and services?					
7.1.5	Are monitoring and measuring resources suitable, maintained, calibrated, or verified where required?					
7.1.6	Is organizational knowledge determined, maintained, made available, and updated when needed?					
7.2	Are competence requirements defined and supported by education, training, experience, or evaluation records?					
7.3	Are personnel aware of the quality policy, objectives, contribution to QMS effectiveness, and consequences of nonconformity?					
7.4	Are internal and external QMS communications defined, including what, when, with whom, and by whom?					
7.5	Is documented information controlled for creation, approval, review, distribution, access, revision, retention, and disposal?					
8.1	Are operational processes planned, controlled, and supported by documented criteria where necessary?					
8.2.1	Are customer communications managed for enquiries, contracts, feedback, complaints, and changes?					
8.2.2	Are product and service requirements determined before commitment to supply?					
8.2.3	Are customer, statutory, regulatory, and organizational requirements reviewed before acceptance?					
8.2.4	Are changes to product or service requirements reviewed, documented, and communicated?					
8.3	Where design and development applies, are stages, inputs, controls, outputs, changes, verification, and validation controlled?					

8.4	Are externally provided processes, products, and services controlled based on their impact on conformity?					
8.4	Are supplier evaluation, selection, monitoring, re-evaluation, and communication criteria defined and recorded?					
8.5.1	Are production and service provision activities performed under controlled conditions?					
8.5.2	Is identification and traceability maintained where necessary for product or service conformity?					
8.5.3	Is property belonging to customers or external providers identified, protected, and controlled?					
8.5.4	Are preservation requirements maintained during production, service delivery, storage, handling, and delivery?					
8.5.5	Are post-delivery activities controlled where applicable, such as warranty, servicing, support, or regulatory obligations?					
8.5.6	Are changes in production or service provision reviewed, controlled, and documented?					
8.6	Are product and service outputs released only after planned arrangements are completed or approved?					
8.7	Are nonconforming outputs identified, controlled, corrected, segregated, accepted by concession, or prevented from unintended use?					
9.1.1	Are monitoring, measurement, analysis, and evaluation methods defined for QMS performance and process effectiveness?					
9.1.2	Is customer satisfaction monitored and evaluated using suitable methods?					
9.1.3	Are data and trends analyzed for conformity, satisfaction, process performance, supplier performance, and improvement needs?					
9.2	Is an internal review program planned and implemented based on process importance, changes, and previous results?					
9.2	Are internal review results reported, corrective actions taken, and records maintained?					
9.3	Does management review the QMS at planned intervals with					

	required inputs and documented outputs?					
9.3	Do management review outputs include decisions on improvement, changes, and resource needs?					
10.1	Are improvement opportunities identified and selected to enhance products, services, and QMS performance?					
10.2	Are nonconformities and complaints controlled through correction, root-cause review, action, effectiveness checks, and updates?					
10.3	Is continual improvement supported through objectives, performance data, review outputs, and corrective action learning?					

Gap Closure Action Plan

Transfer all partial and gap findings into this action plan. Prioritize actions that affect customer requirements, statutory and regulatory compliance, process control, release of outputs, competence, complaints, nonconformity control, and management review.

Ref.	Gap Description	Risk / Impact	Action Required	Owner	Due Date	Closure Evidence
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						

Certification Readiness Review

- ☐ QMS scope is defined and consistent with actual activities, products, services, and locations.
- ☐ Process interactions, responsibilities, risks, and performance measures are understood by process owners.
- ☐ Key documented information is controlled and available where required.
- ☐ Customer requirements, complaints, feedback, and satisfaction data are reviewed and acted upon.
- ☐ Internal review and management review activities are completed with retained records.
- ☐ Corrective actions are supported by root-cause review and effectiveness checks.
- ☐ Applicable statutory and regulatory requirements are identified and included in operational controls.
- ☐ All major gaps from this template have assigned owners and planned closure dates.

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