CERTIFIED ISO 9001: 2015 LEAD AUDITOR

GAP ANALYSIS TEMPLATE

GSDC
Global Skill Development Council

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Introduction

Overview of the Gap Analysis Process

Current Status: Document the initial understanding of the organization's Quality Management System (QMS) as it relates to ISO 9001:2015 requirements. This includes an overview of existing processes, policies, and procedures relevant to the standard's scope.

Evidence: Relevant documentation includes the QMS Manual (if applicable), organizational charts, process maps, existing quality policies, and any prior audit reports or assessments. Evidence should reflect the current state of the system before detailed clause-by-clause review.

Gap Identification

Systematically review the QMS against ISO 9001:2015 requirements to pinpoint areas of non-conformance or where compliance evidence is lacking.

Priority Assessment

Evaluate the significance of identified gaps based on their potential impact on product/service conformity, customer satisfaction, and overall QMS effectiveness. Prioritize high-risk gaps for immediate action.

Corrective Actions

Develop clear and actionable plans to address each identified gap. Define specific tasks, required resources, and desired outcomes to achieve compliance and improve the QMS.

Assignment

Assign responsibility for implementing corrective actions to specific individuals or teams. Establish realistic timelines for completion and define methods for verifying the effectiveness of implemented changes.

Section 1: Context of the Organization

Clause 4.1: Understanding the organization and its context

Current Status: Describe how external and internal issues are identified and monitored. Document the processes used to analyze market conditions, regulatory changes, competitive landscape, and internal capabilities that affect the QMS.

Evidence Required: Strategic planning documents, SWOT analysis, meeting minutes, environmental scanning reports, risk assessments, stakeholder feedback records.

Gap Identification

Note any missing or incomplete analysis of organizational context, including failure to document external/internal issues or lack of systematic monitoring.

Priority Assessment

High / Medium / Low - Assess based on potential impact on QMS effectiveness and certification readiness.

Corrective Actions

Specific steps to close the gap, such as implementing context analysis procedures or establishing review schedules.

Assignment

Responsible Person: Name/Role | Target Completion Date: Specify date

Section 2: Understanding Interested Parties

Clause 4.2: Understanding the needs and expectations of interested parties

Current Status: List all identified interested parties including customers, suppliers, employees, regulators, shareholders, and community stakeholders. Document their specific requirements, expectations, and how these influence the QMS. Describe the mechanisms for ongoing engagement and feedback collection.

Evidence: Stakeholder registers, customer feedback systems, supplier performance records, employee surveys, regulatory compliance tracking, communication logs, and contract requirements.

Gap Identification

Identify missing stakeholder groups, inadequate requirement documentation, or lack of systematic engagement processes.

Priority Assessment

Assess based on potential impact on QMS effectiveness and certification readiness: High / Medium / Low.

Corrective Actions

Develop stakeholder engagement strategy, update registers, establish communication protocols, and assign responsibilities.

Assignment

Responsible Person: Name/Role | Target Completion Date: Specify date.

Section 3: Determining the Scope of the QMS

Clause 4.3: Determining the scope of the quality management system

Current Status: Document the boundaries and applicability of the QMS. Include all products, services, sites, and processes covered. Clearly state any exclusions and provide robust justifications based on the organization's context, interested party requirements, and products/services offered.

Evidence: Scope documentation, organizational charts, process inventory, site listings, product/service catalogs, and exclusion justifications with supporting rationale.

Gap Identification

Look for missing scope statements, unclear boundaries, or unjustified exclusions related to the QMS.

Priority Assessment

Evaluate the importance of identified gaps, assigning a High, Medium, or Low priority level based on impact and urgency.

Corrective Actions

Develop and implement actions such as drafting/revising the QMS scope statement and validating any exclusions.

Assignment

Assign responsible personnel and set target completion dates for all corrective actions related to the QMS scope.

Section 4: QMS and its Processes

Clause 4.4: Quality management system and its processes

Current Status: Document all QMS processes including their sequence, interactions, inputs, outputs, resources, risks, and performance criteria. Describe how processes are monitored, measured, and controlled. Include both core operational processes and supporting management processes.

Evidence: Process maps, flowcharts, turtle diagrams, procedures, work instructions, process performance indicators, monitoring records, and process improvement documentation.

Gap Identification

Missing process documentation, unclear interactions, inadequate performance measures

Priority Assessment

Evaluate criticality to quality objectives and customer satisfaction

Corrective Actions

Document processes, map interactions, establish KPIs and monitoring systems

Assignment

Designate responsible process owners with clear deadlines

Section 5: Leadership

Clause 5.1-5.3: Leadership and commitment, Policy, Organizational roles

Current Status: Assess top management's active involvement in the QMS, including taking accountability for effectiveness, ensuring quality policy and objectives are established, integrating QMS requirements into business processes, and promoting improvement culture. Document the quality policy's availability, communication, and alignment with organizational purpose.

Evidence: Quality policy documents, management review minutes, resource allocation records, communication materials, organizational charts with defined roles and authorities, and leadership meeting documentation.

Gap Identification

Assess limited leadership engagement, unclear policy communication, ambiguous role definitions, or insufficient resource commitment.

Priority Assessment

Evaluate impact on QMS effectiveness, compliance, and strategic organizational goals.

Corrective Actions

Enhance leadership participation, clarify and communicate quality policy, define roles explicitly, and allocate adequate resources.

Assignment

Designate responsible individuals and set clear timelines for implementation and review.

Section 6: Planning

Clause 6.1-6.3: Risks and opportunities, Quality objectives, Planning of changes

Current Status: Describe how risks and opportunities are identified, assessed, and addressed throughout the QMS. Document quality objectives at relevant functions and levels, ensuring they are measurable, monitored, communicated, and updated. Explain the process for planning and controlling changes to the QMS to maintain integrity during transitions.

Evidence: Risk registers, opportunity logs, risk assessment matrices, mitigation plans, action tracking systems, objectives documentation, measurement plans, performance dashboards, review records, achievement reports, change requests, impact assessments, implementation plans, communication records, and validation documentation.

Gap Identification

Identify absence of documented risk/opportunity analysis, poorly defined or unmonitored quality objectives, and lack of a structured process for planning QMS changes.

Priority Assessment

Evaluate the potential impact of identified planning gaps on QMS effectiveness, product/service conformity, and organizational goals. Prioritize based on severity, likelihood, and regulatory compliance.

Corrective Actions

Develop and implement procedures for systematic risk and opportunity management. Establish measurable quality objectives, and create a formal process for planning and controlling changes to maintain QMS integrity.

Assignment

Responsible Person: Quality Manager / Department Heads. Target Date: [Specify Date]

Section 7: Support

Clause 7.1-7.5: Resources, Competence, Awareness, Communication, Documented information

Current Status: Document resource allocation including personnel, infrastructure, work environment, monitoring equipment, and organizational knowledge. Describe competency management systems including training needs identification, provision, and effectiveness evaluation. Assess awareness of quality policy, objectives, and individual contributions to QMS effectiveness. Evaluate internal and external communication processes and channels. Review document control procedures including creation, updating, approval, distribution, version control, retention, and disposition of documented information. Ensure protection against loss of confidentiality, improper use, or loss of integrity.

Evidence: Training logs, competency matrices, awareness surveys, communication plans, document registers, control procedures, and access logs.

Gap Identification

Identify areas of non-conformance or improvement related to insufficient resources, competency gaps, limited awareness, poor communication, or inadequate document control.

Priority Assessment

Evaluate the impact and urgency of identified gaps to assign appropriate priority levels for resolution.

Corrective Actions

Develop specific corrective actions to address identified gaps, ensuring they are designed to achieve QMS effectiveness.

Assignment

Assign responsible persons for each action and establish clear target completion dates to ensure accountability and timely resolution.

Section 8: Operation

Clause 8.1-8.7: Operational planning and control through control of nonconforming outputs

Current Status: Assess operational planning and control mechanisms for products and services. Evaluate requirements determination, review, and change management processes. For applicable organizations, review design and development activities including planning, inputs, controls, outputs, and validation. Examine supplier selection, evaluation, performance monitoring, and control of externally provided processes. Document production and service provision controls including validated processes, identification and traceability, customer property management, preservation activities, and post-delivery activities. Review product and service release procedures ensuring planned arrangements are satisfied. Assess control of nonconforming outputs including identification, documentation, segregation, correction, and customer notification processes.

Evidence: Operational plans, process control documents, design and development records, supplier evaluation reports, production/service provision records, customer property logs, nonconforming output reports, product release records.

Gap Identification

Identify missing operational controls, weak supplier management, inadequate design and development controls, or poor handling of nonconforming outputs.

Priority Assessment

Evaluate the potential impact and risk of identified gaps on product/service conformity, customer satisfaction, and regulatory compliance.

Corrective Actions

Implement improved operational procedures, enhance supplier qualification processes, establish robust design controls, refine nonconformity management, and conduct targeted internal audits.

Assignment

Assign responsibility for corrective actions to relevant personnel (e.g., Operations Manager, Production Supervisor) with clear target completion dates.

Section 9: Performance Evaluation

Clause 9.1-9.3: Monitoring, Internal audit, Management review

Current Status: Assess monitoring and measurement activities, including quality performance assessment methods, data analysis, and evaluation used to determine the suitability, adequacy, and effectiveness of the QMS. Evaluate the internal audit program's planning, conduct, reporting, and follow-up to ensure QMS conformity and effectiveness. Review management processes to ensure top management regularly reviews the QMS, considering audit results, customer feedback, process performance, product/service conformity, corrective actions, follow-up from previous reviews, changes affecting the QMS, and improvement opportunities.

Evidence: Monitoring and measurement records, data analysis reports, internal audit plans and reports, nonconformity records and corrective actions, management review meeting minutes, and records of decisions and actions from reviews.

Gap Identification

Identify deficiencies in monitoring and measurement activities, internal audit execution, or management review effectiveness. Look for incomplete data, missed audit schedules, or lack of documented management review outputs.

Priority Assessment

Evaluate the impact of identified gaps on QMS performance and conformity. Prioritize based on potential risks to product/service quality, customer satisfaction, or regulatory compliance.

Corrective Actions

Implement actions to improve monitoring methods, enhance the internal audit process (e.g., auditor training, revised schedules), or refine management review inputs and follow-up mechanisms.

Assignment

Assign responsibility for corrective actions to relevant process owners or department heads with defined timelines for implementation and verification of effectiveness.

Section 10: Improvement

Clause 10.1-10.3: General, Nonconformity and corrective action, Continual improvement

Current Status: Document the organization's processes for identifying and selecting opportunities for improvement, implementing actions to meet customer requirements and enhance satisfaction, and managing nonconformities through corrective actions. This includes documenting how nonconformities are reacted to, how root causes are eliminated, the actions taken, their effectiveness reviewed, and how risks and opportunities are updated. Additionally, document continual improvement activities, including initiatives driven by analysis, evaluation results, management reviews, and innovation.

Evidence: Improvement action plans, nonconformity reports, corrective action records (including root cause analysis and verification of effectiveness), records of continual improvement initiatives, and management review outputs related to improvement.

Gap Identification

Identify nonconformities, potential improvements, and areas where customer requirements or QMS effectiveness can be enhanced through audits, feedback, and performance data.

Priority Assessment

Assess the significance and potential impact of identified gaps and opportunities, prioritizing based on risk, customer satisfaction, and strategic objectives.

Corrective Actions

Develop and implement corrective actions for nonconformities to eliminate root causes, and plan improvements to enhance QMS suitability and effectiveness.

Assignment

Assign responsibilities and establish clear timelines for the implementation and verification of corrective actions and improvement initiatives.

Summary of Findings and Recommendations

Section 11 Overview: Consolidated Findings & Action Plan

Current Status: Assess how the organization summarizes identified gaps, prioritizes findings based on QMS effectiveness and compliance risk, and establishes clear action plans. Evaluate the defined implementation timeline and assignment of responsibilities for addressing these findings.

Evidence: Consolidated gap analysis reports, documented prioritization criteria for findings, detailed action plans categorized by severity, and a comprehensive implementation timeline with assigned responsibilities.

Gap Identification

Review audit reports and assessments across all ISO 9001:2015 clauses to identify all areas of non-conformance, deficiencies, and improvement opportunities.

Priority Assessment

Evaluate identified gaps based on their severity (Critical, Moderate, Minor), potential impact on QMS effectiveness, compliance risk, and business performance to determine urgency.

Corrective Actions

Develop clear action plans for each identified gap, outlining specific steps required for correction, addressing root causes, and preventing recurrence. Include critical immediate actions.

Assignment & Timeline

Define responsible parties for each action item, set realistic implementation timelines (e.g., Phase 1: 0-30 days, Phase 2: 31-90 days, Phase 3: 91-180 days), and allocate necessary resources.

Appendix

Glossary of Terms

QMS: Quality Management System
CAPA: Corrective and Preventive Action
KPI: Key Performance Indicator
NCR: Non-Conformance Report
SWOT: Strengths, Weaknesses, Opportunities, Threats

ISO 9001:2015 References

Clause 4: Context of the Organization
Clause 5: Leadership
Clause 6: Planning
Clause 7: Support
Clause 8: Operation
Clause 9: Performance Evaluation
Clause 10: Improvement

Audit Evidence Log Template

Evidence ID	Clause Reference	Document Title	Date Reviewed
E001	4.1	Context Analysis Report	[Date]
E002	5.2	Quality Policy Document	[Date]
E003	9.2	Internal Audit Schedule	[Date]

Auditor Sign-off

Lead Auditor Name: _____

Signature: _____

Date: _____

Audit Team Members: _____

Notes and Observations: Use this space to record additional context, observations during the audit process, stakeholder feedback, or recommendations for future assessments.

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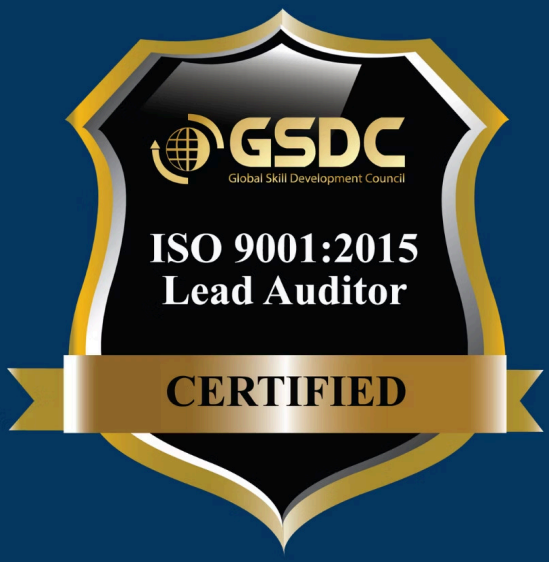

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