

Certified ISO 9001:2015 Lead Auditor

Gap Analysis Checklist



ISO 9001:2015 Gap Analysis Template

Guide to Identifying and Closing Gaps for ISO 9001:2015
Compliance

Introduction

The ISO 9001:2015 Gap Analysis Template is an essential tool designed to help organizations assess their existing quality management system (QMS) against the requirements of the ISO 9001:2015 standard.

ISO 9001:2015 is a globally recognized standard for Quality Management Systems that helps businesses ensure they meet customer and regulatory requirements while continually improving their processes.

This gap analysis template is designed to assist you in identifying areas where your current QMS may not fully comply with the standard's requirements.

Performing a gap analysis allows you to understand where your QMS is performing well and where improvements are necessary.

By using this template, your organization can create a structured action plan to achieve ISO 9001:2015 certification or ensure continued compliance with the standard.

How to Use This Guide

1. **Fill in Your Organization's Information:**

At the top of the template, provide your organization's name, the date the gap analysis is conducted, and the name of the person responsible for completing the analysis. This ensures clarity and ownership of the process.

2. **Assess Each Clause:**

The template is divided by the ISO 9001:2015 clauses. For each clause:

- **Review the Requirements:** Read and understand the clause, referring to the ISO 9001:2015 standard if needed.
- **Assess Compliance:** Evaluate your current QMS practices and determine whether they align with the requirements of each clause. Use the following compliance markers:
 - **Fully Compliant:** The organization's processes and documentation meet the requirements of the clause.
 - **Partially Compliant:** The organization has implemented the clause but needs further work to fully comply.
 - **Not Compliant:** The organization does not meet the requirements of the clause.
 - **Not Applicable:** This clause does not apply to your organization due to specific exclusions or scope.

3. **Document Evidence & Current State:**

For each clause, provide evidence or descriptions of current practices that demonstrate how your organization complies (or does not comply) with the requirements. This could include records, policies,

procedures, or other relevant documents. If the organization is partially or not compliant, describe the gaps.

4. Identify Gaps:

In the “Gaps Identified” column, outline any discrepancies between the current state and the ISO 9001:2015 requirements. Be specific about the issues or areas that need improvement.

5. Propose Recommended Actions:

For each gap identified, provide suggested actions that will help your organization achieve full compliance. These recommended actions should be clear, actionable, and prioritized based on their impact on achieving ISO 9001:2015 certification.

6. Prioritize and Develop an Action Plan:

After completing the gap analysis, summarize the critical gaps that require immediate action. Develop an action plan with timelines, assigned responsibilities, and resources needed to close these gaps.

GAP ANALYSIS TABLE

Clause No.	Clause Title	Compliance Status	Evidence / Current State	Gaps Identified	Recommended Actions
4.1	Understanding the organization and its context				
4.2	Understanding the needs and expectations of interested parties				
4.3	Determining the scope of the QMS				
4.4	Quality Management System				
5.1	Leadership and commitment				
5.2	Quality policy				
5.3	Organizational roles, responsibilities, and authorities				
6.1	Actions to address risks and opportunities				

Clause No.	Clause Title	Compliance Status	Evidence / Current State	Gaps Identified	Recommended Actions
6.2	Quality objectives and planning to achieve them				
7.1	Resources				
7.2	Competence				
7.3	Awareness				
7.4	Communication				
7.5	Documented information				
8.1	Operational planning and control				
8.2	Design and development of products and services				
8.3	Control of externally provided processes, products, and services				
9.1	Monitoring, measurement,				

Clause No.	Clause Title	Compliance Status	Evidence / Current State	Gaps Identified	Recommended Actions
	analysis and evaluation				
9.2	Internal audit				
9.3	Management review				
10.1	Nonconformity and corrective action				
10.2	Continual improvement				

Summary of High-Priority Gaps (Optional)

Clause Description of Major Gap Suggested Immediate Action

Conclusion and Final Notes

The ISO 9001:2015 Gap Analysis Template provides a structured approach for assessing your organization's compliance with the standard and identifying areas for improvement.

It helps ensure that your QMS is robust, aligned with ISO standards, and effective in achieving continuous improvement.

A Few Key Things to Remember When Using This Template:

- **Be Thorough and Honest:** Accuracy is crucial for identifying real gaps. Don't overlook any areas that could benefit from improvement, and be honest about your current compliance status.
- **Prioritize Critical Gaps:** Some gaps may have a higher impact on your QMS and should be addressed immediately. Focus on these first to ensure that your organization is on the right track.
- **Develop a Clear Action Plan:** Each gap identified should have a clear, actionable plan for resolution. Assign responsibilities, set timelines, and allocate necessary resources to ensure timely action.
- **Review Regularly:** Gap analysis is not a one-time exercise. Regular reviews and updates to your analysis will help maintain ISO 9001:2015 compliance and drive continuous improvement.

By using this template, you can systematically address gaps, enhance your QMS, and work towards achieving or maintaining ISO 9001:2015 certification with confidence.

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