www.iso-9001-checklist.co.uk

A gap analysis is a tool for seeing how your quality management system measures up to the requirements ISO 9001. Its purpose is to help your business determine the gaps in respect to these requirements. A gap analysis should be conducted as an initial step in the process of achieving ISO 9001:2015 certification.

Gap Analysis Checklist

ISO 9001:2015 Self-assessment

Table of Contents

Gap Analysis Guidance 5

Introduction 5
What is a Gap Analysis? 5
What Does a Gap Analysis Involve? 5
What Does a Gap Analysis Achieve? 6
Using the Gap Analysis Checklist 6

Gap Analysis Checklist – Part A 8

Clause 4 - Context of the Organization 8
4.1 Understanding the Organization and its Context 8
4.2 Understanding the Needs and Expectations of Interested Parties 9
4.3 Determining the Scope of the Quality Management System 9
4.4 Quality Management System and its Processes 11

Clause 5 - Leadership 12
5.1 Leadership and Commitment 12
5.2 Quality Policy 13
5.3 Organizational Roles, Responsibilities and Authorities 14

Clause 6 - Planning 15
6.1 Actions to Address Risks and Opportunities 15
6.2 Quality Objectives and Planning to Achieve Them 16
6.3 Planning for Changes 17

Clause 7 - Support 18
7.1 Resources 18
7.1.1 General 18

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7.1.2 People 18
7.1.3 Infrastructure 19
7.1.4 Environment for the Operation of Processes 19
7.1.5 Monitoring and Measuring Resources 20
7.1.6 Organizational Knowledge 21
7.2 Competence 21
7.3 Awareness 22
7.4 Communication 22
7.5 Documented Information 23
7.5.1 General 23
7.5.2 Creating and Updating 23
7.5.3 Control of Documented Information 24
Clause 8 - Operation 25
8.1 Operational Planning and Control 25
8.2 Requirements for Products and Services 26
8.2.1 Customer Communication 26
8.2.2 Determining the Requirements for Products and Services 27
8.2.3 Review of Requirements for Products and Services 27
8.3 Design and Development of Products and Services 28
8.3.1 General 28
8.3.2 Design and Development Planning 28
8.3.3 Design and Development Inputs 29
8.3.4 Design and Development Controls 30
8.3.5 Design and Development Outputs 30
8.3.6 Design and Development Changes 31
8.4 Control of Externally Provided Processes, Products and Services 31
8.4.1 General 31

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8.4.2 Type and Extent of Control 32
8.4.3 Information for External Providers 33
8.5 Production and Service Provision 34
8.5.1 Control of Production and Service Provision 34
8.5.2 Identification and Traceability 35
8.5.3 Property Belonging to Customers or External Providers 36
8.5.4 Preservation 37
8.5.5 Post-delivery Activities 38
8.5.6 Control of Changes 38
8.6 Release of Products and Services 39
8.7 Control of Nonconforming Outputs 40

Clause 9 - Performance Evaluation 42
9.1 Monitoring, Measurement, Analysis and Evaluation 42
9.1.1 General 42
9.1.2 Customer Satisfaction 43
9.1.3 Analysis and Evaluation 43
9.2 Internal Audit 44
9.3 Management Review 45
9.3.1 General 45
9.3.2 Management Review Inputs 45
9.3.3 Management Review Outputs 46

Clause 10 - Improvement 47
10.1 General 47
10.2 Nonconformity and Corrective Action 47
10.3 Continual Improvement 48

Gap Analysis Findings List – Part B 50

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Clause 4 - Context of the Organization 50

Clause 5 - Leadership 50

Clause 6 - Planning 51

Clause 7 - Support 52

Clause 8 - Operation 52

Clause 9 - Performance Evaluation 53

Clause 10 - Improvement 53

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Gap Analysis Guidance

Introduction

What is a Gap Analysis?

A gap analysis is a type of survey instrument that is used to determine the differences (gaps, also known as a 'delta') between an organization's management system and the requirements of controlling criteria, such as standards like ISO 9001:2015. A gap exists where existing policies, processes or procedures do not fully meet the stated requirements.

This gap analysis checklist highlights and summarises the requirements contained in ISO 9001:2015; it is not intended to cover all of the requirements from the standard comprehensively, only an overview of them, and is used to capture the gaps in your organization's management system and the requirements of ISO 9001:2015, with the goal of determining:

1. What existing company processes and procedures already meet ISO 9001 requirements?
2. What existing procedures and processes need to be modified to meet ISO 9001 requirements?
3. What additional procedures and processes need to be created to meet ISO 9001 requirements?

Make sure that you purchase copies of ISO 9000:2015 and ISO 9001:2015. Read them both and make yourself familiar with their language and concepts. Although it is written in dense, formal language, the clause titles in ISO 9001:2015 are fairly self-explanatory.

What Does a Gap Analysis Involve?

While the process of becoming ISO 9001 certified is complex, the process of running a gap analysis is considerably less complicated. There are five major steps in the process of completing a gap analysis of ISO 9001; you can read more about these steps in the next section of this document.

Your organization may already have in place a compliant quality management system, or you might be running an uncertified system; the gap analysis checklist provides a structured framework to help assess the current status of your QMS in terms of fulfilling the requirements ISO 9001:2015. After the gap analysis, you should have a clear picture of how your existing quality management system compares with the requirements of ISO 9001. In general, the steps for conducting a gap analysis are:

1. Reviewing what is the present operation/process and what already exists;

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2. Analyzing the relevant sections of the ISO 9001 standard to determine what is actually required;
3. Documenting the differences or gaps.

These differences and gaps should be organized into a detailed task list for review and approval by top management. In summary, the gap analysis should include a review of all processes and procedures for management controls and technical controls, such as sampling, method validation, equipment calibration, qualification and maintenance, employee qualifications, and others. The unique knowledge obtained about the status of your existing quality management system will be a key driver of the subsequent implementation approach.

What Does a Gap Analysis Achieve?

Using the output of the gap analysis, you can develop a findings list, which can include additional tasks such as selecting and dealing with an accreditation or certification body. Not only will this gap analysis template help you to identify the gaps, it will also allow you to recommend how those gaps should be filled. Armed with this knowledge, it allows you to establish accurate budgets, timelines, and expectations that are proportional to the state of your current management system when directly compared to the requirements of the standards.

The gap analysis output, in the form of a findings list, provides a valuable baseline for the implementation process as a whole and for measuring progress. Try to understand each business process in the context of each of the requirements by comparing different activities and processes with what the standard requires. At the end of this activity, you will have a list of activities and processes that comply and ones that do not comply. The latter now becomes the task list and the target of your implementation plan.

Using the Gap Analysis Checklist

This gap analysis checklist is aligned with the requirements of ISO 9001:2015, and it is imperative that gap analysis is undertaken with due reference to the standard. The gap analysis tool is divided into seven sections, which reflect the contents of ISO 9001:2015. The two gap analysis tools, Part A and Part B, listed below provide a structured framework to assess the current status of a QMS in terms of fulfilling the ISO 9001 clauses:

Part A comprises the gap analysis checklist, which is aligned with the clauses of ISO 9001 and provides comments and notes to assist users, while Part B comprises the gap analysis findings list, which details the gaps and proposed remedial actions that are required to close the identified gaps between ISO 9001 and your current management system.

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Gap Analysis Checklist – Part A

Complete the gap analysis checklist below and one full internal audit against the ISO 9001:2015 requirements prior to your organization's certification audit. Please complete the tables below which highlight some of the concepts and themes present in ISO 9001:2015. These concepts will bridge multiple processes, clauses, and functional areas. Ensure that the completed checklist and internal audit records are available prior to commencing formal assessment.

Clause 4 - Context of the Organization

4.1 Understanding the Organization and its Context

Your organization is now required to identify and asses all internal and external issues that could impact upon your quality management system's ability to deliver its intended results. You will need to develop a methodology to understand the needs and expectations of all interested parties. Collate evidence to provide assurance that your organization is regularly, or as necessary, reviewing and updating its external and internal issues.

Ref	Gap Analysis Question	Gap Finding			Action Plan (if OFI or NC)		Notes
		Comply	**OFI [1]**	**NC [2]**	Improvements Needed [OFI 1]	Corrective Action Needed [NC 2]	Objective Evidence & Comments
1	Has your organization determined the external and internal issues (values, culture, knowledge and performance) that affect the ability to achieve intended results?						
2	Has your organization considered international, national, regional or local issues arising from legal, technological, competitive, market, cultural, social and economic environments?						
3	Are these issues reviewed and monitored on a regular basis, how often does your organization review these issues?						

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Gap Analysis Findings List – Part B

Implementation Plan

Where gaps have been identified these should be included in the findings list. This plan should detail the gaps and the actions to be taken (what, when and by whom) to correct and implement the outstanding QMS components. The plan should define responsibilities of different departments and personnel and set target dates for the completion of tasks. Once approved, the Management Representative should control, review and update the plan as documentation and the implementation process proceeds.

Clause 4 - Context of the Organization

Clause Ref	Description of Gap Identified	Proposed Remedial Action	Action Plan (if OFI or NC)			
			Improvements Needed [OFI 1]	Corrective Action Needed [NC 2]	Process Owner	Date Completed

Clause 5 - Leadership

Clause Ref	Description of Gap Identified	Proposed Remedial Action	Action Plan (if OFI or NC)			
			Improvements Needed [OFI 1]	Corrective Action Needed [NC 2]	Process Owner	Date Completed

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