

The gap analysis checklist is one of the first tools available from the auditor's toolbox. The self-assessment questions will help you to identify gaps between your existing Quality Management System and the requirements of ISO 9001:2015.

# Gap Analysis Checklist

ISO 9001:2015 Self-assessment

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## Guidance

### About this Checklist

This gap analysis checklist highlights the new requirements contained in ISO 9001:2015, and is not intended to cover all of the requirements from ISO 9001:2015 comprehensively. The unique knowledge obtained about the status your existing quality management system will be a key driver of the subsequent implementation approach. Armed with this knowledge, it allows you to establish accurate budgets, timelines and expectations which are proportional to the state of your current management system when directly compared to the requirements of the standards.

Your organization may already have in place an ISO 9001:2008 compliant quality management system or you might be running an uncertified system. If this is the case, you will want to determine how closely your system conforms to the requirements ISO 9001:2015. The results of a gap analysis exercise will help to determine the differences, or gaps, between your existing management system and the new requirements. Not only will this analysis template help you to identify the gaps, it will also allow you to recommend how those gaps should be filled.

The gap analysis output 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 list now becomes the target of your implementation plan.

### Summary of Key Changes

#### Process Approach

The process approach was promoted by ISO 9001:2008 and is now a requirement in its own right, which sets out the specific requirements for the adoption of a process approach.

#### Context of the Organization

A new clause and sub clauses are being introduced relating to the context of the organization. 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.

### Scope of the Quality Management System

Greater emphasis has been placed on the definition of scope of the quality management system. The scope of quality management system should be determined in consideration to your organization's context.

### Leadership

The previously titled Management Responsibility from ISO 9001:2008 has been replaced with 'Leadership'. Top management are now required to be actively involved in the operation of the quality management system. The removal of the role of 'management representative' reinforces a need to see the quality management system embedded into routine business operations, rather than operating as an independent system in its own right with its own dedicated management structure.

### Risks and Opportunities

All references to preventive action have been removed from the ISO 9001:2015 and replaced with Clause 6.1 - Actions to Address Risks and Opportunities. Your organization is now required to determine, consider and, where necessary, take action to address any risks or opportunities that might impact your quality management system's ability to deliver conformance, or which might adversely impact customer satisfaction.

### Products and Services

The term 'product' is being replaced by 'products and services'. By including specific reference to services as well as products, ISO 9001:2015 reinforces the idea that quality management systems are applicable to all types of business and not just to are manufacturing or supplying products.

### Control of Externally Provided Products & Services

ISO 9001:2008 Clause 7.4 – Purchasing has been replaced with clause 8.4 'Control of externally provided products and services'. This clause addresses all types of external provision, purchasing from a supplier, or through the outsourcing of processes. Your organization is now required to take a risk-based approach to determine the type and extent of controls that are appropriate for each external provider and all outsourced processes.

### Documented Information

Requirements for a documented quality manual, documented procedures and records have been removed and replaced with the term 'Documented Information'. This is the information your organization is required to control, retain and maintain.

### Self-assessment Checklist

#### Context of the Organisation

Ref	Gap Analysis Question	Finding		Implementation Plan (if No)				
		Yes	No	ISO Clause	Process Owner	Action Needed	Date Planned	Date Actual
1	Have all external and internal issues that are relevant to your organisation's purpose and the achievement of customer satisfaction and the organisation's strategic direction been determined?							
2	Are these issues reviewed and monitored on a regular basis?							
3	Have the needs and expectations of interested parties that are relevant to the QMS been determined?							
4	Was the scope of your QMS determined whilst taking into account of all the external and internal issues, the needs of interested parties and the scope your products and services?							
5	Is your QMS established, and does it include a description of the processes required and their sequence and interaction?							