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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

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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 assess 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?						

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