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ISO 9001:2026 Quality Management Systems - The Gap Analysis Checklist

This gap analysis checklist is prepared for use in evaluating your Quality Management System (QMS) against the requirements of ISO 9001:2026. Each requirement is expressed as a question that the user (auditor / assessor) can use to evaluate your QMS capabilities. You will need to have a copy of the ISO 9001:2026 standard to use along with this checklist so that you can refer to the requirements and the clarification sections of Annex A.

After you have prepared an audit schedule and assigned responsibility to your auditors for different areas or processes to audit, copy each section of the checklist for the auditors working with that section. As you work through the checklist take notes on what is in place, and what needs to be developed. Reference the procedures or other documents that you have reviewed and that will provide information for the new QMS. Take notes on the status of the documents; will they need to be revised for the new system, or can they be used as is? Also note where processes are in place, but documentation is needed. Focus on what is in place, and what needs to be developed.

While you do want to know if procedures and processes are being complied with, compliance is not your main focus for this audit. Remember that the final outcome of this audit should be a list of things that your company needs to do to comply with ISO 9001:2026.

---	QUALITY MANAGEMENT SYSTEM	Currently in Place	Compliant Yes / No	If No - % Complete d	Items Needed
4	CONTEXT OF THE ORGANIZATION				
This clause introduces four sub-clauses relating to the context of the organization. (1) understanding the organization and its context and (2) understanding the needs and expectations of interested parties (3) determining the scope of the quality management system (4) Quality management system. Together they require that you determine the issues and requirements that can impact on the planning of the QMS. In addition, the scope of the QMS and the QMS processes along with their applicability and interactions need to be determined.					
4.1	Understanding the organization and its context				
	Does your company determine the external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its QMS?				

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	Does your company determine whether climate change is a relevant issue? Does your company monitor and review information about these external and internal issues?				
4.2	Understanding the needs and expectations of interested parties				
	Does your company determine: • The interested parties relevant to the QMS? • The relevant requirements of these interested parties? • Which requirements are addressed through the QMS? Does your company monitor and review the information about the interested parties and their relevant requirements?				
4.3	Determining the scope of the quality management system				
	To establish scope, does your company determine the boundaries and applicability of the QMS? When determining the scope, does your company consider the: • External and internal issues (see 4.1)? • Requirements (see 4.2)? • Products and services of your company?				

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	Does your company apply all the requirements of the 9001:2026 standard if they are applicable within the determined scope of its QMS? Does your company's scope state the types of products and services covered? Does your company's scope include justification for any requirement of the ISO 9001:2026 standard that your company determines is not applicable to its QMS? Is the scope available ISO 9001:2026 as documented information? Does your company verify that the requirements determined as not being applicable do not affect the company's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction?				
4.4	Quality management system				
4.4.1	Does your company establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of the ISO 9001:2026 standard? Does your company: • Determine the processes needed for the QMS and their application throughout the organization?				

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	• Determine the inputs required and the outputs expected from these processes? • Determine the sequence and interaction of these processes? • Determine and apply the criteria and methods needed, including monitoring, measurements and related performance indicators, to ensure the effective operation, and control of these processes? • Determine the resources needed for these processes and ensure their availability? • Assign the responsibilities and authorities for these processes? • Address the risks and opportunities as determined in accordance with the requirements (see 6.1)? • Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results? • Improve the processes and the QMS?				
4.4.2	Is your documented information available to the extent necessary: • To support the operation of your company's processes? • As evidence that the processes are being carried out as planned?				