Insert your company's name or logo.

Gap Analysis Checklist

ISO 9001:2026 Edition Self-assessment

4.2 Understanding the Needs and Expectations of Interested Parties

The intent of this requirement is to ensure that your organization considers the requirements of relevant interested parties beyond those of your customer. The intention is to focus on the interested parties that are relevant to the quality management system (QMS).

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
3	Have the needs and expectations of interested parties that are relevant to the QMS been determined?						
4	Has your organization determined all the interested parties' requirements, including those related to climate, and which of these requirements will be addressed through the QMS?						
5	Does your organization monitor and review information about these interested parties and their relevant requirements? If so, what process is used and how frequently is it performed?						

4.3 Determining the Scope of the Quality Management System

Look for confirmation that your organization has determined the boundaries and applicability of the QMS to establish its scope with reference to any external and internal issues referred to in 4.1 and the requirements of relevant interested parties referred to in 4.2. All requirements within the standard are to be met unless they do not apply. The scope of your QMS may include the whole of the organization, specific and identified functions within the organization, specific sections of the organization, or one or more functions across a group of organizations.

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
6	Has your organization determined the boundaries and applicability of your quality management system to establish its scope?						

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8.3.4 Design and Development Controls

Design reviews must be performed according to planned arrangements. These reviews are essential to keeping the project on track and ensuring the product will meet customer and the organization's specifications. Design reviews should be multi-disciplinary. Documented information of the reviews and actions must be kept.

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
87	Does your organization have controls in place for design and development activities? These include functional and performance requirements, statutory and regulatory requirements, standards or codes of practice the organization has committed to implement, and the potential consequences of failure due to the nature of the products or services.						

8.3.5 Design and Development Outputs

Design outputs must be provided in a manner that facilitates verification against inputs. These outputs must meet input requirements, provide information for purchasing, production and service provision, and contain or reference product criteria for safe and proper use.

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
88	Does your organization ensure that design and development outputs meet the input requirements, are adequate for the provision of products and include monitoring, as appropriate?						
89	Does your organization retain documented information on all design and development outputs?						

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