

# INSERT COMPANY NAME/LOGO HERE

## ISO 9001:2015 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 9001:2015. 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 9001:2015 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 9001:2015.

---	QUALITY MANAGEMENT SYSTEM	OBSERVATIONS / COMMENTS	STATUS
4	<b>CONTEXT OF THE ORGANIZATION</b>		
<p>This clause introduces two 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. 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.</p>			
4.1	<b>Understanding the organization and its context</b>		
	Has your company determined the external and internal issues that are relevant to your purpose and strategic direction?  Have you considered the relevant issues that affect your ability to achieve the intended results of the Quality Management System (QMS)?  How do you monitor and review the information		

## INSERT COMPANY NAME/LOGO HERE

### ISO 9001:2015 Quality Management Systems - The Gap Analysis Checklist

	related to the external and internal issues?		
<b>4.2</b>	<b>Understanding the needs and expectations of interested parties</b>		
	<p>With consideration given to their impact or potential impact on your company's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, have you determined:</p> <ul style="list-style-type: none"> <li>• The interested parties that are relevant to the QMS?</li> <li>• The requirements of these interested parties that are relevant to the QMS?</li> </ul> <p>How do you monitor and review the information about the interested parties and their relevant requirements?</p>		
<b>4.3</b>	<b>Determining the scope of the quality management system</b>		
	<p>To establish the scope of the QMS, has your company determined the boundaries and applicability of the QMS?</p> <p>When determining the scope of the QMS, have you considered the:</p> <ul style="list-style-type: none"> <li>• External and internal issues (per 4.1)?</li> <li>• Requirements of relevant interested parties (per 4.2)?</li> <li>• The products and services of your company?</li> </ul> <p>When a requirement of ISO 9001:2015 can be</p>		

## INSERT COMPANY NAME/LOGO HERE

### ISO 9001:2015 Quality Management Systems - The Gap Analysis Checklist

	<p>applied, has your company applied the requirement?</p> <p>When requirements cannot be applied, and in order to claim conformity to ISO 9001:2015, how do you determine if your ability or responsibility to ensure conformity of products and services are not affected?</p> <p>Is the scope of the QMS available and maintained as documented information?</p> <p>In the scope of the QMS, have you stated the products and services covered by the QMS?</p> <p>Has your company provided justification for any instance where a requirement of the standard cannot be applied?</p>		
<b>4.4</b>	<b>Quality management system and its processes</b>		
<b>4.4.1</b>	<p>Has your company obtained the current version of the ISO 9001:2015 international standard?</p> <p>As required by the standard, have you established, documented implemented, maintained and continually improved the QMS? Have you determined the processes needed for the QMS, their interactions and applications throughout your company?</p> <p>For the QMS processes have you determined the:</p> <ul style="list-style-type: none"> <li>• Inputs required and the outputs expected from the processes?</li> <li>• Sequence and interaction of the processes?</li> <li>• Criteria, methods, including measurements and related performance indicators needed to</li> </ul>		

## INSERT COMPANY NAME/LOGO HERE

### ISO 9001:2015 Quality Management Systems - The Gap Analysis Checklist

	<p>ensure the effective operation, and control of the processes?</p> <ul style="list-style-type: none"> <li>• Resources needed and ensure their availability?</li> <li>• Assignment of the responsibilities and authorities for these processes?</li> <li>• Risks and opportunities (per 6.1), and plans to implement the appropriate actions to address them?</li> <li>• Methods for monitoring, measuring, and evaluation of processes and, if needed, the changes to processes to ensure that they achieve intended results?</li> <li>• Opportunities for improvement of the processes and the QMS?</li> </ul>		
<b>4.4.2</b>	<p>Have you maintained the necessary documented information to support the operation of processes?</p> <p>Has your company retained the necessary documented information to provide the confidence that the processes are being carried out as planned?</p>		
<b>5</b>	<b>LEADERSHIP</b>		
<p style="color: blue;">This clause requires that your top management demonstrates leadership and commitment with respect to the QMS and to customer focus. This section also asks top management to establish, review and maintain a quality policy that is appropriate to your company and to ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood.</p>			
<b>5.1</b>	<b>Leadership and commitment</b>		