INSERT COMPANY NAME/LOGO HERE

ISO 9001:2015 to IATF 16949:2016 Quality Management Systems - The Gap Analysis Checklist

This gap analysis checklist is prepared for use in evaluating a Quality Management System (QMS) against the requirements of the new Automotive standard. The IATF 16949:2016 standard includes the requirements of ISO 9001:2015 and specifies additional automotive industry requirements.

In the checklist, each requirement is expressed as a question that the user (auditor / assessor) can use to evaluate your QMS capabilities. You will need to have copies of the IATF 16949:2016 and ISO 9001:2015 standards to use along with this checklist so that, if required, you can refer to the requirements.

- While the structure of the IATF and ISO standards are the same when comparing the contents, the additional automotive requirements are highlighted in yellow in the relevant sections of the checklist.
- The intent of the main clauses of the new standard is summarized in blue font, and additional information is provided for the IATF 16949:2016 to supplement the intent of ISO 9001:2015.

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.

In the space for 'currently in place', list or reference the procedures or other documents, or evidence that you have reviewed and that will provide information for the new QMS. Take notes on the status of the documents, that is, 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 documented information is in place and if procedures and processes are being complied with, compliance is not your focus for this audit. Remember that the outcome of this audit should be a list of things that your company needs to do to comply with the IATF 16949:2016 standard.

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4	**CONTEXT OF THE ORGANIZATION**				
For ISO 9001:2015, 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. **For IATF 16949:2016**, sections are introduced to supplement requirements for the scope of the QMS, customer specific requirements, conformance of products and processes, and product safety.					
4.1	**Understanding the organization and its context**				
	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 related to the external and internal issues?				
4.2	**Understanding the needs and expectations of interested parties**				
	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: • The interested parties relevant to the QMS? • The requirements of these interested parties that				

	are relevant to the QMS? How do you 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 the scope of the QMS, has your company determined the boundaries and applicability of the QMS? When determining the scope of the QMS, have you considered the: • External and internal issues (per 4.1)? • Requirements of relevant interested parties (per 4.2)? • Products and services covered by the QMS?				
	When a requirement of ISO 9001:2015 can be applied, has your company applied it (see also clause 4.3.1 below)? When requirements cannot be applied, and 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? Has your company provided justification for any instance where a requirement of the standard cannot be applied? Is the scope of the QMS available and maintained as documented information?				
4.3.1	**Determining the scope of the quality management system -supplemental**				

	When determining the scope of the QMS, are the supporting on-site or off-site functions, such as design centers, corporate headquarters, and distribution centers, included in the QMS scope?				
	• In determining the scope of the QMS, have you considered product design and development (per clause 8.3) as the only permitted exclusion? • If applicable, is this exclusion justified and maintained as documented information? • Do you recognize that permitted exclusions do not include manufacturing process design?				
4.3.2	**Customer-specific requirements**				
	Has your company evaluated and included customer specific requirements in the scope of the QMS?				
4.4	**Quality management system and its processes**				
4.4.1	Has your company obtained the current version of the ISO 9001:2015 international standard? 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? For the QMS processes, have you determined: • Inputs required and the outputs expected from the processes?				

	• Sequence and interaction of the processes? • Criteria, methods, including measurements and related performance indicators needed to ensure the effective operation, and control of the processes? • Resources needed and ensure their availability? • Assignment of the responsibilities and authorities for these processes? • Risks and opportunities (per 6.1), and plans to implement the appropriate actions to address them? • Methods for monitoring, measuring, and evaluation of processes and, if needed, the changes to processes to ensure that they achieve intended results? • Opportunities for improvement of the processes and the QMS?				
4.4.1.1	**Conformance of products and processes**				
	How does your company ensure conformance to all customer, statutory & regulatory requirements for all products and processes, including service parts and those that are outsourced?				
4.4.1.2	**Product safety**				
	What processes are documented for the management of product safety related products and manufacturing processes?				
	Do the processes include, as applicable:				

