INSERT COMPANY NAME/LOGO HERE

The Gap Analysis Checklist

This list has been prepared for you by the 16949 Store. Keep in mind, this gap analysis worksheet is intended to identify your organization's gaps against the criteria of ISO/TS16949:2009. Since ISO/TS16949:2009 requires process-based audits; this gap analysis checklist is not designed to substitute for your internal audit worksheets. You will need to have a copy of the ISO/TS16949:2009 Standard to use along with this checklist. There are some spaces on the checklist that you will need to fill in from the Standard. You will see these as you review the checklist. You will see questions on the checklist that refer to the specification and highlighted in yellow are the ones that are additions to ISO 9001 and required for ISO/TS compliance of your Quality Management System.

As you work through the checklist take notes on what is in place, and what needs to be developed. Reference 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 organization needs to do to conform to ISO/TS 16949:2009.

Quality Manual, Procedures and Forms

For a complete set of ISO/TS16949:2009 documentation, visit the 16949 Store. We have designed and documented a Quality Management System for you to use as the foundation of your documentation system. This system addresses all of the requirements of the Standard, from setting quality objectives and measurement criteria for your processes to internal audits and continual improvement. All the procedures interrelate to provide you with an efficient, effective Quality Management System.

Customize these documents instead of starting from scratch and benefit from the expertise of our ISO/TS16949 professionals. We guarantee our products and are confident that using our documentation will save you time and effort and result in a superior Quality Management System.

Our ISO/TS16949 professionals support our products and are available to answer your questions as you proceed with your project. Add our expertise to your implementation team and let us help you succeed.

4 QUALITY MANAGEMENT SYSTEM

	REQUIREMENTS	CURRENTLY IN PLACE (List documents or evidence)	CONFORMING Y/N? Estimated % Complete	ITEMS NEEDED
4.1	**General Requirements**			
This clause asks you to identify how management applies the process approach to achieve the effective and efficient control of processes, resulting in performance improvement. Specifically this section is looking for an overall process evaluation of all quality related processes and their interrelationships. Look to see that your organizational processes are defined and that consideration is given to the items described below.				
	Is there a Quality Management System in place that has been established and documented to meet the requirements of the ISO/TS 16949:2009 Technical Specification?			
	Look for documentation of the processes included in the QMS			
	Look for information on the relationship and sequence of the QMS processes.			
	Ask Management if operation and control of processes is effective. How do they know if it is effective?			
	Ask how they are able to know if resources and information needed to support processes have been provided.			
	Is there any information on the effectiveness of processes?			

	REQUIREMENTS	CURRENTLY IN PLACE (List documents or evidence)	CONFORMING Y/N? Estimated % Complete	ITEMS NEEDED
	How are improvements made to processes?			
	Is there implementation of process measure, monitoring and analysis?			
	What processes does your organization outsource? How are the process controlled?			
4.1.1	**General Requirements - supplemental**			
	Do the controls over outsourced processes ensure your responsibility to conform to all customer requirements?			
4.2	**Documentation Requirements**			
This section addresses how you use documents and records to support effective and efficient operation of your organization. A review of your processes, procedures, work instructions, and records will determine if the standard requirements are met.				
4.2.1	**General**			
	Does your quality system documentation include the documentation required by the technical specification ISO/TS 16949?			
	Is the documentation sufficient to ensure adequate operation of the QMS?			