

ISO 13485:2016 Gap Analysis Checklist

4 QUALITY MANAGEMENT SYSTEM

ISO 13485:2016 Gap Analysis Checklist New 2016 Requirements are Shaded in Yellow		
REQUIREMENTS		OBSERVATIONS
4.1	General Requirements	
4.1.1	Is there a Quality Management System in place that has been established and documented to meet the requirements of the ISO 13485:2016 Standard and the applicable regulatory requirements?	
	When the standard specifies that a requirement, a procedure, an activity or arrangement be "documented", is it implemented and maintained?	
	Are the role(s) undertaken by your company under the regulatory requirements (as a manufacturer, a distributor, an authorized representative, or an importer) documented?	
4.1.2	Determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization	
	Is a risk-based approach to the control of processes applied?	
	Are the sequence and interaction of the processes determined?	
4.1.3	Determine criteria and methods needed to ensure that both the operation and control of these processes are effective	
	ensure the availability of resources and information necessary to support the operation and monitoring of these processes	

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