The ISO 13485:2003 to ISO 13485:2016 Gap Analysis Checklist

This list has been prepared for you by the 13485 Store. You will need to have a copy of the ISO 13485:2016 Standard to use along with this checklist. You will see questions on the checklist that refer to the standard where each requirement is expressed as a question. This checklist is based on the information provided in the 2016-03-01 release of the ISO 13485:2016 international standard.

You have the ISO 13485:2003 quality management system in place and to help you with the implementation of ISO 13485:2016, we have highlighted in yellow the requirements that are revisions / additions to the 2003 version.

After you have prepared your audit schedule, and assigned responsibility to your auditors for different areas or processes to audit, copy each section of the checklist and the section of the standard 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 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 comply with ISO 13485:2016.

Keep in mind that the standard requires six (6) mandatory procedures. In the checklist, we have highlighted in **Bold letters** where **a documented procedure is required,** such as with clauses 4.2.4, 4.2.5, 8.2.4, 8.3, 8.5.2, and 8.5.3. For other clauses of the standard, the phrase such as ‘documented procedures’ is used to specify that a process, a method, a system, a work instruction, or an arrangement be documented. For your purposes, you may apply the most appropriate word.

Quality Manual, Procedures and Forms

For a complete set of ISO 13485:2016 documentation, visit the 13485 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 13485 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 13485 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)	COMPLIANT Yes / No 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 maintaining the effectiveness of the quality system. 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 documented.				
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?			
	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	For the undertaken role(s), are the processes needed for the QMS applied throughout the company?			
	Is a risk based approach to the control of processes applied?			
	Are the sequence and interaction of the processes determined?			
4.1.3	Is the system maintained and is there evidence that its effectiveness is maintained?			

	• Look for methods and criteria needed to ensure that operation and control of the processes are effective.			
	• Look for the resources and information needed to support the operation and monitoring of the QMS processes.			
	• Ask Management how actions are implemented to achieve planned results and maintain effective processes.			
	• Ask how they measure, monitor and analyze the QMS processes.			
	• Look for records that demonstrate conformance to ISO 13485:2016 and comply to applicable regulatory requirements.			
4.1.4	Are changes to QMS processes evaluated for their impact on the QMS? How are changes to the processes evaluated for their impact on the medical devices produced under the QMS? Are changes to the QMS processes controlled in accordance with the ISO requirements and regulatory requirements?			