The 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.

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 and in the checklist, we have highlighted in **yellow** 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 'document a process' 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.

	How are the processes controlled?			
	Where are the controls defined and documented?			
	Are the controls proportionate to the risk involved and to the ability of external providers to meet requirements?			
4.1.6	Is a system in place for the validation and revalidation of computer software used in the QMS?			
	Is the approach proportionate to the risk associated with the software?			
	Are records maintained?			
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 procedures, work instructions, and records will determine if the standard requirements and regulatory requirements are met.				
4.2.1	**General**			
	Does your quality system documentation include the documentation required by ISO 13485:2016?		Blue text provides additional informaiton	
	Does it include:			
	• Documented statements of the Quality Policy and Quality Objectives?			
	• A Quality Manual?			

	Do these documents define the complete manufacturing process and, if applicable, requirements for installation and servicing?			
4.2.4	**Control of Documents**			
A documented procedure is required for the control of documents. Documents such as, work instructions, procedures, specifications, forms and records, must be controlled.				
	Do you have a formal procedure regarding the control of documents for your company?	Yellow highlight shows where a documented procedure is required		
	• Are documents reviewed and approved for adequacy prior to issue?			
	• Are documents updated and re-approved?			
	• How are changes identified?			
	• How does the company ensure that changes to documents are reviewed and approved by either the original approving function or another designated function, which has access to pertinent background information upon which to base its decisions?			
	• Are documents available to those that need to use them?			
	• How is the most current version kept in the correct locations?			
	• Can users easily identify documents?			

5.4.2	**Quality Management System Planning**			
Review the documents or evidence in the QMS complying with this clause. Verify planning includes requirements for meeting customer specifications. Verify quality planning includes resources and takes into account the needs of your organization as changes occur.				
	What quality planning process is in place?			
	How is planning of the QMS carried out?			
	Is top management involved to ensure that the QMS meets the requirements outlined in clause 4.1?			
	How is the integrity of the QMS maintained when changes are planned and implemented?			
	How are changes evaluated and approved?	Uses logical document numbering scheme {ex: 5.5, 5.5.1,ect)		
5.5	**Responsibility, Authority and Communication**			
5.5.1	**Responsibility and Authority**			
Verify how top management has defined responsibilities and authorities. This information could be in the form of an organizational chart.				
	How does top management ensure that responsibilities and authorities are defined, documented, and communicated within the company?			
	Has top management established the interrelation of all personnel who manage, perform and verify work-affecting quality?			
	Is the independence and authority necessary to perform these tasks assured?			