The ISO 13485:2016 / FDA.QSR 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 and the quality system FDA.QSR (21 CFR 820) regulations 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 and on the code of federal regulations of 2016-05-26. The applicable parts of the regulation that result in additions or revisions for FDA are highlighted in yellow.

Provided in Microsoft Word for easy customization

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, note the differences between the standard and the regulation. 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 and (21 CFR 820) Quality System Regulation.

Keep in mind that the standard requires six (6) mandatory procedures and in the checklist, we have noted 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 and for the quality system regulation, the phrases such as 'document a process' and 'establish and maintain procedures' are 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 / FDA 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 and the QSR, 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 of the applicable regulatory requirements?			
	Are the role(s) undertaken by your company under the regulatory requirements (as a manufacturer, distributor, authorized representative, or importer) documented?	Additions or revisions for FDA are highlighted in yellow		
	Is the QMS established and maintained for the specific medical device(s) designed or manufactured, and meets the requirements of (21 CFR Part 820) and part 820.5?			
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?			

	Do the medical device files include as required information such as:			
	• The general description of the medical device intended use or purpose, and labelling, including any instructions for use?			
	• Design and development specifications for the product, and records of changes?			
	• Procedures or specifications for manufacturing, packaging, storage, handling and distribution?			
	• Measuring and monitoring procedures?			
	Do these documents define the complete manufacturing process and, if applicable, requirements for installation and servicing?			
	For (21 CFR Part 820) does the process for medical device files consider the:			
	• DMR, device master record per 820.181?			
	• DHF, design history file per 820.30 j?			
	• DHR, design history record per 820.184?			
	• QSR, quality system record per 820.186?			
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?			