

The ISO 13485:2016 Internal Audit Checklist

This checklist is based on the information provided in the 2016-03-01 release of the ISO 13485:2016 international standard. The checklist is best used by trained and practicing auditors to evaluate or assess Quality Management Systems requirements based on the standard. You will see questions on the checklist that refer to the standard, and for each clause, provisions are made for additional questions.

The auditors are expected to keep in mind that the standard requires six (6) mandatory procedures, 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.

The auditors must use a great deal of discretion and therefore must be careful and thoughtful prior to establishing a deficiency against a requirement. Evidence for visible top management leadership, commitment and quality management action must be looked for.

The **bold** numbers and tittles used in the first two columns of the checklist indicate the "Requirements" and may be referred to on nonconformity reports prepared by the auditor.

During assessment of each requirement, auditors record the status of the evaluation by indicating in the right hand column a

Yes - for Acceptable Condition or No - for Deficient Condition



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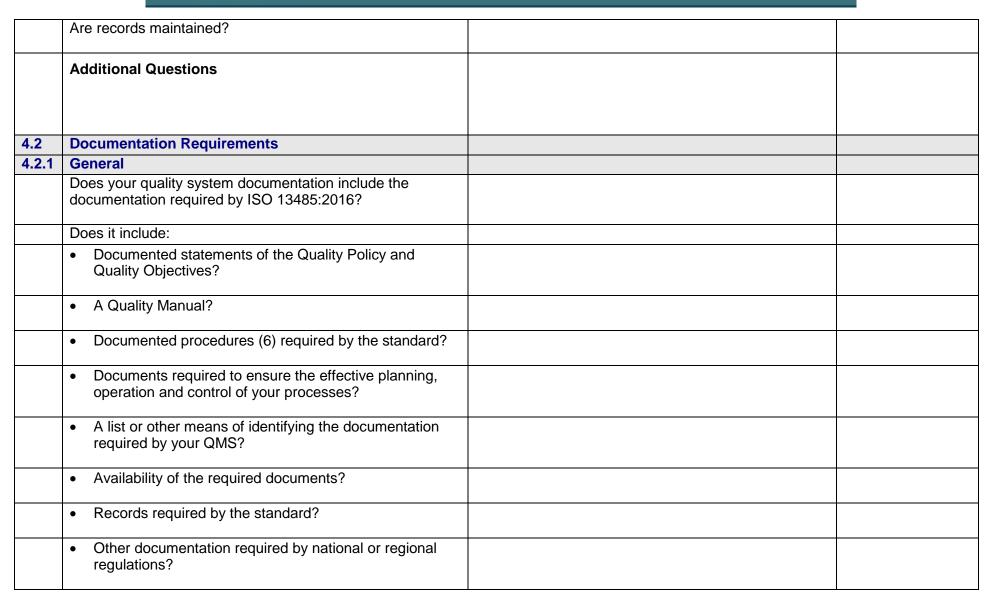
4 QUALITY MANAGEMENT SYSTEM

	REQUIREMENTS	OBSERVATIONS / COMMENTS / DOCUMENTS REVIEWED	RESULT
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?		
	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. 		



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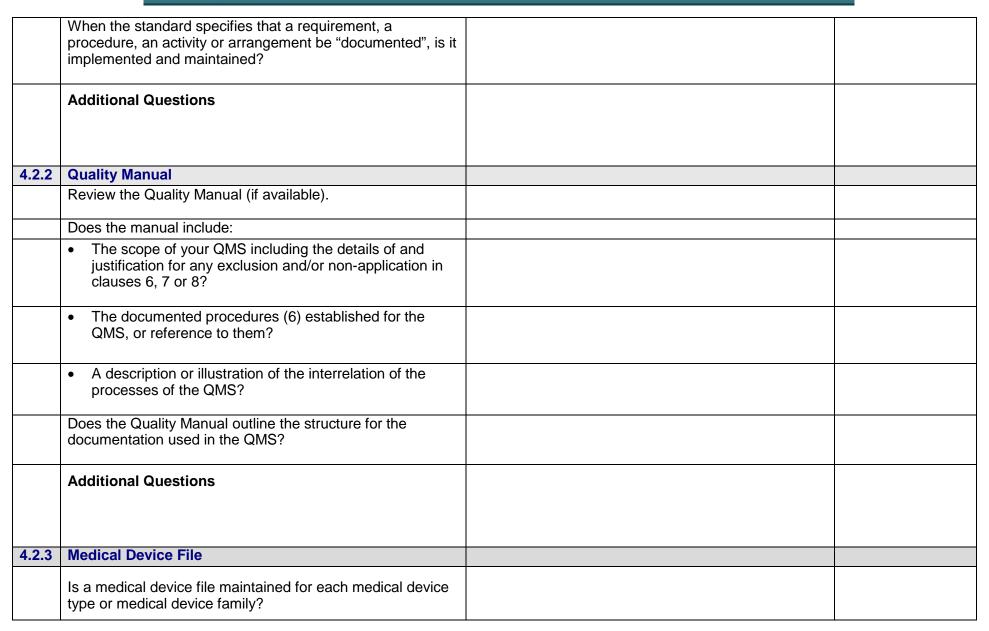
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