The ISO 13485:2016 / FDA-CFR Internal Audit Checklist

This list has been prepared for you by the 13485 Store. You will need to have copies of the ISO 13485:2016 standard and Part 820, quality system regulation / code of federal regulations (21 CFR 820) to use along with this checklist.
You will see questions on the checklist that refer to the standard and the regulation where the requirements are expressed as questions. 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.

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, and for requirements of the quality system regulation, 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

	REQUIREMENTS	OBSERVATIONS / COMMENTS / DOCUMENTS REVIEWED	RESULT
	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?		
	Additional Questions		
4.2.4	**Control of Documents**		
	Do you have a formal procedure regarding the control of documents for your company?		
	• 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 either by the original approving function or another designated function which has access to pertinent background information upon which to base its decisions?		

	REQUIREMENTS	OBSERVATIONS / COMMENTS / DOCUMENTS REVIEWED	RESULT
	• Are they consistent with the quality policy and how do they contribute to meeting the quality policy?		
	Additional Questions		
5.4.2	**Quality Management System Planning**		
	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?		
	For 820.5 and 820.20 d, is a quality system and the quality planning, that are appropriate for the specific medical devices, established and maintained?		
	As part of management responsibility and for 820.20.d is the process for a quality planning established and maintained to define the quality practices, resources, and activities relevant to devices, that are designed and manufactured, and describe how the requirements for quality are met?		

	Are the inspection results reviewed, verified and approved prior to release?		
	For (21 CFR 820 and for production and process controls, is consideration given to the following control requirements of part 820.70:		
	• 820.70.a General requirements?		
	• 820.70.b Production and process changes?		
	• 820.70.c Environmental control? - also in clause 6.4		
	• 820.70.d Personnel? - also in clause 6.2		
	• 820.70.e Contamination control?		
	• 820.70.f Buildings? - also in clause 6.3		
	• 820.70.g Equipment? - also in clause 6.3		
	• 820.70.h Manufacturing material? - also in clause 6.3		
	• 820.70.i Automated processes and software validation? - also in clause 7.6.		
	Additional Questions		
7.5.2	**Cleanliness of Product**		
	Are there documented requirements for cleanliness?		
	Has the company established documented requirements for cleanliness of product if:		
	• Product is cleaned by the company prior to sterilization and/or its use?		