A Guide to Internal Auditing

ISO 13485:2016

Introduction: Why are you here?

- To learn more about ISO 13485:2016
- To be able to evaluate you own area and make improvements.
- To understand the audit process.
- To be able to participate in the audit process.

Performing an Internal Audit
»Techniques
More about audits and auditing techniques

• Auditees must be made comfortable during interviews and there are techniques that are used by auditors to make it easier.

• Experienced auditors learn to read body language and other non-verbal clues.

• The auditor will question the auditee, listen to the answers, and anticipate the answer to the question.

• It is necessary to listen critically, analyze the answer, record the information and at the same time prepare the next question.

Internal Audits: Conclusion

The Internal Audit process is one of the most important in ISO 13485 or any ISO based standard.

Conduct internal audits to determine if the QMS:

- Conforms to planned arrangements for quality management .. this includes both the requirements of the ISO standard and your own operational requirements.

- Has been properly implemented and is maintained.

- Provide information on results of audits to the management group.

13485 Store

The tools you need to Achieve and Maintain ISO 13485

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
	Does the Quality Manual outline the structure for the documentation used in the QMS?		
	Additional Questions		
4.2.3	**Medical Device File**		**4.2.3**
	Is a medical device file maintained for each medical device type or medical device family?		
	Do the files reference the documents generated to demonstrate conformity to requirements of the ISO standard and compliance with regulatory requirements?		
	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?		

	REQUIREMENTS	OBSERVATIONS / COMMENTS / DOCUMENTS REVIEWED	RESULT
	• The requirement for medical device files and considers the related requirements for 820.30 j design history file, 820.181, device master record and for 820.184 device history record?		
	• The requirement for 820.40 b, that approved changes are communicated to the affected personnel in a timely manner?		
	• The requirement for 820.40 that records of changes include a description of the change, identification of the affected documents, the signature of the approving person(s), the approval date, and when the changes become effective?		
	Additional Questions		
4.2.5	**Control of Records**		
	Is there a documented procedure in place for the control of records?		
	Where are records kept?		
	Is this location identified so that users can easily find records?		
	Can users identify the records?		
	Are the records legible?		
	Can changes to records be identified?		

	REQUIREMENTS	OBSERVATIONS / COMMENTS / DOCUMENTS REVIEWED	RESULT
	• Quality assurance procedures and specs?		
	• Packaging and labeling specs?		
	• Installation, maintenance & servicing procedures?		
	• The requirement for 820.184 to prepare and maintain the DHR, design history record, for each batch, lot, or unit & include or refer to the location for:		
	• The dates of manufacture?		
	• The quantity manufactured?		
	• The quantity released for distribution?		
	• The acceptance records which demonstrate the device is manufactured according to the DMR?		
	• The primary identification label and labeling used for each production unit?		
	• Any device identification & control number used?		
	Additional Questions		