ISO 13485:2016
Internal Auditor Training

Trainer's Guide

AGENDA

I. The Standard

	Introduction to Auditing
0:15	Presentation: Guide to Internal Auditing ISO 13485:2016
0:15	Review Document: ISO 13485:2016
0:30	Exercise: Is it a Requirement?
2:00	Presentation: Requirements of ISO 13485:2016
0:45	Exercise: Find the Requirement
0:15	Questions

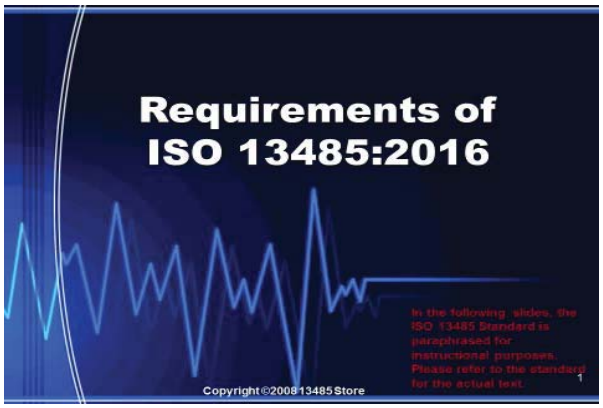
II. The Audit

0:30	Scheduling the Audit
0:30	Planning the Audit
0:45	Opening Meeting
0:45	Audit 5.3 Quality Policy
0:45	Audit 7.1 Planning of product realization
0:45	Audit 7.2 Customer Related Processes
0:45	Audit 7.4 Control of External providers
0:45	Audit 8.5.2 Corrective Action
0:30	Audit 5.6 Management Review
0:30	Auditors Document Findings
0:30	Final Audit Report
0:30	Closing Meeting
0:30	Creating the Audit File

ISO 13485:2016 Requirements

Now that the students are familiar with the organization of the standard, this section will outline ***the requirements*** of each section – what it is really asking them to do.

Requirements of ISO 13485:2016 Power Point presentation



First, there is a brief 8-page introduction to serve as a review:

- What is ISO 13485:2016?
- What are the steps for Registration?
- Benefits of Registration
- The Process Model

Second, the rest of this presentation outlines the requirements of ISO 13485:2016.

- ISO 13485:2016: Clause by Clause Review
  - What does ISO 13485 Require?
  - What are key points of clauses?
  - What should Auditors look for?
- What are the next steps?
- Appendix: Summary of Key ISO 13485:2016 Requirements

If you use the speaker's notes this review could take about 2+ hours.

- Students can take notes in their manual.
- We've included the presentation in this Trainer's Guide so you can review the notes while presenting.

We saw an earlier in 5.4.2 the requirements for planning of the QMS.

Here is the requirement to plan the product realization processes.

• Identify work instructions needed to control processes. What processes require documentation in order to be performed with consistency between employees?

• A Quality Planning Worksheet could be developed for new products or processes that would be completed each time a new product or process or equipment is introduced.

• Special Processes must be identified and validated. A special process is defined as a process for a product or service that cannot be inspected to determine conformance.

The organization shall establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained.