Requirements of ISO 13485:2016

Trainer's Guide

Requirements of ISO 13485:2016

Materials

This course is designed to train employees on the requirements of ISO 13485:2016. The course covers the structure, emphasis, and requirements of the standard.

The course is approximately two hours long; the length may be changed by covering less detail, or by adding the suggested group exercises.

To begin preparing for the training session:

- Print a copy of the Student Manual. You will then be able to prepare for the presentation using this guide and student manual.

The content of the student manual matches the information in the PowerPoint slides. Let students know this at the beginning of the presentation to make it easier for them to take notes.

You will need one copy of the standard for the trainer, and you may want copies for each student to refer to for details. **Standards are available electronically from:** http://13485store.com/buy-standards.aspx

Agenda

Determine the appropriate time frame for your audience. The PowerPoint presentation is 96 slides. If you cover all the slides your session will run about 2 hours.

• The 13485 Standard
• Steps to Registration
• Benefits
• Process Approach
• Requirements
• Details of the Standard: Sections 4 through 8
• Summary
• Tools for Implementation

Sample Agenda: (This agenda allows for time for attendees to ask questions during the presentation, as well as at the end)

8:00 Introduction/Coffee
8:15 ISO 13485:2016 Overview (Registration, Benefits)
8:30 ISO 13485:2016 Requirements & Process Approach
8:45 Details (Each Section of the Standard)
9:15 Break
9:30 Details (Continued)
9:50 Implementation Steps

For a more in-depth training, add the group exercises to the agenda.

Suggestions for Group Exercises

1. Identify Key Processes for each department represented. (In department groups)
    - Process Map these processes
    - List procedures required

1. Identify permissible exclusions

2. Review current quality policy. Develop measurable goals for each department to support this policy.

3. Develop a program to communicate the importance of meeting customer requirements.

4. Develop a communication program for training employees on the importance of their position and its effect on meeting quality objectives.

Additional Information

ISO 13485 Training: http://www.13485store.com/13485-2016-Employee-Training.aspx

Medical Device Industry Resources: http://www.13485store.com/Resources.aspx

Order standards online from: http://www.13485store.com/Buy-Standards.aspx

Guidance for ISO 13485:2016 Available online from www.iso.org

Questions we will cover today:

- What is ISO 13485:2016?
- Steps to registration
- Benefits of registration
- The Process Model/Process Approach
- What are the requirements of ISO 13485?
  - Section 4 – General Requirements
  - Section 5 – Management Responsibility
  - Section 6 – Resource Management
  - Section 7 – Product Realization
  - Section 8 - Measurement, Analysis and Improvement
- Appendix – Key Requirements

Each member country has representatives that make up a Technical Advisory Group (TAG).

These groups draft the standard, then members comment and vote on the standard.

The document then becomes and ISO standard.

These standards are not regulations.

They are a method of getting a standard set of criteria for quality management systems.

An outside agency, the registrar, will then audit to see if you have all the required elements in place.

If you do, you will get ISO 13485 registration. This registration tells others all over the world that you have this quality system in place.

As we go through the training, and cover the requirements you will see that these requirements are basically just good business practice.