

Course Outline for ISO 13485:2016 Lead Auditor Training

Course objective

This course gives an overview of all important aspects for managers of an organization in order to implement and maintain an ISO 13485:2016 compliant management system, Lead or participate in Internal or Supplier audits.

Course length

5-7 days are required to complete the ISO 13485:2016 Lead Auditor course (doing a couple of hours/day).

Who should attend?

This is the ideal course for anyone who does NOT have time to allocate a full week to take a LIVE class on ISO 13485:2016, wants to quickly and efficiently understand the requirements, and learn how to lead audits to ISO 13485:2016. It is also the ideal course if you need to upgrade your knowledge and expertise from ISO 13485:2003 to ISO 13485:2016.

The structure of the training is as follows:

- The Standard
- The Process Approach
- Scope
- Quality Management System
- Management Responsibility
- Resource Management
- Product Realization
- Measurement, Analysis and Improvement
- ISO 19011 the guideline on how to audit management systems
- Cases Studies on ISO 13485:2016 in various medical device companies

Worldwide Course Recognition:

CALISO online training courses are recognized by all registrars, notified bodies and hiring companies as objective evidence of effective training on the particular standard and regulation. Since 1999, they have been the most popular and most widely used training courses in English, with over 25,000 trainees in the US and worldwide. The standards and regulations are provided online under licensing agreements.

Course requirements

The training is optimized for recent versions of all major Internet browsers.

Certificate requirements

The course uses a continuous evaluation method with on-going quizzes to facilitate the information retention. If your final average is equal or greater to 70% you will be issued a **training certificate**. If your final average evaluation is less than 70%, you will have to take a final exam and score above 70% to be issued the training certificate.