

Course Outline for ISO 13485:2003/ ISO 19011 Auditor

Course objective

This course has been specifically designed to meet the needs of the Medical Device Industry and is for individuals responsible for planning and scheduling an audit program for ISO 13485 and those who must perform audits to ISO 13485 for quality assurance. It provides in-depth understanding of the ISO 13485 Audit Process.

Course length

2-3 days are required to complete the ISO 13485 auditor course (doing a couple of hours/day).

Who should attend?

This is the ideal course for anyone who wants to quickly and efficiently learn how to audit to ISO 13485:2003, upgrade his/her expertise from auditing ISO 13485:1996 to ISO 13485:2003, and upgrade his/her expertise from auditing with the guidance ISO 19011:2002 to ISO 19011:2011.

The structure of the training is as follows:

1. DEFINITIONS
2. TYPES OF AUDITS
3. AUDIT OBJECTIVES
4. ROLES AND RESPONSIBILITIES
5. AUDITOR ACTIVITIES
6. INITIATING THE AUDIT
7. PREPARING THE AUDIT
8. EXECUTING THE AUDIT
9. WHAT THE AUDITOR IS LOOKING FOR
10. AUDIT DOCUMENTS
11. AUDIT TECHNIQUES: TELL ME/SHOW ME
12. AUDIT TECHNIQUES: AUDIT PATH
13. AUDIT TECHNIQUES: GRADUAL ELEVATION
14. AUDIT TECHNIQUES: SAMPLING
18. AUDIT COMPLETION AND CORRECTIVE ACTION FOLLOW-UP
19. MEDICAL DEVICE CASE STUDIES

Worldwide Course Recognition:

CALISO online training courses are recognized by all registrars 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 15,000 trainees in the US and worldwide. The standards and regulations are provided online under licensing of the American National Standard Institute (ANSI), SAE International, or courtesy of the Federal Drug Administration (FDA).

Course requirements

- If you are not familiar with the ISO 13485:2003 standard, it is recommended to take the ISO 13485:2003 training course first.
- The training is optimized for Microsoft Internet explore 5.0 or higher and Netscape 4.5 or higher.

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.