

Course Outline for ISO 13485:2003 Lead Auditor Training

Course objective

This course is based on the quality management system (QMS) standard ISO 9001:2008, the guideline document for implementing and improving QMS's, and the Fundamentals and vocabulary for QMS's ISO 9000:2005. It is also based on ISO 19011:2011, which is a guideline document for auditing management systems. The case studies in the later part of the course will be presented along with the applicable sections of ISO 13485:2003.

Course length

5-6 days (doing a couple of hours/day) are required to complete the ISO 13485:2003 lead auditor course.

Who should attend

Anyone who wants to quickly and efficiently understand and learn how to audit or lead an audit using the QMS and EMS auditing guideline to ISO 19011.

Course includes

The structure of the training is as follows

- 1.0 THE STANDARD
- 2.0 THE PROCESS APPROACH
- 3.0 SCOPE
- 4.0 QUALITY MANAGEMENT SYSTEM
- 5.0 MANAGEMENT RESPONSIBILITY
- 6.0 RESOURCE MANAGEMENT
7. 0 PRODUCT REALIZATION
- 8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT
- 9.0 DEFINITIONS
10. TYPES OF AUDITS
11. AUDIT OBJECTIVES
12. ROLES AND RESPONSIBILITIES
13. AUDITOR ACTIVITIES
14. INITIATING THE AUDIT
15. PREPARING THE AUDIT
16. EXECUTING THE AUDIT
17. WHAT THE AUDITOR IS LOOKING FOR



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18. AUDIT DOCUMENTS
19. AUDIT TECHNIQUES: TELL ME/SHOW ME
20. AUDIT TECHNIQUES: AUDIT PATH
21. AUDIT TECHNIQUES: GRADUAL ELEVATION
22. AUDIT TECHNIQUES: SAMPLING
23. AUDIT COMPLETION AND CORRECTIVE ACTION FOLLOW-UP
24. INDUSTRY 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

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.