Apex
Quality Assurance

5-Day

ISO 13485:2016 with 21CFR820

Lead Auditor Training

Medical Device Quality Management Systems

Register by phone

919-635-5581

Register online

www.apexqualityassurance.com

Exemplar Global

ISO 13485:2016 & 21CFR820
(5-Day)

At A Glance

Lead Auditor Training for Medical Quality Management Systems

This course provided from Apex is taught in conjunction with Omnex, an Exemplar Global Certified TPECS provider for Exemplar Global MD, AU and TL Competency Units.

This five-day course has been developed to satisfy the Exemplar Global MD, AU and TL Examination Profiles and, as such, all attendees who successfully pass the exams during this course will achieve a Certificate of Attainment for the following competency units:

- Exemplar Global MD
- Exemplar Global AU
- Exemplar Global TL

This seminar fully covers the ISO 13485:2016 requirements. Auditing topics from ISO 19011 such as the auditing process and methodologies, e. g. planning and conducting an audit, writing nonconformity statements, preparing an audit summary and report, and verifying corrective actions are also covered with a focus on ISO 45001:2018.

Auditing case studies to develop skills for identifying nonconformities will be used.

This class also covers the comparable 21 CFR 820 content for additional guidance for organizations in the Medical Device sector.

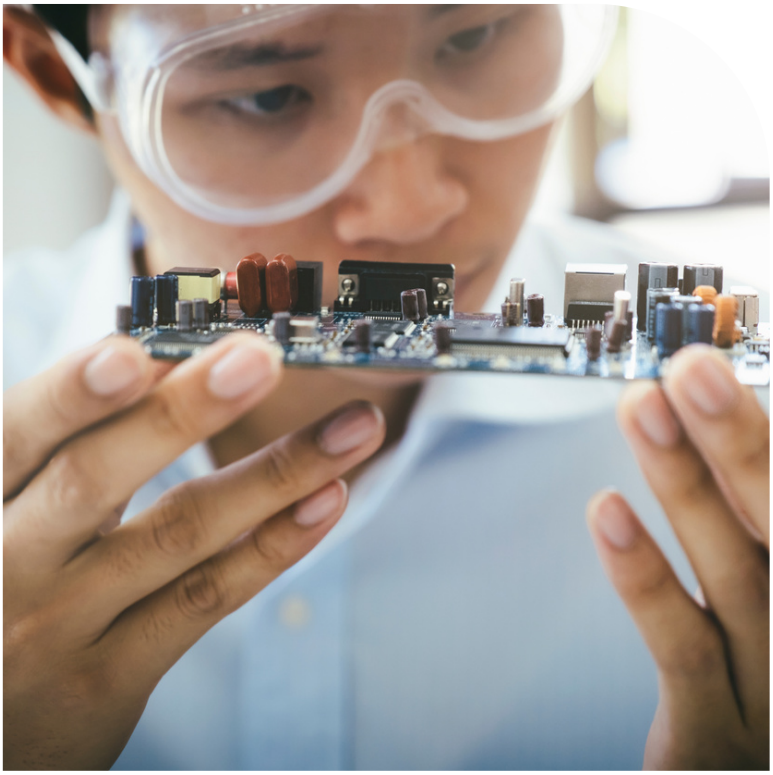
ISO 13485:2016 & 21CFR820 (5-Day)

Who Should Attend

Lead Auditor Training for Medical Device Quality Management Systems

This seminar is designed for Management Representatives, ISO 13485:2016 Implementation Teams, Auditors and others who would like to learn the widely used international management systems auditing process.

An understanding of the ISO 13485:2016 requirements and a minimum 12 months of work experience in applying or auditing quality management systems is recommended. The first 1.5 and 3 days of this class are offered separately for those new to auditing or quality management.



ISO 13485:2016 & 21CFR820
(5-Day)

Seminar Goals

Lead Auditor Training for Medical Device
Quality Management Systems

- Understand the application of Quality Management Principles in the context of ISO 13485:2016.
- Relate the quality management system to the organization's medical devices and provision of related services.
- Understand the application of the principles, procedures and techniques of management systems auditing.
- Understand the application of the principles, procedures, and techniques of auditing.
- Understand the conduct of an effective audit in the context of the auditee's organizational situation.
- Understand the application of the regulations, and other considerations that are relevant to the management system, and the conduct of the audit.
- Practice personal attributes necessary for the effective and efficient conduct of a management system audit.
- Establish, plan and task the activities of an audit team. Communicate effectively with the auditee and audit client.
- Communicate effectively with the auditee and audit client.
- Organize and direct audit team members.
- Understand conflict management principles.
- Prepare and complete the audit report.

ISO 13485:2016 & 21CFR820
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Seminar Outline

Lead Auditor Training for Medical Device Quality Management Systems

Day One:

- Introduction to ISO 13485
- The ISO 13485 Standard Explained
  - **MD Written Exercise 1**
- Overview of ISO 13485:2016 Requirements
  - **MD Written Exercises 2a, 2b (Audit Scenarios)**

Day Two:

- Overview of ISO 13485:2016 Requirements (cont'd)
  - **MD Written Exercise 2c (Audit Scenarios)**
  - **MD Written Exercise 3**
- Introduction to Management System Audit Trails
- Management of Audit Programs
- Management System Audit Planning and Preparation
  - **Breakout Exercise 1:** Writing an Objective and Scope Statement
  - **Breakout Exercise 2:** Documentation Review
  - **Breakout Exercise 3:** Creating an Audit Plan

Day Three:

- Performing the Audit
  - **Breakout Exercise 4:** Performing an Audit
- Writing Nonconformity Statements
  - **Breakout Exercise 5:** Writing Nonconformity Statements
- Closing Meeting
- Completing the Audit Report
- Corrective Action and Closeout
- **Management Systems Auditing Exam**

Day Four:

- Leading Audit Teams
- Customer Specific Requirements
- Management System Certification Scheme and Auditor Qualifications
- **Leading Audit Teams Mock Audit Case Study**

Day Five:

- Review of Audit Process and Audit Management Strategies
- **Leading Audit Teams Exam**
- Practical Application of Audit Principles and Instructor Interviews

Attendees successfully completing the examinations provided in conjunction with this course receive a Certificate of Completion from Omnex a partner of Apex Quality Assurance.