APEX
QUALITY ASSURANCE

4-Day

ISO 13485:2016 with 21CFR820

Lead Auditor Training

Medical Device Quality Management Systems

EXEMPLAR GLOBAL
RTP Certified Training

Register by Phone:
919-635-5581

Register Online:
www.apexqualityassurance.com

Exemplar Global

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

At A Glance

Lead Auditor Training for Medical Quality Management Systems

This course, provided by Recognized Training provider APEX QA, is a great way to complete the mainstays of medical device quality training.

This four-day experience was developed to satisfy the Exemplar Global MD, AU and TL Examination Profiles. All attendees who pass exams at the conclusion of 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 ISO 13485:2016 requirements while providing practical experience along the way. Learn auditing topics from ISO 19011 *and* ISO 45001:2018, such as the auditing process and methodologies,

Alongside lectures, practical applications of auditing skills are a cornerstone of our curriculum. Alongside experienced instructors, write nonconformity statements, prepare audit summary reports, verify corrective actions, and perform mock audits on carefully developed case studies.

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

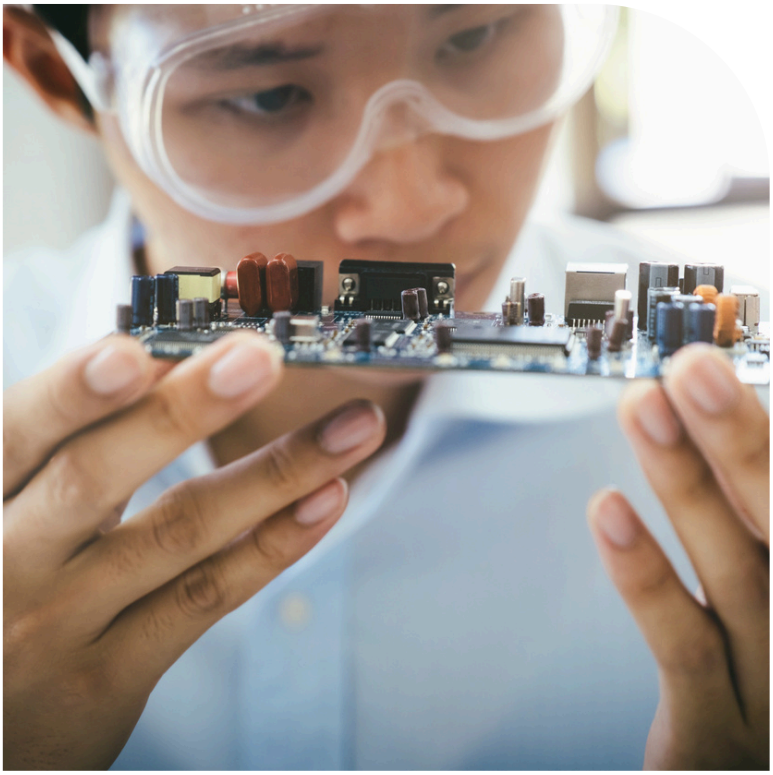
ISO 13485:2016 & 21CFR820 (4-Day)

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 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
(4-Day)

Seminar Goals

Lead Auditor Training for Medical Device Quality Management Systems

- To understand the application of Quality Management Principles in the context of ISO 13485:2016.
- To relate the quality management system to the organization's medical devices and provision of related services.
- To understand the application of the principles, procedures and techniques of management systems auditing.
- To 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.
- To understand the application of the regulations, and other considerations that are relevant to the management system, and the conduct of the audit.
- To employ the necessary behavioral attributes for the efficient conduction of a management system audit.
- To establish, plan, and task the activities of an audit team.
- To communicate effectively with an auditee and audit client.
- To organize and direct audit team members.
- To understand conflict management principles.
- To prepare and complete the audit report.

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

Seminar Outline

Lead Auditor Training for Medical Device Quality Management Systems

Day One:

- Lecture: Intro to Management Systems
- Lecture: Quality Standards Including 13485
- Workshop: Terms and Definitions ISO 19011
- Lecture: ISO 13485
- Workshop: Analyzing Processes

Day Two:

- Exam: ISO 13485 Self Study
- Workshop: ISO 13485 Clauses
- Lecture: Auditing Management Systems
- Lecture: Developing Process-Based Management Systems
- Lecture: Audit Planning and Preparation
- Exam: ISO 13485

Day Three:

- Workshop: Reviewing System Docs + Preparing Audit Schedules
- Workshop: Reviewing Processes and Checklists
- Lecture: Performing Lead Audit Investigation
- Workshop: Verifying Facts
- Lecture: Concluding the Audit
- Workshop: Determining Nonconformities

Day Four:

- Workshop: Writing Nonconformity Statements
- Workshop: Interviewing Auditees
- Workshop: Closing Meeting Preparation
- Workshop: Report Writing

Attendees who complete examinations provided in conjunction with this course receive a Certificate of Completion from APEX Quality Assurance: a Recognized Training Partner of Exemplar-Global.