

**3-Day**

# ISO 13485:2016 with 21CFR820

## Internal Auditor Training

Medical Device Quality Management Systems



EXEMPLAR  
GLOBAL

RTP Certified  
Training

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919-635-5581

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Exemplar  
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**ISO 13485:2016 & 21CFR820  
(3-Day)**

# At A Glance

## Internal Auditor Training for Medical Quality Management Systems

This 3-day course has been developed to satisfy the Exemplar Global MD, AU 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:

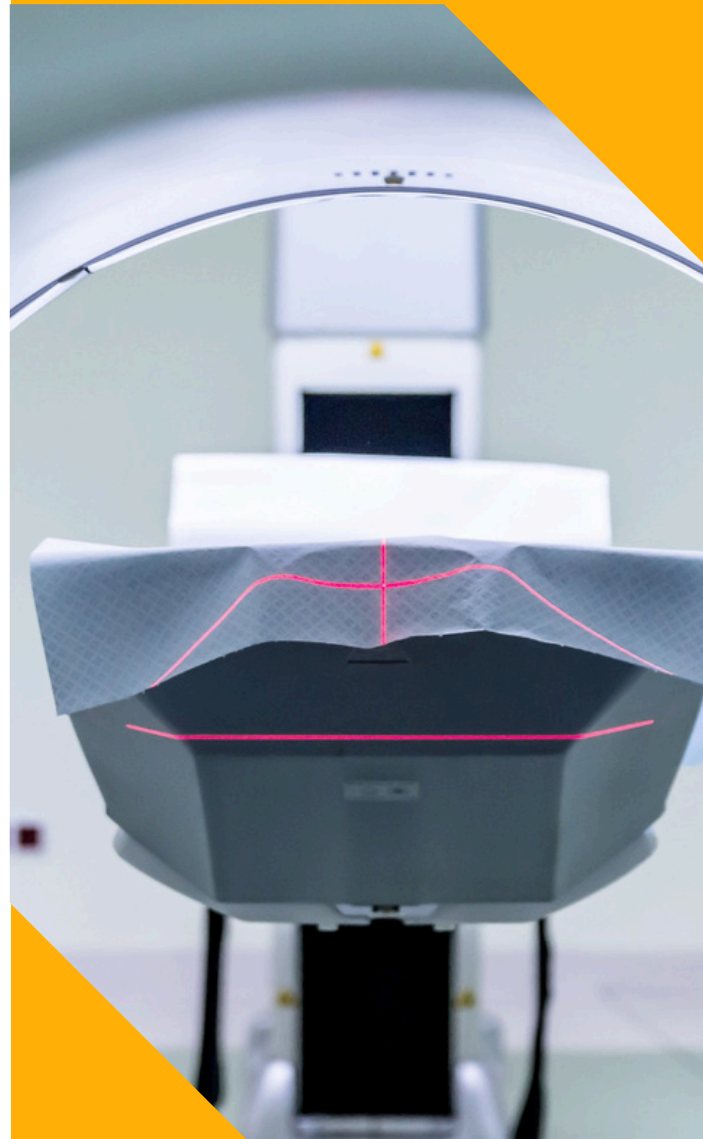
- Exemplar Global MD
- Exemplar Global AU

APEX QA is an Exemplar Global Certified Recognized Training Partner (RTP), and all participants who pass the exam at the end of instruction will receive an Exemplar Global Certification.

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

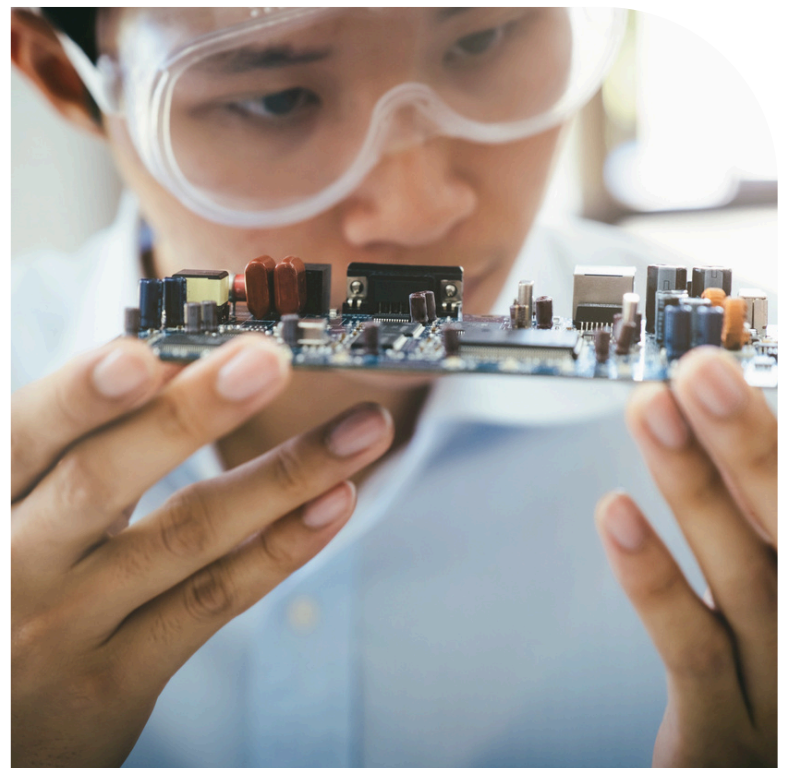


# Who Should Attend

## Internal 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 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.



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# Seminar Goals

## Internal Auditor Training for Medical Device Quality Management Systems

- Understand the application of Quality Management Principles in the context of ISO 13485:2016 and 21 CFR 820.
- Relate the quality management system to the organization's medical devices and supporting processes.
- Interpret the requirements of ISO 13485:2016 and 21 CFR 820 in practical, audit-relevant terms.
- Apply the principles, procedures, and techniques of internal auditing.
- Conduct effective audits within the context of the auditee's organizational situation.
- Recognize and evaluate objective evidence through audit trails and documentation review.
- Practice communication skills necessary to interact effectively with auditees during an internal audit.
- Write clear, objective nonconformity statements.
- Prepare and complete internal audit reports.
- Understand the process of corrective action and audit closeout.
- Demonstrate personal attributes necessary for the effective and efficient conduct of an internal audit.



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# Seminar Outline

Internal 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 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 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

*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.*