Apex
Quality Assurance

2-Day

Understanding the Requirements of ISO 13485: 2016

Medical Device Quality Management Systems

Register by phone

919-635-5581

Register online

www.apexqualityassurance.com

Understanding ISO 13485: 2016

At A Glance

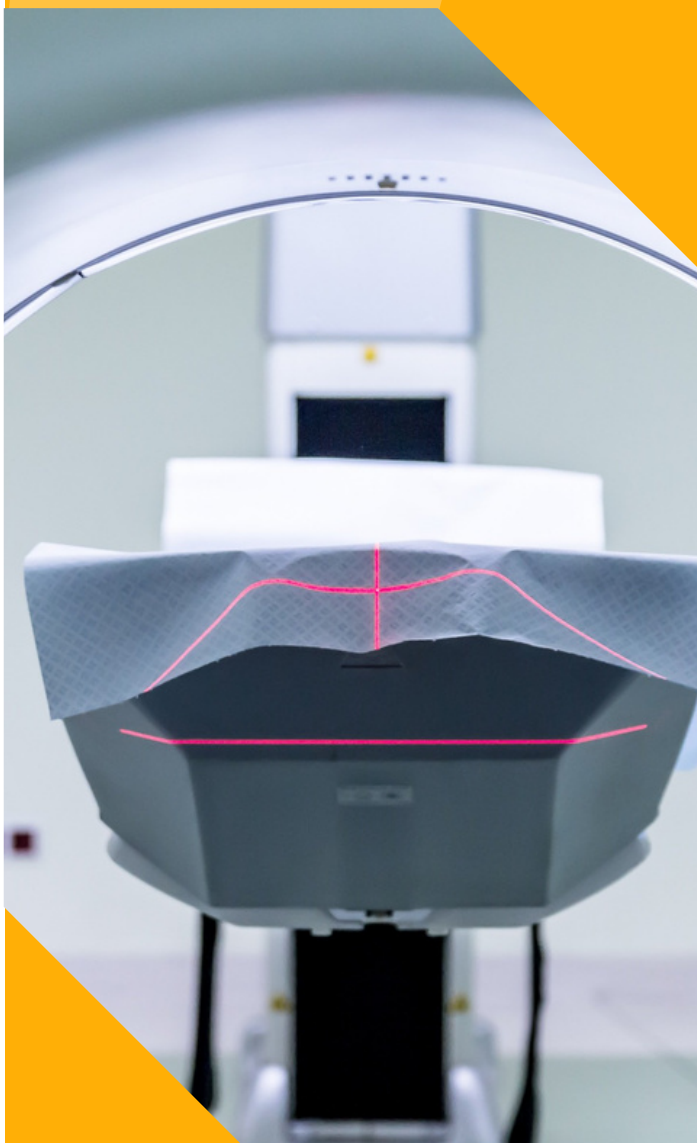
Understanding the Requirements of ISO 13485: 2016 for Model Medical Quality Management Systems

The two-day ISO 13485-compliant medical device requirements.

Medical device auditing requires technical knowledge as well as a deep understanding of international medical device regulations. Students participating in this course will gain knowledge and skills to implement a QMS with ISO13485:2016 management system requirements.

Many medical device companies are utilizing ISO 13485 as a platform to build their business management systems because of its value or because third-party certification is a specified requirement by customers and/or regulators.

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

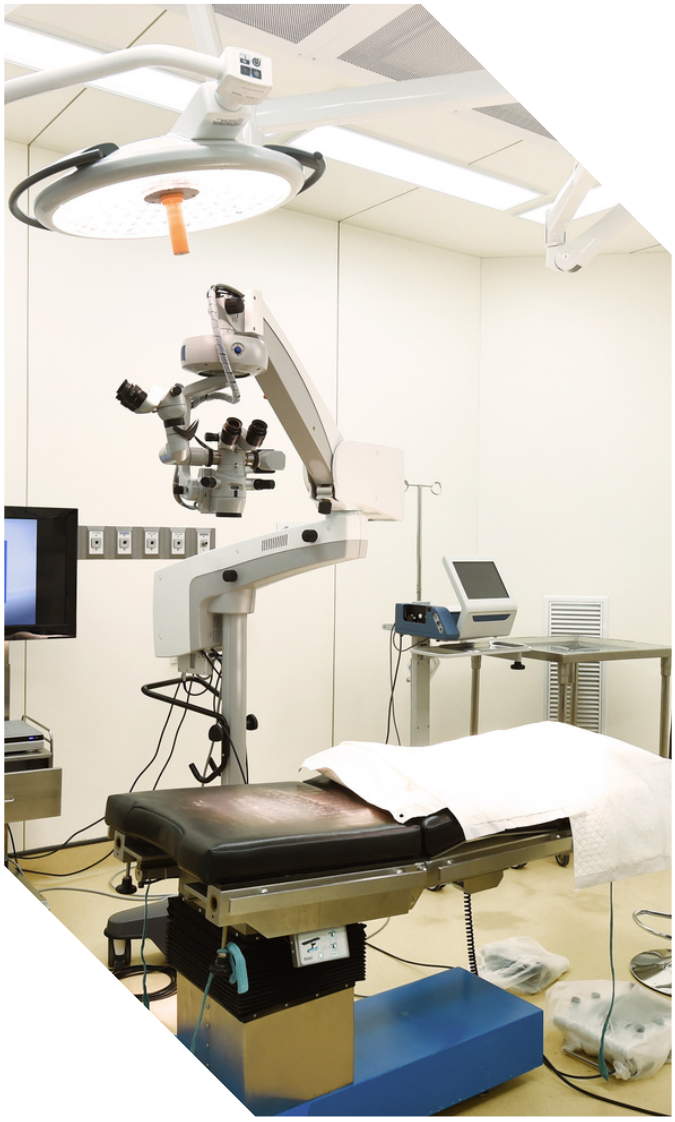


Who Should Attend

Understanding the Requirements of ISO 13485: 2016 for Model Medical 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.

Quality Assurance and Regulatory Affairs professionals within medical device organizations currently active in participating jurisdictions and organizations expanding their market reach to jurisdictions participating in ISO 13485:2016 will also benefit from this course.



Seminar Goals

Understanding the Requirements of ISO 13485: 2016 for Model Medical 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.
- Quality Management Principles
- System and Process audit- An Overview
- Planning and Preparation
- Interpretation of ISO 13485
- Preforming the audit
- Terms and Definitions ISO 19011
- ISO 13485 Clauses
- Auditing Scheduling
- Reviewing Processes and Preparing Checklists
- Audit Investigation- Obtaining and evaluating Evidence
- Determining/Writing Nonconformity Statements

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

The Certificate of Completion provides evidence of knowledge competency as a Quality Management Systems Auditor.