Apex
Quality Assurance

2-Day

Understanding the Requirements of ISO 13485: 2016 & International MDSAP Audit Model

Medical Device Quality Management Systems

Register by phone

919-635-5581

Register online

www.apexqualityassurance.com

Exemplar Global

Understanding ISO 13485: 2016 & International MDSAP Audit Model (2-Day)

At A Glance

Understanding the Requirements of ISO 13485: 2016 & International MDSAP Audit Model Medical Quality Management Systems

The two-day training program focuses on international MDSAP and ISO 13485-compliant medical device requirements. 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.

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 in accordance with the new MDSAP Audit Model.

Understanding MDSAP training course will teach students to plan, develop and implement a QMS in accordance with MDSAP and ISO 13485:2016 requirements.

Considering the ISO 13485:2016 management system requirements and various regulatory authorities' compliance requirements around the world and the global supply chains involved, a comprehensive program is incredibly valuable. The course provides extensive practical training and hand-on exercises, which will help prepare medical device implementers to identify critical MDSAP requirements and set up a QMS to meet international regulatory requirements.

ISO 13485: 2016 & International MDSAP Audit Model At A Glance *(Continued)*

The course is designed for medical device professionals with responsibility for implementing, maintaining and preparing the QMS internal, supplier or corporate management systems. Quality directors, regulatory managers and professionals responsible for managing internal, corporate, supply chain or certification responsibilities may also benefit from this unique training.

Upon completion the participants will be capable to effectively develop, implement and support a QMS to maintain compliance to ISO 13485 and jurisdiction requirements in the countries participating in the MDSAP program.

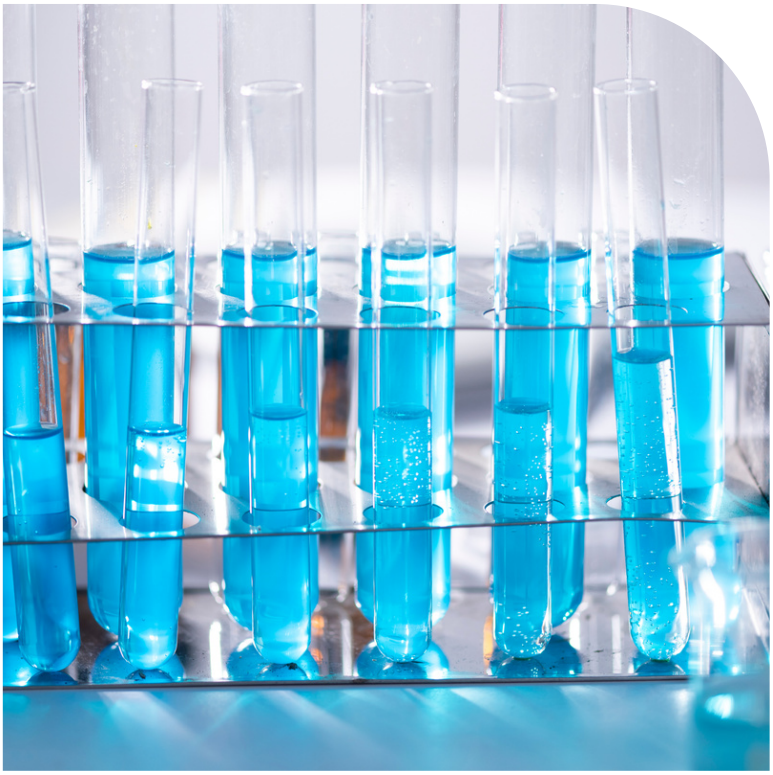
Participants of the training will learn from highly experienced instructors with decades of experience in medical device quality management systems.

Who Should Attend

Internal Auditor Training for Medical Device Quality Management Systems

This seminar is designed for Management Representatives, ISO 13485:2016 and International MDSAP 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 MDSAP will also benefit from this course.



Seminar Goals

Medical Device Quality Management Systems

- Improve understanding of regulatory auditing
- Improve competence for MDSAP development, implementation, and maintenance of a QMS that meets all MDSAP audit requirements.
- Assess your own audit models and suggest an improvement
- Be prepared to support an efficient MDSAP audit by your selected Auditing Organization
- Demonstrate awareness of MDSAP fundamentals
- Explain the structure and scope of the MDSAP audit
- Understand MDSAP and regulatory compliance
- Understand MDSAP reporting and nonconformity grading methods
- Determine MDSAP documentation requirements
- Understand the seven MDSAP auditing process requirements
- Analyze data sources and control interactions required during process audits
- Use correct jurisdictional terminology

Understanding ISO 13485: 2016 & International MDSAP Audit Model (2-Day)

Seminar Outline

Medical Device Quality Management Systems

Day One:

- Introduction and Welcome
- Chapter 1: MDSAP Background
- Chapter 2:MDSAP Audit Structure
- Chapter 3: Quality Management System
- **Exercise 1: Risk Management**
- Chapter 4:MDSAP Audit Model and Tasks
- Management Processes
- Device Marketing Authorization and Facility Registration
- Measurement, Analysis and Improvement
- Exercise 2: Audit Scenarios

Day Two:

- Chapter 4: MDSAP Audit Model and Tasks (cont'd)
- Medical Device Adverse Events & Advisory Notices Reporting
- Design and Development
- Production and Service Controls
- Purchasing
- **Exercise 3:** Audit Scenarios
- Understanding MDSAP Final Exam

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