Apex
Quality Assurance

5-Day

ISO 13485: 2016 & International MDSAP Audit Model

Lead Auditor Training

Medical Device Quality Management Systems

Register by phone

919-635-5581

Register online

www.apexqualityassurance.com

Exemplar Global

ISO 13485: 2016 & International MDSAP Audit Model (5-Day)

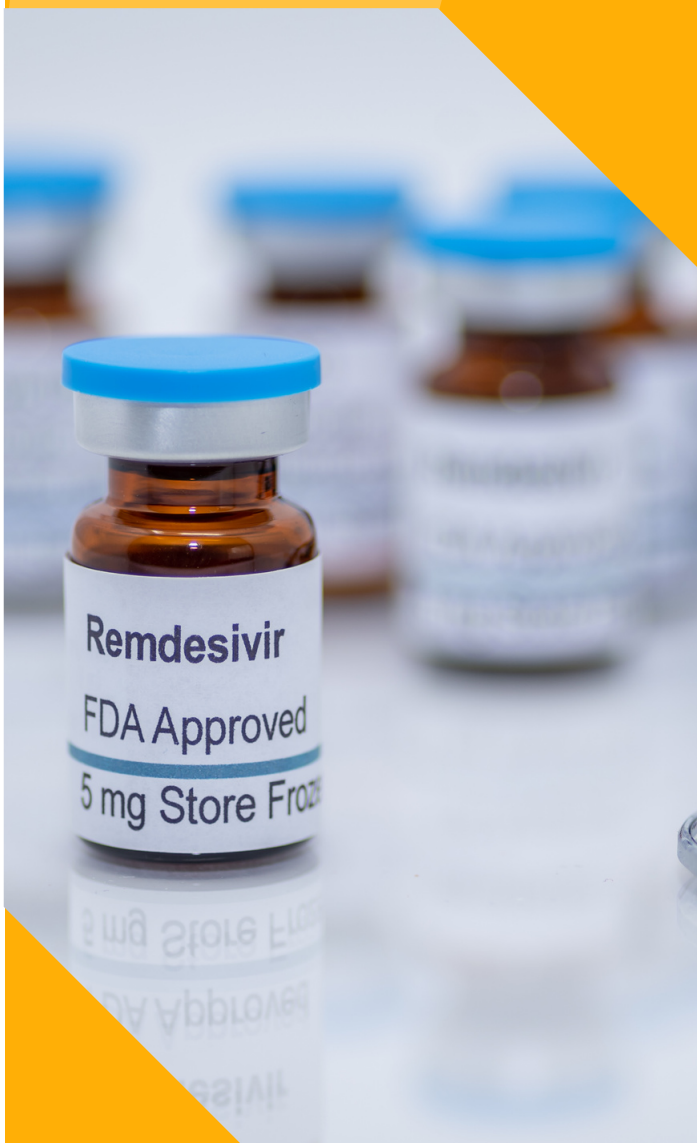
At A Glance

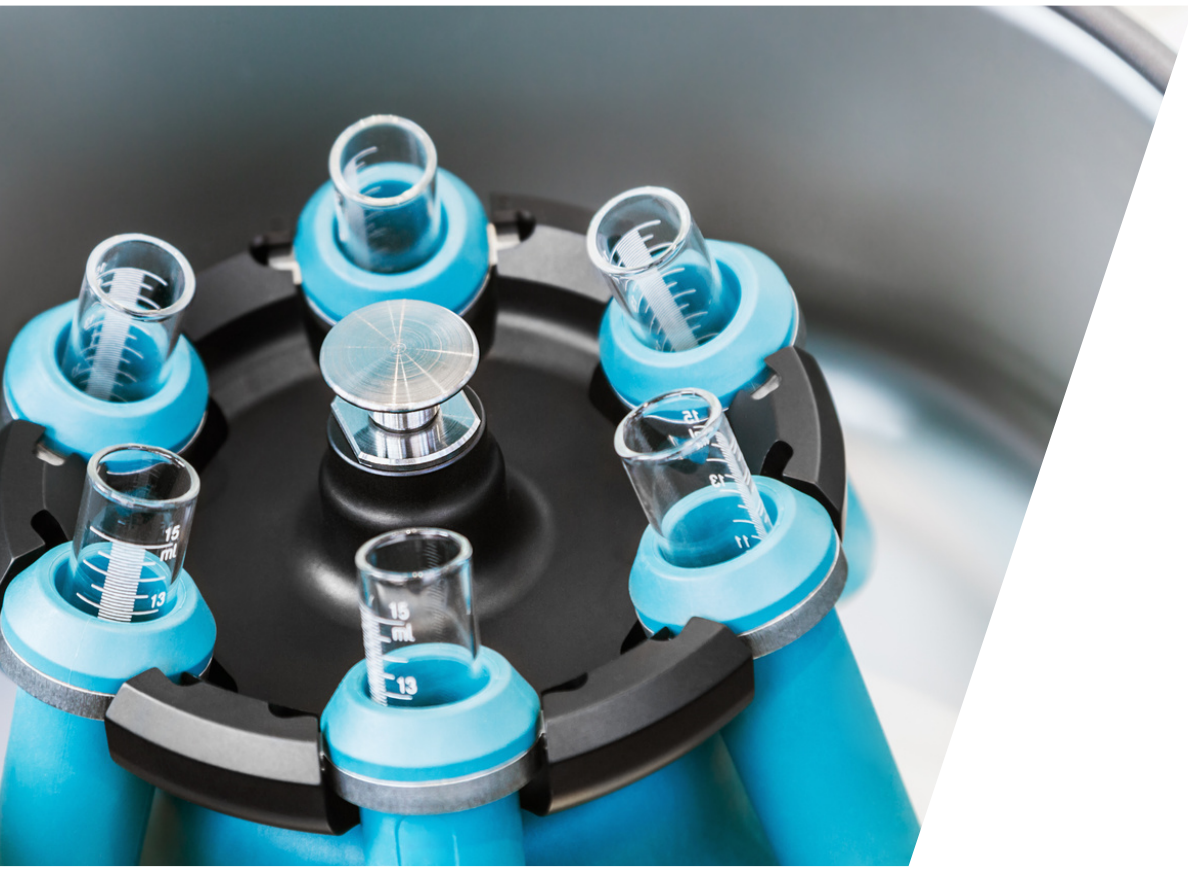
ISO 13485: 2016 & International MDSAP Audit Model Lead Auditor Training for Medical Quality Management Systems

The ISO 13485:2016 and international Medical Device Single Audit Program (MDSAP) five-day training is focused on international MDSAP and ISO 13485 compliant medical device requirements and auditing methods. 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 conduct audits of ISO13485: 2016 management system requirements in accordance with the new MDSAP Audit Model.
The Lead Auditor Training course will teach students to plan, conduct, report and follow-up on QMS audits in accordance with ISO 13485:2016 and MDSAP. Auditing standards include MDSAP requirements, ISO 19011 and ISO 17021 (MDSAP auditors need to follow ISO 17021).

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 like our MDSAP Lead Auditor Training' is incredibly valuable. The course provides extensive practical training and hand-on exercises, which will help prepare medical device auditors to identify critical nonconformities and 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 conducting or implementing internal audits, supplier audits or corporate audits. Quality directors, regulatory managers and professionals responsible for managing internal, corporate, supply chain or certification responsibilities may also benefit from this unique program.

Upon completion the participants will be capable to audit ISO 13485:2016 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.

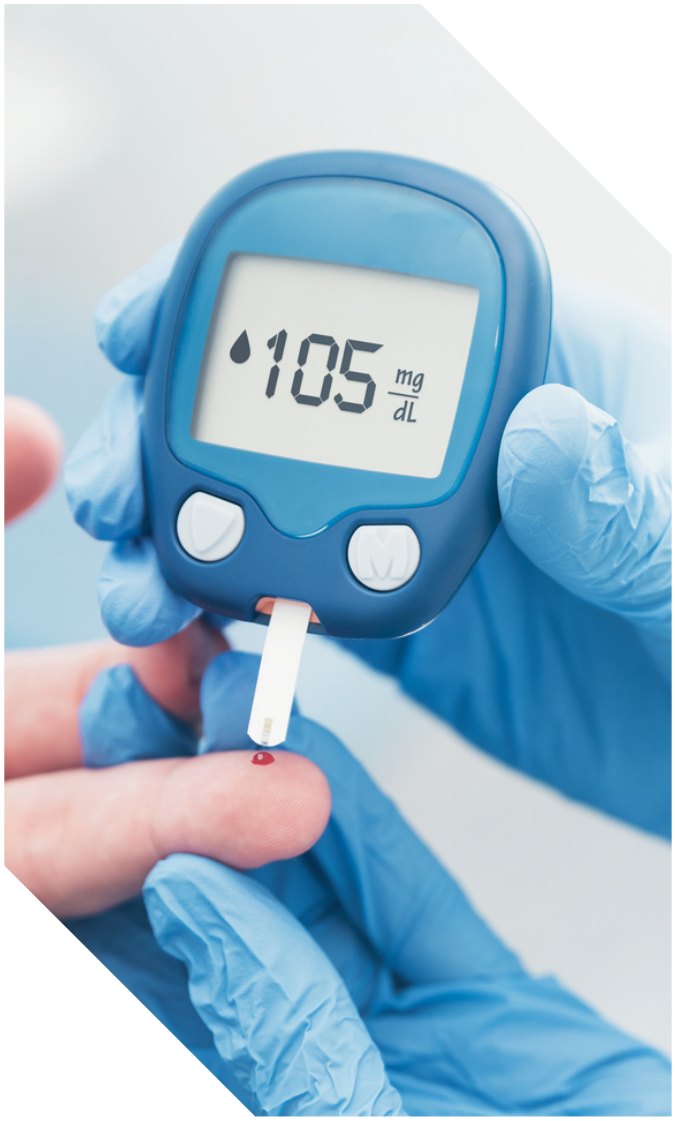
ISO 13485: 2016 & International
MDSAP Audit Model (4-Day)

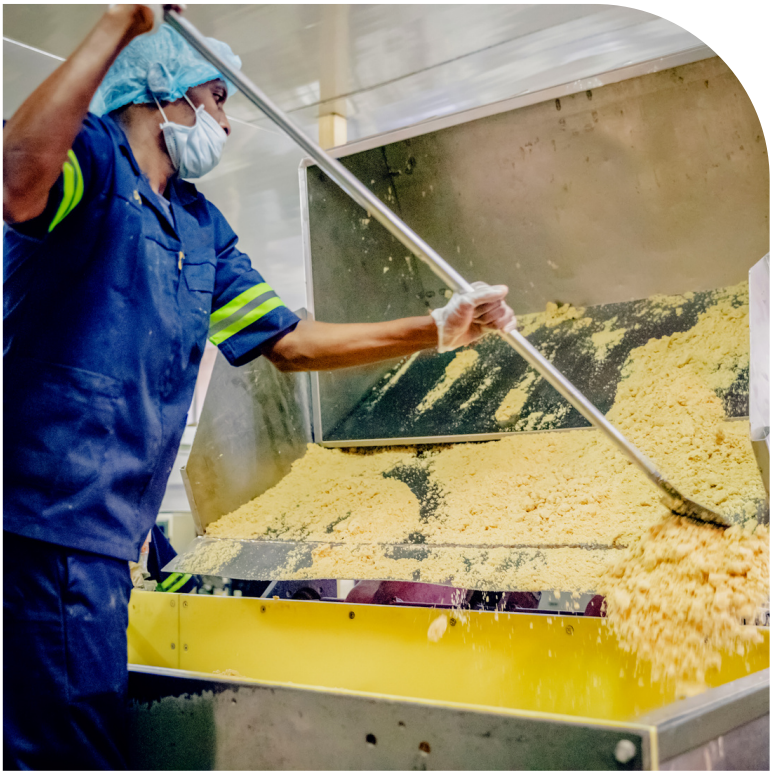
Who Should Attend

Lead 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.





ISO 13485: 2016 & International MDSAP Audit Model (4-Day)

Seminar Goals

Lead Auditor Training for Medical Device Quality Management Systems

- Improve auditing skills focused on regulatory auditing
- Assess your own audit models and suggest improvement
- Be prepared to support an efficient MDSAP audit by your selected Auditing Organization
- Comprehend MDSAP Background and Acceptability
- Comprehend MD-QMS documentation and MDSAP structure
- Audit MDSAP tasks and various compliance requirements in Management processes
- Determine requirements for device marketing
- Comprehend Measurement, Analysis and Improvement processes
- Determine Medical Device Adverse Event & Advisory Notices Requirements (AEANR)
- Comprehend MDSAP Design & Development processes
- Comprehend MDSAP Production and Service Control processes
- Comprehend MDSAP Purchasing process
- Plan for an audit using the MDSAP approach
- Conduct an audit using the MDSAP approach
- Understand MDSAP reporting and nonconformity grading methods
- Explain the differences between MDSAP and other QMS audits such as ISO 13485:2016
- Plan, conduct and lead MDSAP audits

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

Seminar Outline

Lead Auditor Training for Medical Device Quality Management Systems

Day One:

- Introduction and Welcome
- MDSAP background and Acceptability
  - **Written Exercise 1:** Risk Assessment
- Chapter 1: Management Processes
- Chapter 2. Device Marketing Processes Overview of ISO 13485:2016 Requirements
  - **Written Exercise 2:** Audit Scenarios- Management Process and DMAFR
- Chapter 3: Measurement, Analysis and Improvement (MAI) processes
- Chapter 4: Adverse Event and Advisory Notices Requirements (AEANR) Processes
  - **Written Exercises 3:** Audit Scenarios- Measurement Analysis and Improvement and AEANR

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

Day Two:

- Chapter 5: Design & Development Processes
  - **Written Exercise 4:** Audit Scenarios – Design & Development
- Chapter 6: Production and Service Controls
- Chapter 7: Purchasing Process
  - **Written Exercise 5:** Production and Service Control and Purchasing
- Understanding MDSAP Audit Model Final Exam

Day Three:

- Chapter 8: Planning for the MDSAP Audit
  - **Breakout Exercise 1:** Calculating Audit Duration
  - **Breakout Exercise 2:** Audit Objectives and Scope
  - **Breakout Exercise 3:** Preparing an Audit Plan
  - **Breakout Exercise 4:** Documentation Review

Day Four

- Chapter 8: Planning for the MDSAP Audit (cont'd)
- Chapter 9: Conduct an Audit Using the MDSAP Approach
  - **Breakout Exercise 5:** Raising and Grading Nonconformities
- **MDSAP Auditing Final Exam**

Day Five:

- Chapter 10: Leading Audit Teams
  - **Conduct MDSAP Mock Audit**
- **MDSAP Lead Auditor Final Exam**