OMNEX

DRIVING WORLDWIDE BUSINESS EXCELLENCE

# ISO 13485:2016 Lead Auditor Training for Medical Devices Quality Management Systems

## Course Duration: 5 Days - 8 Hours/day

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## Seminar Content

Omnex is an Exemplar Global Certified TPECS provider for Exemplar Global-MD, Exemplar Global-AU and Exemplar Global-TL Competency Units. This 5-Day course fully covers the **ISO 13485:2016** requirements. Other topics include audit systems, the auditing process and audit instruments; the documentation process, conducting an audit, writing the audit report and evaluating corrective actions. Auditing case studies will be used to develop the required auditing skills based on **ISO 19011**.

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

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
- Exemplar Global - TL

*FOR PUBLIC TRAINING ONLY - The requirements portion of this training is conducted online prior to the in-classroom or virtual course. The seated or virtual classroom portion of the class will begin on Tuesday morning with a review and testing. The Monday of that training week will be offline and for finishing the e-learning or contacting the instructor with questions. The auditor portions (AU and TL) will continue as appropriate according to the dates scheduled.

## Learning Objectives

- 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.
- Understand the application of the principles, procedures and techniques of management systems auditing.
- Understand the conduct of an effective audit in the context of the auditee's organizational situation.
- Understand the application of the regulations, and other considerations that are relevant to the management system, and the conduct of the audit.
- Practice personal attributes necessary for the effective and efficient conduct of a management system audit.
- Establish, plan and task the activities of an audit team.
- Communicate effectively with the auditee and audit client.
- Organize and direct audit team members. Understand conflict management principles.
- Prepare and complete the audit report.



**OMNEX INC**

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## Seminar Outline

### Day 1

- Introduction and Welcome
- Chapter 1 - Introduction to ISO 13485
- Chapter 2 - The ISO 13485 Standard Explained
- MD Written Exercise 1 (individual)
- Chapter 3 - Overview of ISO 13485:2016 Requirements
- MD Written Exercises 2a, 2b (Audit Scenarios)

### Day 2

- Overview of ISO 13485:2016 Requirements (cont'd)
- Breakout Exercise 2c (Audit Scenarios)
- MD Written Exercise (individual)
- Introduction to Management System Audit Trails
- AU Breakout Exercise 1: Scope and Objectives
- Management of Audit Programs
- Management System Audit Planning and Preparation
- AU Breakout Exercise 2: Documentation Review
- AU Breakout Exercise 3: Audit Plan

### Day 3

- Performing the Audit
- AU Breakout Exercise 4: Conducting the Audit
- Writing Nonconformity Statements
- AU Breakout Exercise 5: Writing
- Nonconformities
- Closing Meeting
- Completing the Audit Report
- Corrective Action and Closeout
- AU Written Exercise (individual)

### Day 4

- Review of Audit Process and Audit Management Strategies
- Case Study Mock Audit

### Day 5

- Review of Audit Process and Audit Management Strategies
- Case Study Mock Audit

## Who Should Attend

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.

## Seminar Materials

Each participant will receive a seminar manual and a breakout workbook that includes auditing case studies.

## Pre-Requisite

An understanding of the ISO 13485:2016 requirements and a minimum 12 months of work experience in applying or auditing quality management systems is recommended. The first 1.5 or 3 days of this class are offered separately for those new to auditing or quality management.



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