ISO 13485 Lead Auditor Course

Course Duration: 40 Hrs. **Course Code: ISO13485-LA**

Course Overview

The ISO 13485 Lead Auditor Course is designed to provide participants with the knowledge and skills required to plan, conduct, and manage audits of a Medical Device Management System (MDQMS) in compliance with ISO 13485 requirements and ISO 19011 guidelines. The course focuses on evaluating the effectiveness of quality management processes, ensuring regulatory compliance, and promoting continual improvement in the design, production, and servicing of medical devices.

What you'll learn?

Participants will learn how to interpret ISO 13485 requirements in the context of an audit, apply auditing principles and techniques, plan and execute internal and external audits, and report findings accurately. They will gain expertise in identifying nonconformities, recommending corrective actions, and leading audit teams to enhance medical device quality and compliance.

Target Audience

This course is intended for quality managers, auditors, regulatory compliance officers, consultants, project managers, and professionals responsible for conducting or overseeing MDQMS audits. It is also suitable for individuals seeking to become certified ISO 13485 Lead Auditors or strengthen their knowledge of medical device quality management auditing.

Pre-Requisites

Participants are recommended to have a basic understanding of ISO 13485 standards, medical device regulations, or prior auditing experience. Completion of an ISO 13485 Foundation course or relevant professional experience is beneficial but not mandatory.

Course Content

Module 1: Introduction to ISO 13485 and medical device quality management principles
Module 2: Understanding audit standards, ISO 19011 guidelines, and ISO 13485 requirements
Module 3: Planning and preparing for MDQMS audits
Module 4: Conducting internal and external audits of medical device quality management systems
Module 5: Managing and leading audit teams effectively
Module 6: Identifying nonconformities, reporting, and corrective actions
Module 7: Monitoring, review, and continual improvement of MDQMS audits
Module 8: Preparing for certification audits and ensuring compliance with ISO 13485