

# ISO 13485 Lead Implementer Course

**Course Duration: 40 Hrs.**

**Course Code: ISO13485-LI**

## Course Overview

The ISO 13485 Lead Implementer Course is designed to provide participants with the expertise to implement and manage a Quality Management System (QMS) for medical devices based on ISO 13485. It covers the principles, requirements, and best practices for establishing, maintaining, and continually improving a QMS to ensure compliance with regulatory frameworks and industry standards. This course equips professionals with the knowledge and skills to lead implementation projects effectively, ensuring medical device safety and quality.

## What you'll learn?

In this course, learners will acquire an in-depth understanding of ISO 13485 requirements, implementation strategies, and project management practices. They will learn how to interpret regulatory expectations, manage documentation, establish processes, and support organizations in achieving compliance. Additionally, participants will develop leadership and problem-solving skills necessary to oversee a QMS implementation from start to finish.

## Target Audience

This course is ideal for medical device industry professionals, quality managers, regulatory compliance officers, consultants, and individuals seeking to become implementation leaders. It is also suited for project managers responsible for establishing a QMS within organizations manufacturing or supplying medical devices.

## Pre-Requisites

Participants are expected to have a general understanding of quality management systems and ISO standards. Prior knowledge of ISO 13485 requirements or experience in the medical device sector will be advantageous but is not mandatory.

## Course Content

**Module 1:** Introduction to ISO 13485 and Quality Management for Medical Devices

**Module 2:** Principles, Requirements, and Regulatory Context of ISO 13485

**Module 3:** Planning and initiating an ISO 13485 QMS Implementation

**Module 4:** Documentation, Process Development, and Risk Management

**Module 5:** Leadership, Communication, and Stakeholder Engagement in Implementation

**Module 6:** Performance Monitoring, Measurement, and Continual Improvement

**Module 7:** Certification Preparation and Best Practices for Sustainable QMS