# ISO 13485 Foundation Course

**Course Duration: 16 Hrs.** **Course Code: ISO13485-FC**

## Course Overview

The ISO 13485 Foundation Course is designed to provide participants with a comprehensive introduction to the ISO 13485 standard for quality management systems in the medical device industry. It covers the essential principles, requirements, and benefits of implementing ISO 13485, enabling organizations to ensure compliance, improve product safety, and meet regulatory expectations.

## What you'll learn?

In this course, you will learn the fundamental concepts of ISO 13485, including the scope and structure of the standard, quality management principles, regulatory requirements, and the importance of risk management in medical device manufacturing. You will also gain insights into how ISO 13485 supports compliance and enhances overall operational effectiveness.

## Target Audience

This course is ideal for medical device manufacturers, quality managers, regulatory compliance professionals, auditors, and anyone interested in learning the basics of ISO 13485 and its role in medical device quality management.

## Pre-Requisites

There are no formal prerequisites for this course. However, having a basic understanding of quality management systems or knowledge of the medical device sector will be helpful.



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## Course Content

**Module 1:** Introduction to ISO 13485 and Quality Management Principles

**Module 2:** Overview of the Structure and Requirements of ISO 13485

**Module 3:** Regulatory Framework and Compliance in Medical Devices

**Module 4:** Risk Management and Product Safety in ISO 13485

**Module 5:** Roles, Responsibilities, and Benefits of ISO 13485 Implementation

**Module 6:** Preparing for Further ISO 13485 Training and Certification



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