Implementing ISO 13485 Medical Device Quality Management System

Course Description

This two-day course has been designed to provide participants with the knowledge and process steps to enable them to effectively implement a quality management system in line with the requirements for ISO 13485:2003. The course introduces the concepts needed to understand, develop, and implement a quality management system.

Course Benefits

- Take the first steps towards ISO 13485 certification
- Understand how you can better meet customer and regulatory requirements
- Find ways to increase efficiency and cost savings through quality management
- Monitor supply chains to achieve continuous improvement

Intended Audience

- Anyone involved in defining, planning, or implementing an ISO 13485 based quality management system
- Management representatives
- Implementation team members

Course Duration

2.0 days

Prerequisites

There are no formal pre-requisites for this course.

Agenda

Day 1

Time	Topic
9:00	Introduction
	Participant introductions
	Overview of course structure and learning objectives
	Fundamentals of Management Systems
	Fundamentals of an ISO 13485 QMS
	Overview of ISO 13485:2003
	The ISO 13485 Implementation Process:
	• Gain Top Management Commitment
	• Appoint Implementation Team
	• Promote Awareness
	• Perform Gap Analysis
17:00	Wrap up Day 1

Day 2

Time	Topic
9:00	Welcome back and review of Day 1
	The ISO 13485 Implementation Process:
	• Develop Implementation Plan
	• Approve the Implementation Plan
	• Implement the Plan
	• Operate & Assess the System
	• Continually Improve the System
	• Certification and Registration
17:30	Wrap up Day 2