



*Presented by*  
**Management Forum**

# An Introduction to ISO 13485: 2016 - Quality Management System (QMS) for Medical Devices

**20 November 2024**

This course has been specifically designed to provide an essential introduction to ISO 13485 and the QMS and provides a comprehensive and valuable overview of the requirements and responsibilities involved. Where ever you and your company sit within the medical device arena this is an excellent opportunity to become appraised of the requirements.



**Format:**  
Live online



**CPD:**  
6 hours for your records



Certificate of  
completion

# Overview

**The ISO 13485:2016 standard specifies requirements for a Quality Management System (QMS) where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and regulatory requirements.** Such medical device organisations can be involved in one or more stages of the life-cycle, including; design and development, production, storage and distribution, installation, or servicing of a medical device, and design and development or provision of associated activities such as technical support.

ISO 13485:2016 can also be used by suppliers or external parties that provide products, including QMS-related services to such organisations.

**This course has been specifically designed to provide an essential introduction to ISO 13485 and the QMS and provides a comprehensive and valuable overview of the requirements and responsibilities involved.**

Where ever you and your company sit within the medical device arena this is an excellent opportunity to become appraised of the requirements.

This course will be useful as a refresher or for those new to the medical device industry.

## Benefits of Attending

- Understand the requirements of ISO 13485
- Learn how to develop a Quality Management System (QMS)
- Know your responsibilities
- Comply with the regulatory requirements
- Take part in workshop exercises to consolidate the knowledge gained

## Who Should Attend

- Quality managers
- Quality assurance personnel
- Regulatory affairs managers
- Internal and external auditors
- Medical device designers and developers
- All those who are involved with the implementation of the QMS

# Programme

## Welcome and Introduction

- Objectives for the day
- What do you want from the day?

## Overview of ISO 13485:2016

- Introduction to standards and their use
- Use of ISO13485:2016
- Conformity assessment
- Cost/Benefit of Quality

## Defining the Scope and Objectives of Your QMS

- Quality policy
- Quality objectives
- Quality manual

## Documentation Requirements

- Requirements
- Document control
- Resource management
- Training

## Workshop Exercise: Writing Quality Policy and Objectives

## Intellectual Property (IP) to CE Marking in a QMS

- Design and development

## Supplier Management

- Economic Operators
- Supplier management
- Supply chain control

## Direct Processes

- Change management
- Risk Management
- Control of non-conforming product

## Post Market Surveillance

- What is it?
- The elements
- Reactive vs Proactive

## Workshop Exercise: Quality Management - Functional Interaction

## Summary and Key Take Aways

# Presenter



## **Stuart Angell**

Stuart Angell is a joint director in his own consultancy specialising in global regulatory affairs strategy and compliance for in vitro diagnostics and medical devices focusing on the transition to the new IVD/Medical Device Regulations, MDSAP and ISO13485:2016.

He has over 15 years in the IVD industry and in previous roles has been responsible for designing, reviewing and maintaining regulatory frameworks for self-declared and annex list II products including technical documentation for EU and global submissions (FDA, Health Canada, TGA, Russia, Latin America). He has an excellent understanding of risk management, Post Market Surveillance (PMS) and vigilance.

# Course date

20 November 2024

Live online

09:00-16:45 **UK (London)** (UTC+00)

Course code 14217

GBP **549** ~~649~~

EUR **789** ~~929~~

USD **893** ~~1,049~~

**Until 16 Oct**

## How to book



**Online:**

[ipi.academy/2681](https://ipi.academy/2681)

Alternatively contact us to book, or if you have any queries:



**Email:**

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**Phone:**

[+44 \(0\)20 7749 4749](tel:+442077494749)

## Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

## Further information

### Fee

The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

### Please note

IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

### Terms and conditions

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