IPI Academy

MANAGEMENT forum

Presented by
Management Forum

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

4 July 2024
+ 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 dates

4 July 2024	**Live online** 09:00-16:45 **UK (London)** (UTC+01) *Course code 14216*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 30 May**
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

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

Email:
info@ipi.academy

Phone:
+44 (0)20 7749 4749

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
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Run this programme in-house for your whole team

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With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:

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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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