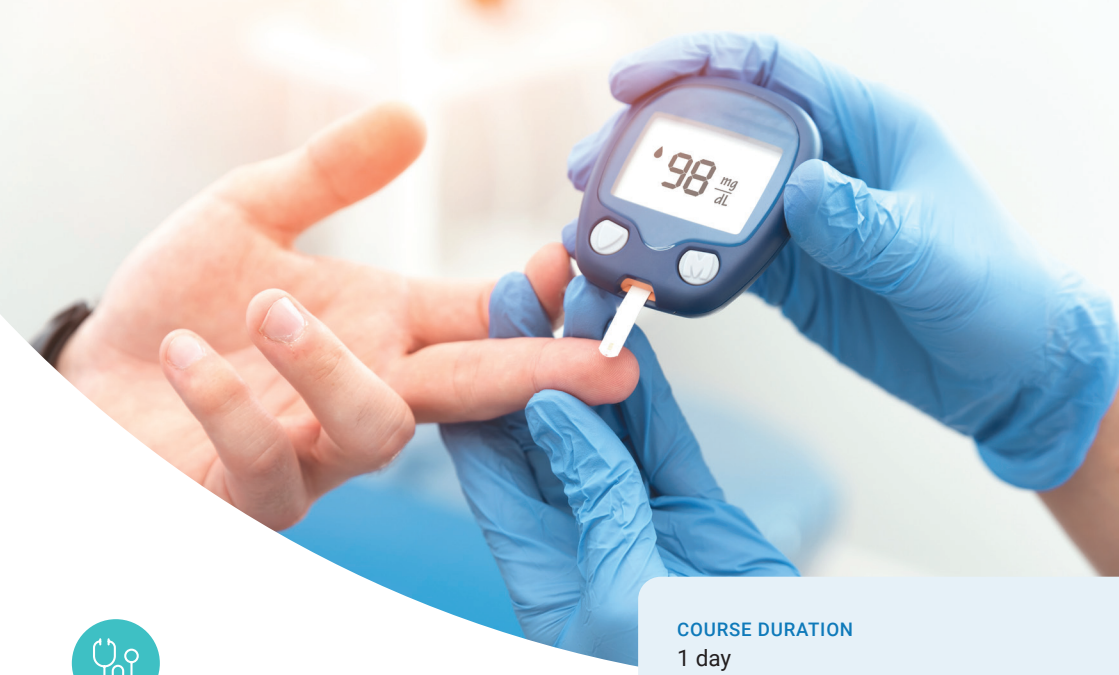

Introduction to ISO 13485

Gain an understanding of the role of quality standards for the medical device industry within your organisation on our Introduction to ISO 13485 for Medical Devices training course.

This 1-day practical course provides a basic background to the structure and requirements of ISO 13485 and how it relates to frameworks such as the Medical Device Regulations (MDR). Students benefit from interactive sessions where they can develop the knowledge they gain.

Upon completion of the course, delegates will have the skills to review their organisation's current processes and systems, understand the benefits and challenges of a process approach to managing a quality management system, and consider how to implement ISO 13485 within their organisation.

COURSE DURATION
1 day

CPD
Equivalent to 7 hours

COURSE PRICE
From £675 + VAT

DATES & VENUES
View dates & venues

CERTIFICATES
All delegates will receive a certificate on completion.

Course details >

Who should attend?

This course is suitable for anyone seeking a detailed overview of ISO 13485 and the process approach to managing a company's quality system, including:

- executives and senior management
- general managers and business unit managers
- quality and regulatory professionals
- management representatives
- internal and external auditors

This course is the ideal introduction for those who are planning to attend our ISO 13485 Internal Auditor training course but first need to develop their understanding of ISO 13485. We can offer a discount of £150 to those who book both courses at the same time.

Skills gained

By the end of this ISO 13485 training course, delegates will be able to:

- explain the purpose, structure and content of ISO 13485
- define key terminology from ISO 13485
- identify key medical devices regulations and explain their relationship with ISO 13485, including:
  - EU MDR
  - UK MDR
  - USA FDA
  - MD SAP
- analyse and apply ISO 13485 requirements
- outline steps for implementing an ISO 13485 QMS

Key topics

Topics covered on the course include:

- the purpose and intent of ISO 13485
- the origins of the standard and the different versions, including latest ISO 13485:2016+A11 2021
- structure and content of the standard and the PDCA cycle
- key terms and definitions
- how the standard supports medical devices regulations and an overview of:
  - UK Medical Device Regulations 2002
  - European Medical Device Regulations 2017
  - USA Food and Drug Administration quality system requirements
  - Medical Devices Single Audit Programme
- the process approach and process-related requirements of ISO 13485
- requirement for documenting the QMS and maintaining records
- overview of all of the 'auditable' requirements of ISO 13485, sections 4-8, with in-depth coverage of key requirements
- technique for conducting an in-depth analysis of the requirements
- an approach to implementing an ISO 13485 QMS

Course agenda >

Course agenda

Our training courses are designed to optimise the learning experience for delegates both in face-to-face settings and in our Virtual Classroom.

Under the guidance of our expert tutors, attendees will follow an agenda which is briefly outlined below:

- Welcome and Introductions
- Module 1 ISO 13485: Background and Purpose
- Module 2 ISO 13485: Content and Structure
- Module 3 Terms and Definitions
- Module 4 Medical Device Regulations
- Module 5 Auditable Requirements
- Course Review and Evaluation

In-company training

Ideal for groups, you can receive this course exclusively for your organisation at your premises or online in our user-friendly Virtual Classroom.

Enjoy cost-effective flexibility and personalised learning with tailored messaging designed to address your unique business challenges. Contact us for a quote.

Delegates will receive a certificate of completion which serves as evidence of their new understanding of ISO 13485.

Reviews & Booking >

> The course content was perfect, and the tutor was very knowledgeable and delivered the course extremely well.

Arjo

> The tutor was highly enthusiastic and extremely competent in answering questions as well as delivering the content. This allowed her to deliver with confidence and made the day more enjoyable as I knew I could ask questions as I went along.

Thermofisher

> The tutor was brilliant, adapted the course to each individuals job titles so we could get the most out of the training. Felt comfortable asking her any questions and kept us all engaged throughout the day.

Vernacare

Read our Medical Devices course reviews

Why train with Bywater?

Bywater is the leading independent provider of professional management systems training in the UK.

Our expert training offers practical understanding of how to realise the benefits and assess the success of implementing and operating successful management systems.

Bywater delegates know they can rely on proven training delivered by experts at times and locations to suit their needs.

40 years established

100+ course titles

15 UK locations

1000+ courses annually

Global Virtual Classroom

CQI & IRCA, ISEP, RSS and IOSH approved training provider.

VIEW DATES & VENUES

Booking is easy

Simply select a course date and venue and fill in the online form. View our full range of courses at **www.bywater.co.uk**

If you have any questions please call us on 0333 123 9001, use our online chat or email **contact@bywater.co.uk**

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