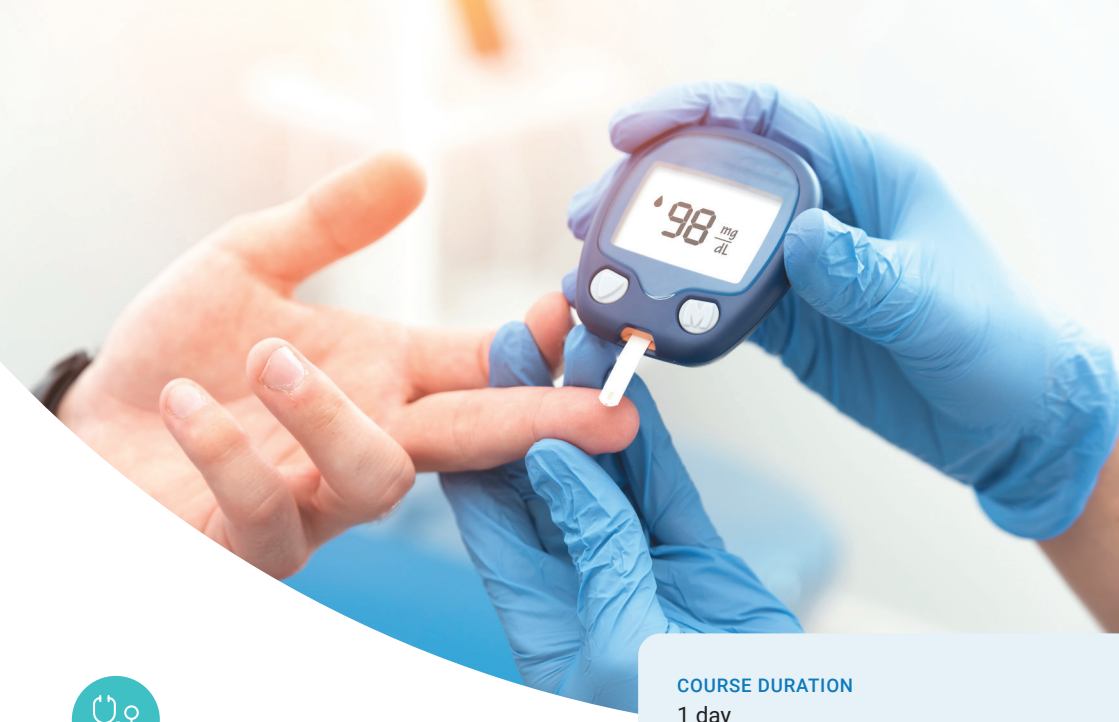

Medical Device Regulation (MDR) Training Course

Gain an essential understanding of medical device regulation (MDR) requirements in the EU on this MDR training course.

This 1-day course offers an introduction to the new regulation (EU) 2017/745 and CE marking. Compliance with this set of regulations is mandatory for any medical device manufacturers who wish to sell their products into the EU marketplace.

By the end of the course delegates will understand how the regulation applies in their organisation and how to begin implementing systems to meet those requirements.

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 who is jointly or fully responsible for regulatory compliance and working in an organisation involved in any aspects of medical device manufacturing, designing, marketing or the supply chain and wants to understand and be able to apply the requirements of the new regulation (EU) 2017/745.

Key topics

Topics covered on the course include:

- scope and definitions
- regulation governance actors
- classification
- conformity assessment procedures
- quality management system requirements
- technical documentation
- general safety and performance
- risk management
- clinical evidence requirements
- post-market surveillance and vigilance
- identification and traceability
- supply chain requirements
- notified bodies

Skills gained

By the end of this MDR training course delegates will be able to:

- apply the requirements of (EU) 2017/745
- explain the European regulation CE marking approach for medical devices, including its legal and operational basis
- describe the structure and scope of the MDR, including classification and conformity routes
- review the safety and performance requirements checklist applicable to CE marking under the new regulation
- understand the new requirements when creating technical documentation to support the product throughout its life cycle
- understand the level of clinical evidence necessary to demonstrate conformity
- know how to develop a robust and proactive post-market surveillance system under the new MDR, including vigilance reporting and monitoring
- identify the regulatory significance of a robust quality management and risk management system
- gather the business impacts of the regulation and start to develop a transition plan.

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

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
- Section 1 Introduction
- Section 2 Scope & Definitions
- Section 3 Regulation Governance Actors
- Section 4 Classification
- Section 5 Conformity Assessment
- Section 6 Quality Management System
- Section 7 Technical Documentation
- Section 8 General Safety and Performance Requirements (GSPR)
- Section 9 Clinical Evaluation and Clinical Investigations
- Section 10 Post-market Surveillance, Vigilance and Market Surveillance
- Section 11 Risk Management
- Section 12 Identification and Traceability
- Section 13 Supply Chain & Economic Operators
- Section 14 Notified Bodies & Competent Authorities
- Section 15 Transition and next steps
- Section 16 Summary & Tools

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.

Very good course, information was communicated very clearly and was very time effective. The tutor was very knowledgeable.

Natrox Wound Care

Tutor was very clear, understood the levels of the attendees and tailored the speed to match.

Vernacare

The tutor was exceptionally knowledgeable, professional yet friendly, open and approachable.

Talarmade Ltd

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.

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1000+ courses annually

Global Virtual Classroom

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

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Booking is easy

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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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