In Vitro Diagnostic Regulations (IVDR) Training Course

Gain an understanding of the requirements placed on the development and supply of in vitro diagnostic medical devices on this In Vitro Diagnostic Regulations (IVDR) training course.

IVDR is replacing the In Vitro Diagnostics Directive (IVDD) for greater patient protection and smoother market function.

This 1-day course explores the requirements of EU regulations for those involved in the medical devices supply chain.

Upon completion of the course delegates will be able to apply EU 2017/746 within their organisation and help to identify areas for improvement on a continual basis.

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 appropriate for anyone who is jointly or fully responsible for regulatory compliance, and is working in an organisation involved in any aspects of in vitro diagnostic 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 2017/746.

Skills gained

On completion of this IVDR training course delegates will be able to:

- apply the requirements of EU 2017/746
- explain the European regulation CE marking approach for medical devices including its legal and operational basis
- describe the structure and scope of the IVDR 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
- learn how to develop a robust and proactive post market surveillance system under the new IVDR including vigilance reporting and monitoring
- identify the regulatory significance of a robust quality management and risk management system
- gather information about the business impacts of the regulation and start to develop a transition plan

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

Delegates will receive a certificate of completion, evidencing of their new understanding of IVDR.

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 Introduction & Context
- Module 2 Transitional Provisions & Strategic Planning
- Workshop 1 Transition Planning
- Module 3 Classification Rules & Borderline Cases
- Workshop 2 Device Classification
- Module 4 PMS, Evidence & Lifecycle Requirements
- Module 5 Infrastructure, Special Cases & Summary
- Workshop 3 Vigilance & Reporting Determination
- Workshop 4 Vigilance & Reporting Action
- Review & Close

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 knowledgeable tutor, gave interesting examples for the content of the course. Created a positive environment to learn

James Paget University Hospital

Good examples and exercises to prompt application of the knowledge presented.

Vernacare

The tutor was excellent at breaking down and explaining a complex subject for all candidates to understand.

2gether Support Solutions

The tutor was very engaging and made the course content really easy to relate to my work place.

Orthoplastics 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.

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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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