In Vitro Diagnostic Regulation 2017/746

At a glance

- 2-days of interactive training
- Instructor-led virtual classroom
- Certificate of completion
- Q&A session
- Copies of the slides and handouts
- 15% off the IVDR Guidebook
- On-site training available on request

Who should attend?

This training course is recommended for anyone making and selling In vitro diagnostic devices into the European Union:

- Regulatory Affairs Professionals
- Research and Design Engineers
- Quality Managers
- Quality Engineers
- Authorised Representatives
- Consultants

COURSE OVERVIEW

The IVDR will replace the current EU Directive on in Vitro Diagnostic Medical Devices (98/79/EC) and will be effective in all EU member and EFTA states.

Our industry leading experts have created a 2-day course designed to give you an appreciation for the changes and new requirements of the IVDR and provide practical skills and guidance on how to transition to the new regulation.

100%
Achieved The Learning Objectives

Trusted Training Provider

97%
Recommend Our Virtual Classrooms

LEARNING OBJECTIVES

- Understand the purpose and structure of the IVDR
- Be able to Identify the types of devices covered by the IVDR and the rules for classifying these devices
- Understand the requirements for manufactures and economic operators
- Gain a solid understanding of the safety and performance requirements
- Understand post-market surveillance and the associated reports
- Explain the UDI requirements and the relationship with Eudamed

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"Fantastic to have an instructor with subject knowledge that was able to relate to the experience of participants. Presented and delivered at a good pace to allow understanding and ample opportunity for specific questions."

"The course was very comprehensive considering how large the topic is. I learnt a lot more than I expected to and the knowledge of the lecturer was excellent with a lot of hands on experience and advice."

"Thoroughly enjoyed the 2 day course! Rod is very insightful and knowledgeable. It was a great experience that I would highly recommend to any medical professional."

COURSE AGENDA

1

Module One
- Reasons for the IVDR
- Structure and key changes of the IVDR
- Key terminology and definitions
- Introduction to CE Marking

2

Module Two
- Placing a device on the market
- Manufacturer's articles & obligations
- Economic Operator & PRRC Responsibilities
- Declaration of conformity

3

Module Three
- Overview and structure of the classification Annex VIII
- Class Types & Classification Rules
- The General Safety and Performance Requirements

4

Module Four
- Routes to conformity
- Notified Bodies
- UDI
- Overview of Eudamed

5

Module Five
- Clinical evidence
- Performance evaluation and performance studies
- Overview of scientific validity
- Overview of analytical performance
- Overview of clinical performance

6

Module Six
- Post-market performance follow-up
- Post market surveillance - plan, report & period safety update report
- Summary of safety and performance
- Vigilance
- Technical documentation
- Transition timelines
- Guidance

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