Make sure the course is right for you

Who is this course for?

Manufacturers of In Vitro Diagnostic devices, in particular those who have not yet placed an IVD on the market in the EU, especially: Regulatory Affairs, Design and Development, Clinical Affairs Specialists, Quality Management, Quality Assurance personnel, and other Economic Operators including manufacturers, importers, distributors and authorized representatives who are new to, or have little familiarity with, the EU IVD market.

What will I learn?	What are the benefits?

• Identify devices that are within scope of the Regulation
• Understand the roles and responsibilities of the different Economic Operators identified by the Regulation
• Identify other key players and their obligations under the Regulation
• Identify key requirements concerning the following steps for conformity assessment:
  • Determine the risk class of IVD
  • Select conformity assessment procedure
  • Identify applicable General Safety and Performance Requirements (GSPRs)
  • Recognize key elements of Technical Documentation
  • Appreciate the importance of product claims, labelling, Unique Device Identification (UDI) and EUDAMED (The European Database on Medical Devices)
  • Identify requirements of clinical evidence
  • Post-Market Surveillance and updates
	• Identify the key requirements of the In Vitro Diagnostic Regulation
	• Interpret and communicate the key requirements and expectations of the IVDR to your organization
	• Identify the next steps in planning of product realization and commercialization in conformity with the IVDR

Why invest in training from BSI?

We want to make sure you have the best learning experience possible. That's why we offer a range of training courses from beginner to expert. We create a positive learning environment so you retain the knowledge and acquire the skills that will continue to be of use beyond the course.

When you attend a BSI training course, our tutors are the best in the business. They're truly passionate about sharing their knowledge and ensuring you learn. Trusted experts with years of hands-on and business experience, they bring the subject matter to life with relevant and contemporary examples to enhance your learning.

Training delivered at your site could be a convenient and cost effective option, especially if you have multiple delegates. Talk to one of our experts to find out more.

Next steps with the BSI Academy

Want to learn more? You may be interested in:

Application of the IVD Regulation, IVD Directive to IVD Regulation Transition, Technical files and design dossiers for In Vitro Diagnostics (IVDs), Performance evaluation and clinical evidence for In Vitro Diagnostics (IVDs), Suite of ISO 13485 courses.