BSI/UK/1747/TR/0420/EN/GRP

IVD Directive (IVDD) to IVD Regulation (IVDR) Transition Training Course

Training course

STAGE 1 2 3

Essential information about the course

There are significant changes in the European legislation applicable to IVDs. The IVD Regulation has replaced the IVD Directive, which will impose new requirements on manufacturers and other economic operators. By attending this course, you'll discover the new requirements and how these will affect your organization.

Practical activities throughout the day provide the opportunity to apply your knowledge. Learn the generally accepted principles of manufacturing process validation, understand installation, operational and process qualification so you can apply them to your organization.

Our course agenda

- Benefits to you, welcome and introductions
- Boundaries: Conflict of interest and expertise
- Course aim, learning objectives and course structure
- Background to EU and CE marking
- A new regulation
- Transitioning to the new regulation
- Responsibilities
- Scope and risk-based classification
- Conformity assessment
- Clinical expectations
- Technical documentation
- General safety and performance requirements
- Post-market activities
- Managing the transition
- Summary
- Course review and final questions

Upon successful completion of your course, you'll receive an internationally recognized BSI certificate.

Make sure the course is right for you

Who is this course for?

QA regulatory and development personnel involved in CE marking of IVD devices for the European market.

What will I learn?	What are the benefits?
Upon completion of this training, you will be able to: • Explain the background to the IVD Regulation and why the IVD Directive is being replaced • Recognize increased responsibilities of economic operators • Differentiate between the requirements of the IVD Directive and Regulation, including the classification rules under the new IVD Regulation • Recognize conformity assessment routes available under the new Regulation in order to CE mark your products • Identify new requirements for clinical evidence and post-market performance follow-up • Explain the importance of technical documentation for compliance with the new Regulation	This course will help you to: • Identify the requirements of the new IVD Regulation and how this will impact your organization and other operators • Understand the significant changes that are being introduced by the new legislation • Learn what needs to be revised in your current arrangements to meet compliance • Take steps to ensure that existing products CE marked under the IVD Directive comply with the new regulation • Create a plan for your organization to transition to the new regulation for new IVD product development

Prerequisites - you are expected to have the following prior knowledge:

You will benefit from a basic understanding of the IVD Regulation.

This course is aimed at anyone who already has a good knowledge of the existing IVD Directive.

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:
Requirements of the In Vitro Diagnostic Regulation Training Course and Implementation of the In Vitro Diagnostic Device Regulation (IVDR) for CE Marking Training Course

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