BSI/UK/1587/TR/0719/EN/GRP

Technical Documentation for In Vitro Diagnostic Devices (IVDs)

Training course

STAGE 1 2 3

Essential information about the course

This one-day intensive course enables greater understanding of the key requirements for technical documentation for IVDs, in line with the European IVD Regulation (IVDR) requirements in Europe.

A required part of conformity assessment and CE Marking is the need for Technical Documentation which includes the collation of supporting information about your IVD Device. Technical documentation is maintained throughout the product lifecycle. Learn how to assemble this and other types of required information so you can CE Mark your device in Europe.

Our high impact accelerated learning approach increases learning by improving knowledge retention and skill application. This course is activity-based, resulting in a deeper understanding of the material and a greater impact on job performance.

Our course agenda

- What is an IVD and classification?
- Technical documentation and the IVD Regulation
- Technical documentation as a demonstration of conformity
- Overview of technical documentation structure/content
- Technical documentation in detail
- Device description
- Labelling
- Design and manufacturing
- General safety and performance requirements
- Risk Management
- Product verification and validation
- Design validation and clinical performance
- Post market surveillance
- Declaration of conformity

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bsigroup.com/en-IL/medical-devices/training

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?

This course is for QA/Regulatory personnel involved in compiling technical documentation and design dossiers. Product design personnel and those in Research & Development for IVDs intended for the European market.

What will I learn?	What are the benefits?
Upon completion of this training, you will be able to: • Gain confidence in the requirements for technical documentation under the European IVD Regulation • Review and create documentation to support IVD products • Grasp how standards and guidance can be used to improve your technical documentation • Know what is expected by Notified Bodies for technical documentation during reviews and be better prepared • Avoid incomplete technical documentation which can result in unexpected delays or prevent market entry • Recognize the documentation requirements during the product lifecycle and the post market updates needed	This course will help you learn: • Technical documentation requirements under the European IVD Regulation • Be able to review technical files and be able to create new files to support IVD products • How standards and guidance can be used to improve technical documentation • Expectations of Notified Bodies for technical file content during reviews, both at launch and during the product lifecycle

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

It's recommended that you have a basic understanding of European IVD device regulations.

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 Diagnostics Regulation, Application of the In Vitro Diagnostic Regulation and Performance evaluation and clinical evidence for In Vitro Diagnostics (IVDs) courses.

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