BSI/UK/1586/TR/0719/EN/GRP

Performance Evaluation and Clinical Evidence for IVDs

Training course

STAGE 1 2 3

Essential information about the course

If you are involved in planning, conducting or documenting performance evaluation and clinical performance studies for IVD devices in Europe, this intensive one day course will enable a greater understanding of performance evaluation for In Vitro Diagnostic devices under the IVD Regulation, how performance fits into the product development lifecycle and IVD Regulation (IVDR) requirements for clinical evidence.

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

Day 1

- Background
- What is an IVD?
- What is required for "performance" according to the IVD Regulation?
- What are the design and development stages?
- Terminology of performance evaluation
- Performance evaluation
- What analytical performance studies are required?
- Clinical performance regulatory/legal considerations
- Clinical performance study design and protocol considerations
- Special studies and protected study subjects
- Documenting clinical evidence and maintenance schedule

Book today at
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 and R&D scientists involved in planning, conducting or documenting performance evaluation and clinical performance studies for IVD devices in Europe.

What will I learn?	What are the benefits?
Upon completion of this training, delegates will be able to: • Appreciate the need for performance evaluation and how it fits into product development under the European IVD Regulation (EU 2017/746) • Learn key definitions of performance evaluation and clinical evidence under the IVD Regulation • Gain awareness of the scope of the European regulatory requirements for IVD clinical performance studies under the IVD Regulation • Distinguish between non invasive and interventional clinical studies and understand requirements for vulnerable and protected study subjects • Apply practical considerations for study design and protocols • Plan and document clinical evidence under the IVD Regulation; with an appreciation of how this information should be maintained throughout the product lifecycle	This course will help you: • Learn what an In Vitro Diagnostic is and what is required to demonstrate performance according to the IVD Regulation • Appreciate what the design and development stages are during IVD product development • Understand the definitions of performance evaluation that incorporate clinical evidence under the In Vitro Diagnostic Regulation • Identify the analytical performance studies required • Explore clinical performance studies including the legal and regulatory requirements and practical considerations • Document clinical evidence and maintain the documentation throughout the life cycle of the product

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 Course; Application of the In Vitro Diagnostic Regulation Training Course; IVD Directive (IVDD) to IVD Regulation (IVDR) Transition Training Course.

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