BSI/UK/1722/TR/0220/EN/GRP

Clinical Evaluation for Medical Devices

Training course

STAGE 1 2 3

Essential information about the course

The course is designed to provide you with an understanding of the clinical evaluation process including details on the regulatory requirements, the principles of clinical evaluation, how they are performed and documented.

Practical activities throughout the day provide the opportunity to apply your skills in order to perform a clinical evaluation within your organization upon completion of the course.

This one-day intensive course enables you to gain a detailed understanding of the clinical evaluation process for medical devices against the requirements of the Medical Device Regulation (MDR - EU 2017/745), MEDDEV 2.7/1 Revision 4 and relevant MDCG guidance documents.

Our course agenda

Day 1	
• Welcome, benefits to you, and introductions • Boundaries: Conflict of interest and expertise • Course aim, learning objectives and course structure • Regulatory requirements and guidance • Terms and definitions • Regulation (MDR- EU 2017/745) • General principles	• Clinical evaluation • How to conduct a clinical evaluation • Documentation • Actions • Post-market surveillance • Course review and final questions Book today at **bsigroup.com/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 aimed at Clinical and Regulatory Affairs Professionals, Medical Device R&D Engineers and Scientists.

What will I learn?	What are the benefits?
Upon completion of this training, you will be able to: • Identify the key requirements for clinical evaluation according to the MDR, MEDDEV 2.7/1 Revision 4 and relevant MDCG guidance documents • Explain the principles of clinical evaluation • Outline the stages of the clinical evaluation process and documentation requirements • Define how clinical evaluation is performed, including details on clinical evaluation plans (CEP), demonstration of equivalence, identification and appraisal of data and analysis of clinical data • Determine when a clinical investigation is needed for your device • Explain the post-market clinical follow-up (PMCF) requirements • Define the requirements of a clinical evaluation report (CER)	This course will help you to: • Identify the requirements of clinical evaluation against the Medical Device Regulation (MDR - EU 2017/745), MEDDEV 2.7/1 Revision 4 and relevant MDCG guidance documents • Determine when clinical evaluation is undertaken and the frequency of updates • Interpret and communicate the key requirements and expectations of medical device clinical evaluation to your organization • Apply the clinical evaluation process for medical devices within your organization

Prerequisites

Familiarity with your own device, clinical safety and performance issues.
Awareness of:

- General Safety and Performance Requirements (Annex I), Clinical Evaluation and investigations (Annex XIV and XV) of the MDR - EU 2017/745
- MEDDEV 2.7.1 Revision 4 and relevant MDCG guidance documents

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 Medical Device Regulation (MDR) Training Course, Implementation of the Medical Device Regulation (MDR) for CE Marking Training Course and Medical Device Directive (MDD) to Medical Device Regulation (MDR) Transition Training Course.

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