Medical Devices | Clinical Evaluation for Medical Devices

International Training

Number of days 1

Key information about the course

This one-day course offers a robust overview of the clinical evaluation process for medical devices against the medical device regulation (MDR - EU 2017/745), MEDDEV 2.7/1 revision 4 and relevant MDCG guidance documents. Designed for clinical professionals with a base understanding of general safety and performance requirements, this training teaches you how to explain the key principles of clinical evaluation. During this stage of your learning journey, you will gain skills to determine when your device requires clinical investigation, and you will leave with a full grasp of the clinical evaluation process.

Agenda

- 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)
  - Regulatory requirements for clinical evaluation
- General principles
- Clinical evaluation
  - According to MDR - EU 2017/745
  - According to MEDDEV 2.7/1 (Revision 4, June 2016)
- How to conduct a clinical evaluation
  - Definition of the scope and the clinical evaluation plan
  - Identification of clinical data
  - Appraisal of clinical data
  - Analysis of the clinical data
  - Clinical evaluation report
- Documentation
- Actions
- Post-market surveillance
- Course review and final questions
- End of course

Once you have completed the training, you will receive a BSI training certificate.

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Pedagogical objectives

- Fully grasp clinical evaluation requirements in line with the Medical Device Regulation (MDR - EU 2017/745), MEDDEV 2.7/1 revision 4 and relevant MDCG guidance documents
- Able to explain key requirements and expectations of medical device clinical evaluation to your organization
- Apply the clinical evaluation process for medical devices within your organization

Skills to be acquired

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)

Targeted audience

Clinical and Regulatory Affairs Professionals, Medical Device R&D Engineers and Scientists.

Pedagogical, technical and framing means

Course materials including:

- Introduction to the training, detailed program and security assignments
- Course presentation, theory and activities/ role plays
- Answers to the activities
- Videos
- Additional documents, distributed during the sessions, to use for the activities
- Attendance sheet to be signed

Assessment specifics

- Questionnaire to assess the knowledge at the end of the training
- Customer survey

What is included ?

- Course materials, provided electronically
- Letter of attestation
- Official certificate

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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

These training modules are eligible to the subsidizing by the public institutions in France (OPCO);

Each delegate receives a training convention after the enrolment.

Please note that for the public sessions, you have until 48h before the start of the course to confirm your enrolment. For the in-house sessions, the deadline would be of two weeks prior to the start of the course.

Should you be in a disabled situation, please contact us and indicate what details should be taken into account.

You can contact us on **training.france@bsigroup.com** or **01 89 79 00 40**

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