BSI/UK/1734/TR/0320/EN/GRP

Introduction to Medical Device Software

Training course

STAGE 1 2 3

Essential information about the course

BSI's 'Introduction to Medical Device Software' one-day training course has been designed to provide you with knowledge of how the Medical Device Regulation (MDR (EU 2017/745)), standards and guidance documents impact medical device software; software as a medical device; and medical devices with software

This course involves practical activities, group discussions and classroom learning to help you develop a deeper understanding of the material and have a greater impact on job performance.

Our course agenda

- Welcome, benefits to you, introductions and course structure
- Boundaries: Conflict of interest and expertise
- Course aim, learning objectives and course structure
- Introduction to medical device software
- Regulations, standards and guidance documents
- Key terms and definitions
- CE Marking overview
- Specific General Safety and Performance Requirements (GSPRs) related to medical device software
- Medical Device Software Classification (MDR)
- Guidance on qualification and classification
- of software in Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR) – MDCG 2019-11
- Introduction to EN 62304 – Medical device software – Software lifecycle processes:
  - General requirements
  - Software development process
  - Software maintenance process
  - General requirements and software development process
  - Software risk management process
  - Software risk analysis
- EN 60601-1, Clause 14: PEMS
- EN 62304 Second edition
- Summary and course end

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 ideal for you if you're involved in software within the medical device industry.

What will I learn?	What are the benefits?
Upon completion of this training, you will be able to: • Define the medical device software terminology • Identify the relevant standards, directives, and guidance documents recommended to develop, maintain and validate medical device software • Determine if software is covered by an EU Medical Regulation for CE Marking • Classify your medical software as per the MDR • Apply concepts from the key software standards; including EN 62304 (Medical device software - Software lifecycle processes), EN 60601-1 (Medical Electrical Equipment and Systems) and from the MDR EU 2017/745 • Evaluate software lifecycle processes and risk management to ensure they are compliant	This course will help you to: • Understand the key concepts and requirements of EN 62304 • Gain knowledge of the implementation steps of the medical device software lifecycle processes • Correctly classify your medical device software as per the MDR • Perform the necessary risk management and software lifecycle management activities

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

You should have an awareness of Medical Device Regulations and some basic knowledge of medical device software to benefit from this course.

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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