BSI Training Academy

CE Marking Medical Devices with Software training

Essential information about the course

Level 1C

When it comes to creating, testing, and maintaining software for medical devices, the steps you take to define, classify, develop and test your software are critical to both your business and patient health. Achieving and maintaining a CE mark for your medical device software is essential to keeping your product marketable.

If you are unsure how the medical device directives and regulations apply to your software, how your software is classified, and how to develop and maintain it with a CE mark in mind, then this is the course for you. This one day course will help you evaluate your software and processes so you can know what to do during the life-cycle of your software to meet the medical device directives and regulations and get on track. You will learn to determine if software is covered by an EU medical directive for CE marking, and if so how you classify the software.

Packed with practical activities, group discussion and classroom learning, our expert tutors will make sure you complete the course feeling confident that you can apply your new knowledge on your return to your organization.

Our full briefing agenda helps you understand what to expect

- Welcome and introductions
- Course aims, objective and structure
- Introduction to Medical Device Software
  - Directives, standards and guidance documents
- Software CE Marking
  - Definitions
  - Impact of the directives and regulations
- MEDDEV 2.1/6
  - Scope, definitions and guidance
  - Criterion, modules and classification
- BS EN 62304 Software Lifecycle process
  - Software Development process
  - Software Risk Management process
  - Software Maintenance process
  - Software Configuration Management process
  - Software Problem Resolution process
- BS EN 82304 Software Health Applications
  - Health software and related standards
  - Product/system processes and requirements
- BS EN 60601-1 Medical Electrical Equipment
  - Programmable Electrical Medical Systems
  - Relationship between BS EN 62304 to BS EN 60601-1
- MDR (and IVDR)
- Review and final questions

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...making excellence a habit.™

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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 skills that will continue to be of use beyond the course.

Make sure this is the right course for you.

This course is for you if:

- You are involved with software in the medical device industry
- You are involved in software development and maintenance and need to know what to do to meet medical device directives and regulations
- You want to more efficiently achieve a CE mark for your medical device containing software
- Properly classify your software based on medical device directive and regulation parameters

What's the course like?

- One day long
- Led by a BSI expert tutor
- Relaxed and comfortable learning environment
- You'll receive course materials to take away
- Develop professionally
- Network with likeminded peers

How will I benefit?

- Identify relevant directives, standard and guidance documents recommended to develop, maintain and validate medical software according to state of the art
- Apply concepts from key software standards and guidance documents
- Learn to effectively plan software risk management, development, testing, maintenance and problem resolution
- Develop the knowledge to evaluate how to assess software lifecycle processes and risk management to ensure compliancy

Why invest in training from BSI?

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 in-house only

Contact us for a customized quote
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Talk to one of our experts to find out more

Find out more.
Call: **+44 (0)345 086 9000**
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