Medical Devices | Introduction to medical Device Software

International Training

Number of days **1**

Key information about the course

This course is 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.

It will help you to understand how EN 62304 Medical device software - software lifecycle processes can improve your medical device software development, validation and lifecycle process.

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Agenda

Day 1

- Welcome, benefits to you, introductions and course structure
- Boundaries: Conflict of interest and expertise
- Course aim, learning objectives and course outline
- Introduction into cybersecurity for medical device software
- Specific General Safety Performance Requirements (GSPRs) related to medical device software cybersecurity
- Overview of medical software cybersecurity
- Secure design and manufacturing
- Documentation and instruction for use
- Post-market surveillance and vigilance
- Other legislations and guidance for medical device software
- Summary and course end

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

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Introduction to Medical Device Software

Pedagogical objectives

- 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

Skills to be acquired

On completion of this training, you'll 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

Targeted audience

This course is intended for individuals or organizations involved in software within the medical device industry.

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

International training - Introduction to Medical Device Software

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

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

Each delegate receives a training convention after the enrollment.

Please note that for the public sessions, you have until 48h before the start of the course to confirm your enrollment. 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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