Medical Devices | Medical Device software with Cybersecurity

International Training

Number of days 1

Key information about the course

This course is designed to provide you with the knowledge to appropriately address the medical device software cybersecurity requirements of the MDR 2017/45 and related MDCG guidance documents.

You will also gain knowledge on performing the necessary risk and software lifecycle management activities in order to mitigate cybersecurity risks.

International training

Medical Device Software with Cybersecurity

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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Pedagogical objectives

- Understand the key concepts of cybersecurity for medical device software
- Gain knowledge of the cybersecurity requirements of the MDR 2017/45 and related MDCG guidance documents
- Appreciate the lifecycle stages of secure design and manufacture for medical device software
- Gain awareness of the post-market surveillance and vigilance requirements related to cybersecurity incidents/vulnerabilities

Skills to be acquired

On completion of this training, you'll be able to:

- Define the cybersecurity terminology related to medical device software
- Identify the key concepts of medical device software cybersecurity
- Apply the cybersecurity requirements of the MDR 2017/45 and related MDCG guidance documents
- Develop a secure design and manufacturing process for medical device software
- Prepare the appropriate documentation specific to security requirements
- Appropriately manage cybersecurity incidents and vulnerabilities via post-market surveillance and vigilance

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 - **Requirements of the MDR for CE Marking**

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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