



Introduction to Medical Device Software - International



Your partner
in progress



Course descriptive

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.

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

Upon completion of this training, delegates 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



Targeted audience

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

Prerequisites

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

Duration

1 day – 7 hours



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



Agenda - Day 1

Time	Topic	
09:00	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: <ul style="list-style-type: none"> • General requirements • Software development process • Software maintenance process • General requirements and software development process • Software risk management process • Software risk analysis • Software configuration management process • Software problem resolution process • Software field problem 	
	EN 60601-1, Clause 14: PEMS	
	EN 62304 Second edition	
	Welcome, benefits to you, introductions and course structure	
	Boundaries: Conflict of interest and expertise	
	Course aim, learning objectives and course structure	
	17:00	Close day 1



- *These training modules are eligible to the subsidizing by the public institutions in France (OPCO);
- **Each delegate receives a training convention after 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 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**.