CEISO
TRAINING CENTER

Medical Device Software Development

REF. GR03 - INTRA/INTER

MANAGING RISKS

COURSE DESCRIPTION

At the end of this course, participants will understand the concepts set out in EN 62304:2006/AC 2008/A1:2015 regarding software development and better grasp the regulatory and normative requirements governing market authorization for medical devices (MD) with incorporated software or stand-alone software as a medical device in Europe. They will also be able to identify the documentary deliverables required based on the Software Safety Classification.

DURATION
1 day/7 hours

IN-PERSON

VIRTUAL CLASSROOM

OBJECTIVES

- Identify regulatory requirements for MD software
- Understand the specificities of the different types of software, which implies a thorough understanding of their development
- Distinguish and understand the ties between the Analysis and Management of MD Risks and the Software Safety Classification
- Identify the normative requirements for the development of MD software

TARGET TRAINEES

MD manufacturers, and more particularly:

- R&D Manager
- Software Development Manager and any individual who works on the development of software and/or MD design/development
- The individual responsible for ensuring compliance with the regulations
- Quality Manager
- Regulatory Affairs Manager

PREREQUISITES

- Familiarity with the MD sector
- Familiarity with software concepts

TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Case studies
- Reference to Regulation (EU) 2017/745
- Quizzes

COURSE CONTENT

Participants welcomed and presented/Presentation of the course objectives and method to check that they are achieved

1. Identify regulatory requirements for MD software
2. Understand the specificities of the different types of software, which implies a thorough understanding of their development
   a. Stand-Alone Software
   b. Software embedded in a microprocessor or microcontroller
   c. Software embedded in another component (firmware)
3. Distinguish and understand the ties between the Analysis and Management of MD Risks and the Software Safety Classification according to EN 62304
4. MD software development process
5. Summary/Q&A
6. Training evaluation and conclusion

Virtual classroom training: the course can be divided into two half-days

EVALUATION METHODS

Course evaluation quiz
Satisfaction survey
Attendance certificate

This training is assessed based on an evaluation of each individual's acquisition of knowledge via quizzes during and at the end of the program *(success criteria >= 75%).*

Do you have a question? Contact us!
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