CEISO
TRAINING CENTER

REF. GR05 - INTRA/INTER

MANAGING RISKS

Application of Usability Engineering

COURSE DESCRIPTION

At the end of the course, participants will better understand the requirements regarding implementation of the "usability" process and be able to comply with these requirements appropriately.

DURATION
1 day/7 hours

IN-PERSON

VIRTUAL CLASSROOM

OBJECTIVES

- Update knowledge on the usability engineering process: EN 62366-1 requirements
- Raise the participants' awareness of the role they play in this process

TARGET TRAINEES

Medical Device (MD) manufacturers, and more particularly:
- R&D team
- Production
- Quality Manager
- Regulatory Affairs Manager

PREREQUISITES

- Familiarity with the MD sector

TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Standard document examples
- Regulatory references
- Quizzes

COURSE CONTENT

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

1. Regulatory requirements for the implementation of a Usability Engineering Process
   a. EN 62366-1, its objectives, and the tie to the ISO 14971 risk analysis
   b. Key definitions
   c. The specific case of the User Interface of Unknown Provenance
2. User specifications
3. User interface
4. Known or foreseeable dangerous phenomena and situations
5. User scenarios related to dangerous phenomena and the validation thereof (summative evaluation)
6. Draw up specifications for the User interface
7. Draw up the evaluation plan for the User interface
8. Design and check the User interface
9. Validate the User interface
10. Summary/Q&A
11. Course evaluation and conclusion

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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