CEISO
TRAINING CENTER

REF. RL23 - INTRA/INTER

EUROPEAN REGULATIONS

Regulation (EU) 2017/746: Compliance with the General Safety and Performance Requirements

COURSE DESCRIPTION

To place *In Vitro* Diagnostic Medical Devices (IVDMD) on the market in Europe, the requirements of Regulation (EU) 2017/746 must be met.

The manufacturer must design and manufacture its devices so as to ensure that, under normal conditions of use, they are suited for their intended use, safe and effective, and do not endanger the clinical condition or safety of patients or the safety or health of users.

DURATION
1 day/7 hours

IN-PERSON

VIRTUAL CLASSROOM

OBJECTIVES

- Understand and apply the general safety and performance requirements
- Demonstrate GSPR compliance
- Take GSPR into account during the design process

TARGET TRAINEES

Manufacturers of *In Vitro* Diagnostic Medical Devices, and more particularly:

- R&D
- Regulatory Affairs
- All individuals involved in the device's design process

PREREQUISITES

- Familiarity with Regulation (EU) 2017/746 is a plus.

TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Case studies
- Experience sharing
- Quizzes

COURSE CONTENT

Participants welcomed and presented/Course objectives/ Presentation of the course content

1. Regulatory framework
2. General safety and performance requirements (GSPR)
   a. General information
   b. Tie to design and development
   c. Tie to risk management
   d. Tie to the technical documentation
   e. Evidence to prove/demonstrate compliance
3. GSPR review and responses
   a. General requirements
   b. Design and manufacturing requirements
   c. Requirements relative to information provided with the device
4. Summary/Q&A
5. 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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