CEISO
TRAINING CENTER

REF. RL13 - INTRA/INTER

EUROPEAN REGULATIONS

Regulation (EU) 2017/746 on *In Vitro* Diagnostic Medical Devices - Introduction to the Regulation

COURSE DESCRIPTION

The design, production and marketing of *In Vitro* Diagnostic Medical Devices (IVDMD) in Europe must comply with the requirements of Regulation (EU) 2017/746.

Operators in this market must be able to evaluate the impact of these requirements on their products' compliance, the information to be provided in the technical files and how it is organized so as to define an action plan to ensure compliance.

DURATION
1 day/7 hours

IN-PERSON

VIRTUAL CLASSROOM

OBJECTIVES

- Understand the regulatory framework for MDs - learn the basics.
- Identify the impacts on the products and regulatory documents.
- Identify the impacts on the organization (responsibilities, UDI).
- Raise the awareness of attendees on the role they play.

TARGET TRAINEES

IVDMD manufacturers/subcontractors, and more particularly:

- R&D team
- Production
- Purchasing
- Sales
- Regulatory Affairs
- Quality Management

PREREQUISITES

- Familiarity with the IVDMD sector
- Familiarity with Regulation (EU) 2017/746 may facilitate a better understanding of its requirements.

TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Case studies
- Distribution of Regulation (EU) 2017/746
- Quizzes

COURSE CONTENT

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

1. General information
   a. Purpose and scope
   b. Structure and management of the regulation
   c. Transition from a Directive to a Regulation
2. Economic operators subject to the regulation
   a. Regulation impacts
   b. Individual responsible for ensuring compliance with the regulation
3. EUDAMED and UDI
4. Conformity assessment procedure
   a. Device classification
   b. Evaluation procedures
5. General safety and performance requirements
6. Performance evaluation and clinical evidence
7. Technical documentation - Conformity declaration and CE-marking
8. Post-market surveillance
9. Quality Management System
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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