CEISO
TRAINING CENTER

REF. RL15 - INTRA/INTER

EUROPEAN REGULATIONS

Preparation of Technical Documentation in accordance with Regulation (EU) 2017/746

COURSE DESCRIPTION

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

The Technical Documentation the manufacturer must draw up and present must be clear, organized and unambiguous, in a form that can be easily read, and include, in particular, the items listed in Annexes II and III of the MDR.

DURATION
1 day/7 hours

IN-PERSON

VIRTUAL CLASSROOM

OBJECTIVES

- Identify requirements to draw up the Technical Documentation according to Regulation (EU) 2017/746
- Know how to draw up the Technical Documentation and ensure it is up to date
- Integrate the Technical Documentation requirements into the design process

TARGET TRAINEES

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

- Regulatory Affairs
- R&D
- Any individual involved in the preparation or review of the technical documentation

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

a. Regulatory review
b. Technical documentation objectives
c. Technical documentation structure and format
   - The basic elements and ties to the design and production file
   - Content of the different sections
   - File coherence: key points
d. The roles that contribute to the compilation of the technical documentation
e. Tie to the ISO 13485:2016 quality management system: post-market surveillance - Change control
f. Notified body sampling of technical documentation reviews
g. Summary/Q&A
h. 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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