CEISO
TRAINING CENTER

REF. RL08 - INTRA/INTER

INTERNATIONAL REGULATIONS

Compliance with US Market Authorization Requirements for Medical Devices - 510(k) Submission

COURSE DESCRIPTION

Compliance with FDA (Food and Drug Administration) requirements is mandatory to place Medical Devices on the US market.

The technical documentation that the manufacturer is to provide must be presented in accordance with the regulatory requirements of 21 CFR 807.

DURATION
1 day/7 hours

IN-PERSON

VIRTUAL CLASSROOM

OBJECTIVES

- Identify the requirements to draw up the technical documentation for the 510(k).
- Know how to draw up the technical documentation and ensure it is up to date
- Understand relations with the FDA

TARGET TRAINEES

Medical Device manufacturers, and more particularly:
- Regulatory Affairs
- R&D
- Any individual involved in the preparation or review of the technical documentation

PREREQUISITES

- Familiarity with Regulation (EU) 2017/745, particularly Annex II, 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. 510(k): context and definitions
2. Background - Regulatory framework - Organization of the FDA
3. Market authorization process in the US
4. US classification of Medical Devices
5. Premarket notification/Application
   a. Concepts underlying the 510(k) procedure and the products involved
   b. Why a 510(k)?
   c. Definition of “substantial equivalence”
   d. How to compare a product?
6. Prepare a 510(k) submission
   a. Content of a 510(k) submission
   b. Method/Acceptable evidence
7. Communications with the FDA
   a. Relations with the FDA contact - Submission procedure
   b. Costs
8. Summary/Q&A
9. 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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