CEISO
TRAINING CENTER

Post-Market Clinical Follow-Up of a Medical Device

REF. CL09 - INTRA/INTER

CLINICAL

COURSE DESCRIPTION

The demonstration of a Medical Device's compliance with the General Safety and Performance Requirements requires the implementation of Post-Market Clinical Follow-Up (PMCF) to collect, record and analyze relevant clinical data on the quality, performance and safety of a device throughout its lifecycle. This system must be documented and implemented in accordance with the requirements of Regulation (EU) 2017/745.

DURATION
1 day/7 hours

IN-PERSON

VIRTUAL CLASSROOM

OBJECTIVES

- Become familiar with the terms and vocabulary
- Understand the requirements of Regulation (EU) 2017/745 in terms of post-market surveillance and post-market clinical follow-up
- Become familiar with the different options regarding post-market clinical follow-up activities

TARGET TRAINEES

- Medical Device manufacturers
- Medical Device development or market operators

PREREQUISITES

- No prior knowledge required

TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Discussions based on the regulation and guidelines
- Distribution of the texts presented
- Quizzes

COURSE CONTENT

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

1. Post-market clinical follow-up: context and definitions
   a. Terms and definitions
   b. Process inherent in post-market surveillance
   c. Goals
2. Identification of regulatory requirements
   a. Regulation (EU) 2017/745
   b. Practical guidelines
   c. Documents to be prepared
3. Nature of PMCF activities
4. Documents to be prepared
   a. PMCF plan
   b. PMCF report
5. Post-market clinical data
   a. What data?
   b. How to analyze/use it?
   c. Implementation of the different documents and related documents
   d. Practical examples
6. Summary/Q&A
7. Course evaluation and conclusion

EVALUATION METHODS

Course evaluation quiz
Satisfaction survey
Attendance certificate

This training is assessed based on each individual's acquisition of knowledge via quizzes during and at the end of the program *(success criteria >= 80%).*

Do you have a question? Contact us!
Email: formation@ceiso.fr
Tel.: +33 6 42 58 94 52