CEISO
TRAINING CENTER

Post-Market Surveillance of Medical Devices

REF. RL20 - INTRA/INTER

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The demonstration of a Medical Device's compliance with essential requirements requires the implementation of a post-market surveillance system to collect, record and analyze relevant 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

TARGET TRAINEES

- Medical Device manufacturers
- MD development or market operators

PREREQUISITES

- No prior knowledge required

TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Experience sharing based on the regulation and related guidelines
- Quizzes

COURSE CONTENT

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

1. Post-market surveillance: context and definitions
   a. Terms and definitions
   b. Objectives
2. Identification of regulatory requirements
   a. Regulation (EU) 2017/745
   b. Practical guidelines
3. Documents to be drafted
   a. PMS and PMCF plans
   b. Post-market surveillance report
   c. Periodic safety update report (PSUR)
   d. Ties between the documents
4. Post-market surveillance data
   1. What data?
   2. How to analyze/use it?
   3. Drawing up the different documents
   4. Practical examples
5. Summary/Q&A
6. 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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