CEISO
TRAINING CENTER

REF. RL07 - INTRA/INTER

EUROPEAN REGULATIONS

Medical Devices: European Materiovigilance Requirements

COURSE DESCRIPTION

When Medical Devices (MD) are placed on the market in Europe, the post-market phase must be supervised, in particular via the collection and analysis of adverse events, so that any action required to protect the safety of patients, users and third parties can be taken.

Regulation (EU) 2017/745 requires operators in this market to implement and maintain notification processes for serious incidents and corrective safety measures as part of their vigilance obligation.

DURATION
1 day/7 hours

IN-PERSON

VIRTUAL CLASSROOM

OBJECTIVES

- Understand the regulatory framework for MDs - learn the basics
- Identify the impacts on the organization of feedback processing and the implementation of corrective actions
- Identify the impacts on the organization (responsibilities, information channels - collection and processing)
- Raise the awareness of attendees on the role they play

TARGET TRAINEES

Medical Device manufacturers/ subcontractors, and more particularly:
- Regulatory Affairs
- Quality Management

PREREQUISITES

- Familiarity with the Medical Device sector
- Familiarity with Regulation (EU) 2017/745 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) 2017/745
- Quizzes

COURSE CONTENT

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

1. Context
2. Objectives and requirements - the regulation
3. A few definitions
4. Who is concerned?
5. Materiovigilance
   a. General principle
   b. Feedback analysis
   c. Manufacturer's Incident Report (MIR)
   d. IMDRF codes
   e. FSN and FSCA
   f. Communication - Reports
6. Summary/Q&A
7. 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!
Email: formation@ceiso.fr
Tel.: +33 6 42 58 94 52