CEISO
TRAINING CENTER

REF. RL24 - INTRA/INTER

EUROPEAN REGULATIONS

# *In Vitro* Diagnostic Medical Devices: European Vigilance Requirements

## COURSE DESCRIPTION

When *in vitro* diagnostic medical devices (IVDMD) 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 2017/746 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 IVDMDs; 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

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

## PREREQUISITES

- Familiarity with the IVDMD sector
- Familiarity with Regulation (EU) 2017/746 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) 2017/746
- 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. *In vitro* diagnostic medical device vigilance
   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