

Post-Market Performance Follow-Up of an *In Vitro* Diagnostic Medical Device

COURSE DESCRIPTION

The demonstration of an *In Vitro* Diagnostic Medical Device's compliance with the General Safety and Performance Requirements includes the implementation of Post-Market Performance Follow-up (PMPF) 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) 2017/746.

DURATION

1 day/7 hours



IN-PERSON



VIRTUAL CLASSROOM

OBJECTIVES

- Become familiar with the terms and vocabulary
- Understand the requirements of Regulation (EU) 2017/746 in terms of post-market surveillance and post-market performance follow-up
- Become familiar with the different options regarding post-market performance follow-up activities

TARGET TRAINEES

- IVDMD manufacturers
- IVDMD 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 performance 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) 2017/746
 - b. Practical guidelines
3. Nature of PMPF activities
4. Documents to be prepared
 - a. PMPF plan
 - b. PMPF report
5. Post-market performance 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 an evaluation of 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!

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