Medical Device and IVD Post-Market Surveillance Training Course

5 – 9 April 2027
Rome

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Ref: 1540_213754 **Date:** 5 – 9 April 2027 **Location:** Rome **Fees:** 5700 Euro

Overview

Medical device and IVD post-market surveillance is an advanced one-week course for quality, regulatory, vigilance and safety professionals who need a Post-Market Surveillance and Vigilance Control File. The course addresses fragmented evidence through PMS planning, complaint intake, signal and trend analysis, reportability decisions, serious-incident escalation, field safety corrective action, PSUR and PMPF interfaces, governance and audit readiness. Agile Leaders Training Center places medical device and IVD post-market surveillance within lifecycle safety management.

Who Should Attend

- Teams responsible for medical-device and IVD quality-system evidence
- Functions responsible for regulatory reporting and authority communication
- Personnel responsible for PMS, vigilance and safety signal review
- Teams responsible for complaint handling and investigation records
- Clinical and performance specialists responsible for post-market evidence
- Managers responsible for escalation, governance and audit readiness

The course assumes participants already work with regulated-device quality or safety records and leaves out ISO 13485 foundations, design controls and premarket submission preparation.

Departments and Industries

The course supports departments and organizations that manufacture, monitor or support medical devices and IVDs after market placement.

- Medical-device and IVD manufacturers
- Regulatory affairs and quality assurance functions
- Complaint handling and customer-quality teams
- Clinical, safety and performance-evaluation functions
- Distribution and economic-operator quality teams
- Testing, laboratory and healthcare-technology organizations

Learning Objectives

By the end of this course, participants will be able to:

- Apply risk-proportionate PMS planning and governance controls
- Use complaint, incident and signal intake taxonomies
- Analyze trends, thresholds and reportability evidence
- Build serious-incident and FSCA decision records
- Prioritize PSUR, PMPF and risk-management updates
- Evaluate data quality, escalation and audit readiness

Course Agenda

Day 1: PMS System Architecture

- MDR and IVDR PMS Obligation Map
- Risk-Proportionate PMS System Design
- PMS Plan Evidence-Source Matrix
- Lifecycle Document Interface Map
- PMS Governance and Responsibility Chart

Day 2: Complaints, Incidents and Signals

- Complaint Intake and Coding Taxonomy
- Device Event Investigation Record
- Serious-Incident Assessment Decision Tree
- Signal Detection and Validation Log
- Data Quality and Case-Completeness Checklist

Day 3: Vigilance and Corrective Action

- Reportability Decision and Rationale Template
- Vigilance Escalation Workflow
- Trend Reporting Threshold Method
- Field Safety Corrective Action Decision Pack
- Field Safety Notice Review Checklist

Day 4: Periodic Evidence and Governance

- PMS Report and PSUR Content Matrix
- PMPF and Post-Market Evidence Interface
- Benefit-Risk and Risk-Management Update Map
- Management Review PMS Dashboard
- Audit Trail and Inspection-Readiness File

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Day 5: PMS and Vigilance Practice

- Suggested Exercise: Complaint-to-Signal Case Review
- Suggested Exercise: Serious-Incident Reportability Decision
- Suggested Exercise: Trend Threshold and Escalation Review
- Suggested Exercise: FSCA and Periodic Report Evidence Check
- Capstone Exercise: Post-Market Surveillance and Vigilance Control File

Practical Exercises

The course uses suggested activities based on medical-device, IVD, laboratory and distribution cases.

- Suggested activity: map PMS data sources to risk, performance and corrective-action decisions.
- Suggested activity: assess a complaint cluster for signal validation, trend reporting and escalation.
- Suggested activity: document a reportability decision and proposed field safety corrective action.
- Suggested activity: audit a periodic safety file for traceability, interfaces and missing evidence.

FAQs

Who does the medical device and IVD post-market surveillance course suit, and what does it assume?

The course suits experienced quality, regulatory, vigilance, complaint and safety personnel and assumes familiarity with regulated-device records, risk evidence and organizational quality processes.

How does medical device and IVD post-market surveillance differ from ISO 13485 foundation training?

Post-market surveillance focuses on active market evidence, incidents, signals, trends, periodic reporting and corrective action, while foundation training explains broader quality-management requirements.

What evidence belongs in a medical device PMS plan?

A PMS plan organizes proactive and reactive data sources, analysis methods, indicators, responsibilities, reporting outputs, document interfaces and routes for preventive or corrective action.

How are vigilance reportability decisions documented?

Reportability decisions record event facts, seriousness, device relationship, applicable criteria, uncertainty, escalation, reporting action and the evidence supporting the rationale.

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How do PSUR and PMPF connect to IVD post-market surveillance?

PSUR and PMPF outputs connect periodic safety and performance evidence with trend evaluation, benefit-risk review, risk management and updates to lifecycle documentation.

Conclusion

Participants leave with a Post-Market Surveillance and Vigilance Control File containing PMS architecture, intake taxonomy, signal logs, reportability records, trend methods, FSCA evidence and periodic-report interfaces. The file makes safety decisions and document updates traceable. It supports governance across quality, regulatory, clinical, performance and management functions.