# Medical Device and IVD Post-Market Surveillance Training Course

15 – 19 August 2027
Johannesburg

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**Ref:** 1540_213783 **Date:** 15 – 19 August 2027 **Location:** Johannesburg **Fees:** 4500 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.