CONCEPT

Medical Device Post-Market Surveillance and Vigilance: Complaints, Trends and Field Actions

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Introduction:

Medical device post-market surveillance breaks down when complaints sit in customer service logs, service reports never reach quality, trends are spotted only after several patients are affected and nobody can say quickly whether an event must be reported. This Core Concept course trains regulatory affairs, quality, complaint handling and distributor staff to run a proactive surveillance system for medical devices and IVDs, from data collection and complaint investigation to signal detection, incident reporting, field safety corrective actions and periodic safety reports. Participants produce a Post-Market Surveillance Plan and Vigilance Decision Pack.

Course Objectives:

- Design a post-market surveillance plan that defines data sources, collection frequency, responsibilities and escalation routes for a device or IVD family
- Investigate complaints and service reports to a documented procedure, including sample retrieval, root cause analysis and closure records
- Analyse complaint and incident data with trend charts and statistical thresholds to detect safety signals early
- Decide whether an event is a reportable incident using a documented decision tree and prepare an incident report within the applicable deadline
- Plan and execute field safety corrective actions, field safety notices and recalls with manufacturers, importers, distributors and users
- Compile periodic safety reports and feed surveillance conclusions back into ISO 14971 risk management and ISO 13485 corrective action

Target Audience:

- Regulatory affairs staff who prepare incident reports, field safety notices and periodic safety reports
- Quality assurance staff who run complaint handling, CAPA and management review inputs for device portfolios
- Complaint handling and customer service staff who receive, log and triage user feedback on devices and IVDs
- Distributor and importer quality staff who record complaints, maintain traceability and carry out field actions
- Clinical and application specialists who collect field feedback, service findings and user errors from healthcare sites

Course Outline:

Day 1: Post-Market Surveillance Purpose, Roles and Data Landscape

- Post-Market Surveillance Versus Vigilance: Proactive Collection and Reactive Reporting
- Economic Operator Roles: Manufacturer, Authorised Representative, Importer and Distributor Duties
- Surveillance Data Source Map: Complaints, Service Records, Literature, Registries and User Surveys
- IVD Specific Feedback: External Quality Assessment Results and False Result Reports
- Surveillance Maturity Self-Assessment Against Current Complaint and Feedback Records

Day 2: ISO/TR 20416, ISO 13485 Feedback Clauses and IMDRF Terminology

- ISO/TR 20416 Post-Market Surveillance Process: Planning, Collection, Analysis and Action
- ISO 13485 Feedback, Complaint Handling and Reporting to Regulatory Authorities Clauses
- ISO 14971 Production and Post-Production Information Requirements
- IMDRF Adverse Event Terminology and Coding Annexes at Overview
- Post-Market Surveillance Plan Template: Scope, Sources, Methods, Indicators and Review Cycle

Day 3: Complaint Investigation, Trend Analysis and Signal Detection

- Complaint Intake Form, Triage Criteria and Complaint Versus Feedback Decision
- Returned Product Evaluation, Device History Record Review and Root Cause Analysis Tools
- Complaint Rate Calculation Using Units Sold, Installed Base and Test Volumes
- Trend Charts, Control Limits and Statistically Significant Increase Thresholds
- Literature Search Protocol and Similar-Device Data Screening Worksheet

Day 4: Reportable Incidents, Field Actions and Periodic Reporting

- Reportable Incident Decision Tree: Serious Deterioration, Death and Public Health Threat Criteria
- Incident Report Content, Follow-Up and Final Report Workflow Within Applicable Deadlines
- Field Safety Corrective Action Planning: Scope, Affected Lots and Effectiveness Checks
- Field Safety Notice Wording, Customer Acknowledgement Forms and Reconciliation Records
- Periodic Safety Report and Post-Market Surveillance Report Structure and Conclusions

Day 5: Case Study Workshop: Surveillance Plan and Vigilance Decisions

- Case Study: Glucose Meter Complaint Cluster and IVD False Low Result Signal
- Case Study: Orthopaedic Implant Registry Revision Rate and Field Safety Notice
- Case Study: Distributor Handling of a Recall Across Hospitals and Clinics
- Mock Incident Report and Field Safety Notice Drafting With Peer Critique
- Post-Market Surveillance Plan and Vigilance Decision Pack Assembly and Review

Skills You Will Gain:

- Complaint Investigation
- Surveillance Data Analysis
- Safety Signal Detection
- Reportability Assessment
- Incident Report Writing
- Field Action Coordination
- Periodic Safety Reporting
- Adverse Event Coding

Why Attend This Course:

- Return with a Post-Market Surveillance Plan and Vigilance Decision Pack built for a device or IVD family you handle
- Make reportability calls faster by working a single documented decision tree instead of case-by-case debate
- Run field safety notices and recalls with clear handoffs between manufacturer, importer, distributor and hospital
- Test your complaint and trend practice against peers from manufacturers, importers and diagnostic suppliers

Conclusion:

A device stays safe in use when field data reaches the people who can act on it. The course moves from surveillance purpose, operator roles and data sources, through ISO/TR 20416, ISO 13485 feedback clauses, ISO 14971 post-production information and IMDRF terminology, to complaint investigation, trend analysis and signal detection, then to reportable incidents, field safety corrective actions and periodic reports. The final day works real-style cases and produces a Post-Market Surveillance Plan and Vigilance Decision Pack ready for internal approval.