CORE CONCEPT

Medical Device Registration and Post-Market Surveillance Training Course

15 – 26 November 2026
Jeddah - Corniche four-star

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Introduction:

Medical device registration and post-market surveillance is the subject of this 2-week course for regulatory affairs, quality, authorised representative and vigilance staff, ending with a Device Regulatory Dossier for a device in their own portfolio. Organisations lose market access when classifications are challenged, authorisations lapse after unnotified changes or adverse events and field actions are handled late. Nominees already prepare SFDA submissions or maintain device files; teaching is by case study, and week two adds software, change control, vigilance, field actions, inspections and metrics. CoreConcept Training Center delivers this medical device registration and post-market surveillance course.

Course Objectives:

- Allocate regulatory duties among the manufacturer, authorised representative, importer and distributor across the device lifecycle
- Classify general and IVD devices under MDS-G008 and the IVD rules and select the marketing authorisation route
- Assemble technical documentation, clinical or performance evidence and bilingual labelling that meet MDS-REQ 1 and submit them through GHAD
- Control software changes, renewals, advertising approval and inspection readiness so marketing authorisations stay valid
- Run post-market surveillance under MDS-REQ 11, NCMDR reporting, field safety corrective actions and recalls, and measure compliance with KPIs and internal audits
- Produce a Device Regulatory Dossier with a post-market compliance plan for a device in the participant's own portfolio

Target Audience:

- Regulatory affairs staff responsible for device marketing authorisations, renewals and deficiency responses
- Quality assurance staff responsible for technical documentation, risk management files and CAPA records
- Authorised representative staff responsible for overseas manufacturers' submissions, vigilance and recalls
- Post-market surveillance and vigilance staff responsible for complaint trending and adverse event reports
- Importer and distributor compliance staff responsible for establishment licences, shipment release and UDI records

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Course Outline:

Day 1: Regulatory Foundations and Device Lifecycle Responsibilities

- SFDA Medical Device Sector Mandate and Lifecycle Controls
- Manufacturer, Authorised Representative and Importer Duty Allocation
- MDS-REQ 9 Establishment Licence Scope for Distributors
- Device Lifecycle Map From Design Freeze to Withdrawal
- Regulatory Strategy Baseline for a Multi-Market Device Portfolio

Day 2: Classification Rules and Marketing Authorisation Standards

- MDS-G008 Rule Logic for General Medical Devices
- IVD Classification Rules for Reagents, Analysers and Self-Tests
- MDS-REQ 1 Marketing Authorisation Evidence Expectations
- ISO 13485 Quality Management System Certificate Scope Checks
- ISO 14971 Risk Management File Structure and Acceptability Criteria

Day 3: Technical Documentation Building and Clinical Evidence

- Technical Documentation Index Mapped to Essential Requirements Checklist
- Clinical Evaluation Report Appraisal for Equivalence Claims
- Performance Evaluation Evidence for IVD Analytical Validity
- Bilingual Labelling and Instructions for Use Drafting
- Declaration of Conformity and Free Sale Evidence Assembly

Day 4: GHAD Submission, UDI Data and Import Systems

- GHAD Account Set-Up, User Roles and Application Tracking
- GHAD Marketing Authorisation Form Completion and Attachment Rules
- MDS-REQ 7 UDI Database Record Creation and Maintenance
- MDS-REQ 5 Shipment Release Documentation and Port Checks
- Deficiency Letter Triage and Evidence Resubmission Workflow

Day 5: Case Study on a Marketing Authorisation File

- Case Device Classification Decision and Rationale Memo
- Case Technical File Gap Analysis Against MDS-REQ 1
- Case Labelling Review for Lay and Professional Users
- Case GHAD Submission Record and Deficiency Response
- Week-One Marketing Authorisation File Peer Review

Day 6: Software, Device Changes and Authorisation Renewal

- IEC 62304 Software Lifecycle Evidence for Medical Device Software
- Software as a Medical Device Qualification and Risk Class
- Combination Product and Accessory Boundary Decisions
- Significant Change Assessment and Variation Notification Routes
- Marketing Authorisation Renewal Planning and Portfolio Rationalisation

Day 7: Post-Market Surveillance, Vigilance and Field Actions

- MDS-REQ 11 Post-Market Surveillance Plan Content
- NCMDR Adverse Event Report Preparation and Follow-Up
- Field Safety Corrective Action Planning and Field Safety Notices
- Recall Classification, Effectiveness Checks and Close-Out Records
- Complaint Trend Analysis Linked to ISO 14971 Risk Updates

Day 8: Stakeholders, Promotion and Regulatory Communication

- MDS-REQ 8 Advertising Approval and Promotional Claim Review
- Authorised Representative Agreement Clauses and Escalation Paths
- Healthcare Provider Communication During Field Safety Notices
- Regulatory Inspection Readiness and Document Request Handling
- Regulatory Intelligence Briefings for Commercial and Service Teams

Day 9: Compliance Metrics, Audits and Continuous Improvement

- Regulatory KPI Dashboard for Submission Cycle Times
- Post-Market Surveillance Report Indicators and Trend Signals
- Internal Regulatory Audit Programme Against ISO 13485 Clauses
- CAPA Effectiveness Review for Recurring Deficiency Findings
- Approval Time Benchmarking Across Device Classes and Routes

Day 10: Case Study Capstone and the Device Regulatory Dossier

- Own-Portfolio Device Classification and Authorisation Route Selection
- Own-Device Post-Market Surveillance Plan Drafting
- Own-Device Vigilance and Field Action Procedure Assembly
- Compliance Calendar for Renewals, UDI Data and Licences
- Device Regulatory Dossier Completion and Panel Presentation

Skills You Will Gain:

- Device Classification Rationale
- Clinical Evidence Appraisal
- Regulatory Submission Management
- Software Change Assessment
- Adverse Event Reporting
- Field Safety Action Coordination
- Regulatory KPI Tracking
- Inspection Readiness Management

Why Attend This Course:

- Deliver a Device Regulatory Dossier to the head of regulatory affairs and the post-market safety committee
- Decide whether a design, labelling or supplier change needs a variation notification or a new authorisation
- Avoid lapsed authorisations, late adverse event reports and uncontrolled field actions that halt sales
- Equip quality, sales and service colleagues with complaint intake, advertising and field notice checklists

Conclusion:

Back at work, the participant presents the Device Regulatory Dossier to the head of regulatory affairs, the quality manager and the post-market safety committee. They use it to confirm each device's authorisation route, approve the post-market surveillance plan, assign vigilance and field action roles and set renewal and UDI deadlines in the compliance calendar. After the first complaint trend review or deficiency letter under the dossier, the unit should compare the findings with the dossier's risk entries and KPIs and revise any procedure that missed them.

Frequently Asked Questions FAQ:

What should participants prepare before medical device registration and post-market surveillance training?

Participants should already prepare device submissions or maintain technical files, complaint records or vigilance reports. Bringing an anonymised technical file, risk management file or complaint log from their own portfolio lets the capstone dossier reflect a real device.

How does medical device registration and post-market surveillance training differ from a shorter registration course?

A shorter registration course focuses on classification and the first marketing authorisation. This course adds a second week on software, changes and renewals, post-market surveillance, adverse event reporting, field safety corrective actions, inspections and compliance metrics.

Why does medical device registration need post-market surveillance after authorisation?

A marketing authorisation reflects the evidence at one point in time. Post-market surveillance collects complaints, adverse events and performance data in use, so the manufacturer can update risk files, report incidents, take field actions and keep the authorisation valid.

What do participants take back from medical device registration and post-market surveillance training?

Participants take back a Device Regulatory Dossier: a classification rationale, technical file gap analysis, post-market surveillance plan, vigilance and field action procedure and compliance calendar for renewals, UDI data and licences, ready to apply to their own devices.