CONCEPT

Medical Device Regulatory Affairs: Classification, Technical Files and Registration

11 – 22 April 2027
Jeddah - Corniche four-star



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Introduction:

Medical device regulatory affairs slows market access when intended purpose statements are vague, classification rules are applied inconsistently, technical documentation is assembled late from scattered design records and design or supplier changes reach the market before anyone screens their regulatory impact. This Core Concept course trains regulatory, quality and product staff at manufacturers, distributors and importers to classify devices and IVDs, evidence the essential principles, structure a technical file, plan clinical and performance evidence, select conformity and registration routes and control lifecycle changes. Participants produce a Regulatory Strategy and Technical File Plan for a case device.

Course Objectives:

- Define a device's intended purpose and qualification status and apply risk-based classification rules to devices, accessories and IVDs with a documented rationale
- Complete an essential principles checklist that links each applicable principle to recognised standards, test reports and biological, electrical and software evidence
- Structure technical documentation and a design dossier that draws on design history outputs, verification summaries and risk management conclusions
- Plan clinical evaluation for devices and performance evaluation for IVDs, including equivalence claims and literature appraisal
- Select conformity assessment routes and registration pathways, including reliance on prior reference authority approvals, and control labelling, IFU and UDI content
- Assess design, material, software and labelling changes for significance and maintain registrations across a device portfolio

Target Audience:

- Regulatory affairs staff who prepare device submissions, maintain registrations and answer reviewer queries
- Quality assurance staff who own change control, supplier documentation and conformity records for device portfolios
- Product and design engineering staff who supply verification, biocompatibility, electrical safety and software evidence
- Distributor and importer regulatory staff who register imported devices and verify manufacturer documentation
- Clinical and scientific affairs staff who compile clinical evaluation and IVD performance evidence

Course Outline:

Day 1: Device Regulatory Lifecycle, Definitions and Intended Purpose

- Device Regulatory Lifecycle Map: Concept, Premarket Submission, Market Placement, Change and Retirement
- Medical Device Definition Tests: Primary Mode of Action, Borderline Products and Drug-Device Combinations
- Intended Purpose Statement Drafting: Indications, Patient Population, Intended Users and Use Environment
- Accessories, Systems, Procedure Packs and Kits Qualification Decision Tree
- Regulatory Affairs Function Map: Interfaces With R&D, Quality, Clinical, Marketing and Supply Partners

Day 2: Risk-Based Classification Rules and Harmonisation Guidance

- International Harmonisation Guidance on Classification Principles and Regulatory Convergence
- Classification Rule Criteria: Invasiveness, Duration of Contact, Active Energy Source and Body System
- Non-Invasive, Surgically Invasive, Implantable and Active Device Rule Walkthroughs
- IVD Classification by Individual and Public Health Risk: Self-Testing, Companion and Blood Screening Assays
- Classification Rationale Record With Worked Examples From Wound Care, Orthopaedics and Diagnostics

Day 3: Essential Principles of Safety and Performance and Standards Evidence

- Essential Principles Checklist Structure: Applicability, Conformity Method and Evidence Reference
- Recognised Standards Selection and Justification for Non-Applied Clauses
- Biological Evaluation Under ISO 10993: Nature and Duration of Body Contact and Endpoint Selection
- Electrical Safety and Electromagnetic Compatibility Evidence Under the IEC 60601-1 Series
- Sterility Assurance, Shelf-Life and Packaging Integrity Evidence Summaries

Day 4: Technical Documentation Architecture and Design Dossier Assembly

- Summary Technical Documentation Format and Table of Contents From Harmonisation Guidance
- Device Description, Variants, Configurations and GMDN Nomenclature Code Assignment
- Design and Manufacturing Information Section: Sites, Critical Suppliers and Process Flow
- Design Controls Link: Design History File Outputs Feeding Verification and Validation Summaries
- Risk Management Summary Placement and Benefit-Risk Cross-References Within the Dossier

Day 5: Week-One Case: Classification and Technical File Gap Review

- Case Device Pack: Powered Infusion Accessory With Embedded Control Software
- Case Task: Intended Purpose Statement and Classification Rationale Record
- Case Task: Essential Principles Checklist With Standards Mapping
- Case Task: Technical Documentation Gap Register With Remediation Owners
- Peer Challenge Panel on Borderline and Disputed Classification Determinations

Day 6: Software as a Medical Device, Clinical Evaluation and IVD Performance Evidence

- Software as a Medical Device Qualification and Risk Categorisation Framework From Harmonisation Guidance
- Software Lifecycle Evidence Under IEC 62304 and Usability Engineering File Under IEC 62366
- Clinical Evaluation Plan: Scope, Equivalence Demonstration and Literature Appraisal Protocol
- Clinical Evaluation Report Structure: Current Clinical Practice Benchmarks, Clinical Data Analysis and Benefit-Risk Conclusion
- IVD Performance Evaluation: Scientific Validity, Analytical Performance and Clinical Performance Reports

Day 7: Conformity Assessment Routes, Registration Pathways and Reliance

- Conformity Assessment Route Selection by Class: Self-Declaration, QMS Audit and Design Examination
- Declaration of Conformity Content and Certificate Scope Verification
- Registration Pathway Options: Full Review, Abridged Review and Listing Notification
- Reliance on Prior Reference Authority Approvals: Eligibility, Evidence Bundle and Same-Device Declaration
- Submission Dossier Assembly, Reviewer Query Log and Registration Tracker

Day 8: Labelling, Instructions for Use, UDI and Economic Operators

- Label Content Requirements and Harmonised Symbol Use on Device, Packaging and Sterile Barrier
- Instructions for Use Structure, Electronic IFU Conditions and Lay-User Readability Checks
- UDI Device Identifier and Production Identifier Assignment and Database Submission
- Authorised Representative Mandate Content and Importer and Distributor Verification Duties
- Promotional Claims Review Against Intended Purpose and Approved Labelling

Day 9: Change Control, Significant Change Assessment and Registration Maintenance

- Change Control Intake Form With Regulatory Impact Screening Questions
- Significant Change Assessment Flowchart: Design, Materials, Software, Labelling and Sterilisation Changes
- Registration Renewal, Certificate Surveillance and Licence Portfolio Tracker Indicators
- Post-Market Data Feeding Technical Documentation Updates: Interface With Surveillance Teams
- Regulatory Intelligence Monitoring Log and Standards Transition Planning

Day 10: Capstone: Regulatory Strategy and Technical File Plan

- Case Device Selection and Target Market Portfolio Brief
- Capstone Build: Classification and Conformity Route Decision Matrix
- Capstone Build: Technical File Plan With Evidence Owners and Milestones
- Capstone Build: Registration Sequencing Plan Combining Reliance and Full Review Routes
- Regulatory Strategy and Technical File Plan Presentation to a Mock Review Board

Skills You Will Gain:

- Intended Purpose Definition
- Device and IVD Classification
- Essential Principles Mapping
- Technical File Structuring
- Clinical Evidence Planning
- Conformity Route Selection
- UDI and Labelling Control
- Significant Change Assessment

Why Attend This Course:

- Leave with a Regulatory Strategy and Technical File Plan for a case device, ready to adapt to a product in your own portfolio
- Cut reviewer queries by building the essential principles checklist and technical file index before evidence gaps surface in review
- Shorten time to market by sequencing registrations and using reliance routes where prior reference approvals exist
- Compare classification and submission practice with peers from manufacturers, distributors and importers of devices and IVDs

Conclusion:

Market access for a medical device depends on a clear intended purpose, a defensible class and a technical file that grows with the design. Week one covers definitions, classification rules, essential principles, standards evidence and dossier architecture, closing with a gap review case. Week two adds software, clinical and IVD performance evidence, conformity and registration routes, labelling and UDI, operator roles and significant change control. The final day produces a Regulatory Strategy and Technical File Plan for a case device.