Pharmaceutical Regulatory Affairs: CTD Dossiers, Registration Pathways and Variations

17 – 21 May 2027
Amsterdam - Zuidas business district hotel



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Introduction:

Pharmaceutical regulatory affairs slows product launches when dossiers are filed with gaps in Module 3, when the wrong registration pathway is chosen, when deficiency letters are answered late or partially and when site changes are implemented before the variation is classified. This Core Concept course trains regulatory, quality and medical staff to plan CTD and eCTD submissions, select full, abridged, biosimilar or reliance routes, control labelling and artwork, answer assessor questions and manage variations and renewals. Participants build a Registration Dossier Plan and Variation Strategy for a case product.

Course Objectives:

- Map the regulatory lifecycle of a medicine from development through marketing authorisation, post-approval changes, renewal and withdrawal
- Plan a CTD dossier across Modules 1 to 5 and prepare an eCTD sequence with correct granularity, lifecycle operators and validation checks
- Select a registration pathway for a new active substance, generic, biosimilar or reliance-based application and justify the evidence package each one needs
- Control product information, patient leaflets and packaging artwork from core data sheet to printed component with version traceability
- Draft structured responses to deficiency letters and classify post-approval CMC changes into the correct variation category with supporting data
- Build a regulatory strategy that combines intelligence monitoring, site coordination and a pharmacovigilance interface into a registration and variation plan

Target Audience:

- Regulatory affairs staff who compile, submit and maintain marketing authorisation dossiers
- Quality assurance staff who assess change controls for regulatory impact before implementation
- Medical affairs and scientific staff who author clinical overviews and approve product information text
- CMC and technical transfer staff who supply Module 3 data for new filings and site changes
- Artwork and labelling coordinators who manage leaflet and carton revisions across markets
- Pharmacovigilance officers who feed safety updates into labelling and renewal submissions

Course Outline:

Day 1: Medicine Regulatory Lifecycle and the Registration Landscape

- Regulatory Lifecycle Map: Development, Marketing Authorisation, Post-Approval Maintenance and Withdrawal
- Regulatory Affairs Function Charter: Interfaces With R&D, Quality, Medical, Supply and Commercial
- International Harmonisation Guidelines and Their Role in Aligning Submission Content
- Marketing Authorisation Holder, Applicant and Local Agent Responsibilities Matrix
- Product Portfolio Registration Status Audit Using a Licence Tracker Template

Day 2: CTD Architecture, eCTD Publishing and Registration Routes

- CTD Module 1 Regional Administrative Forms and Module 2 Quality, Non-Clinical and Clinical Summaries
- CTD Module 3 Drug Substance and Drug Product Sections With Stability Summary Placement
- CTD Modules 4 and 5 Non-Clinical and Clinical Study Report Organisation
- eCTD Backbone, Sequence Numbering, Lifecycle Operators and Technical Validation Criteria
- Registration Route Comparison: Full, Abridged Generic, Biosimilar, Reliance and Work-Sharing Procedures

Day 3: Generic Evidence, Product Information and Assessor Queries

- Bioequivalence Dossier Content: Reference Product Selection, Pharmacokinetic Parameters and Confidence Interval Evaluation
- Biowaiver Justification and Pharmaceutical Equivalence Versus Pharmaceutical Alternative Arguments
- Summary of Product Characteristics, Patient Information Leaflet and Readability Testing Workflow
- Artwork Change Control: Core Data Sheet Cascade, Proof Approval and Printed Component Reconciliation
- Deficiency Letter Response Matrix: Question Classification, Evidence Mapping and Clock-Stop Planning

Day 4: Post-Approval Variations, Renewals and CMC Change Management

- Variation Classification Grid: Minor Notification, Moderate Prior Approval and Major Change Categories
- CMC Change Assessment for New Manufacturing Site, Batch Size, Supplier and Specification Changes
- Grouping, Work-Sharing and Change Management Protocol Options for Multi-Market Portfolios
- Renewal Submission Content, Sunset Risk and Addendum to the Clinical Overview
- Pharmacovigilance Interface: Safety Signal Driven Label Updates and Periodic Benefit-Risk Report Inputs

Day 5: Case Product Registration Dossier Plan and Variation Strategy

- Case Product Brief: Generic Oral Tablet Moving to a Second Manufacturing Site Across Several Markets
- Regulatory Intelligence Scan and Pathway Decision Record for the Case Product
- Dossier Gap Analysis Against CTD Modules and eCTD Sequence Plan Build
- Variation Strategy Timeline Linking Site Transfer Milestones, Submissions and Stock Transition
- Registration Dossier Plan and Variation Strategy Defence Before a Mock Assessor Panel

Skills You Will Gain:

- CTD Dossier Planning
- eCTD Sequence Management
- Registration Pathway Selection
- Bioequivalence Dossier Review
- Labelling and Artwork Control
- Deficiency Response Writing
- Variation Classification
- Regulatory Intelligence Monitoring

Why Attend This Course:

- Leave with a Registration Dossier Plan and Variation Strategy built on a realistic case product and tested before a mock assessor panel
- Cut resubmission loops by matching each assessor question to evidence already in the dossier
- Stop site and supplier changes reaching the market before the correct variation is approved
- Compare dossier and variation practice with peers from innovator, generic, biotech and contract manufacturing companies

Conclusion:

A medicine reaches patients and stays on the market only when its dossier, pathway and post-approval changes are managed as one lifecycle. The week moves from the regulatory lifecycle and function interfaces, through CTD Modules 1 to 5, eCTD publishing and registration routes, to bioequivalence evidence, product information, artwork control and deficiency responses. It then covers variation classification, CMC changes, renewals and the pharmacovigilance interface, and closes with a Registration Dossier Plan and Variation Strategy for a case product.