MEDCLINIGEN

REGULATORY AFFAIRS

Advanced Course Syllabus • Regulatory Strategy • Submissions • Compliance

ADVANCED REGULATORY AFFAIRS SYLLABUS

7 structured modules covering regulatory fundamentals, DMF, CTD, eCTD, major regulatory submissions, detailed CTD modules, compliance and industry-oriented practical knowledge.

Module 1 | Introduction to Regulatory Affairs

- Introduction to Regulatory Affairs
- Role & Responsibilities of Regulatory Affairs Professionals
- Regulatory Authorities & Health Authorities
- Drug Development & Regulatory Lifecycle
- Licensing & Registration
- Regulatory Compliance
- Dossier Fundamentals

Module 2 | Drug Master File (DMF)

- Introduction to DMF
- Purpose & Importance of DMF
- US DMF & EU DMF
- Types of DMF — Type I–V
- DMF Contents & Submission Requirements
- Letter of Authorization (LOA)
- DMF Maintenance & Updates

Module 3 | Common Technical Document (CTD)

- CTD Introduction & Structure
- CTD Triangle
- Module 1 — Regional Administrative Information
- Module 2 — CTD Overviews & Summaries
- Module 3 — Quality
- Module 4 — Non-clinical Study Reports
- Module 5 — Clinical Study Reports
- ICH M4 Guidelines

Module 4 | Electronic Common Technical Document (eCTD)

- Introduction to eCTD
- eCTD Structure
- XML Backbone
- PDF & Document Organization
- Hyperlinking & Navigation
- eCTD Submission Process
- eCTD Lifecycle & Updates
- Regulatory Submission Applications

Module 5 | Regulatory Submissions

- New Drug Application (NDA)
- Types of NDA
- Investigational New Drug (IND)
- Abbreviated New Drug Application (ANDA)
- Marketing Authorization Application (MAA)
- BLA
- Submission Requirements
- Regulatory Review & Approval

Module 6 | CTD Modules — Detailed Understanding

- Module 1: Administrative Information
- Module 2: Quality, Clinical & Non-clinical Summaries
- Module 3: Quality / CMC
- Drug Substance
- Drug Product
- Module 4: Pharmacology
- Pharmacokinetics
- Toxicology
- Module 5: Clinical Studies
- Bioavailability & Bioequivalence Studies
- PK & PD Studies
- Efficacy & Safety Studies
- Post-Marketing Experience

Module 7 | Regulatory Affairs Career & Practical Knowledge

•	Regulatory Affairs Functions
•	Regulatory Documentation
•	Regulatory Submission Activities
•	Regulatory–Clinical–Manufacturing Interface
•	Marketing Authorization Lifecycle
•	Regulatory Compliance
•	Industry-Oriented Regulatory Affairs Concepts