

Course Structure

- Introduction to Regulatory Affairs
- Regulatory Strategy
- Marketing Authorization
- Non – Clinical Studies
- Clinical Trials
- Submission & Review
- Good Manufacturing Practice (GMP)

Detailed Program Syllabus

I. Introduction to Regulatory Affairs

- Purpose & principle of Regulations
- The Legal Framework for Regulations
- Guidance Document on Regulatory Affairs

II. Drug regulatory and accrediting agencies of the world

- ISO
- WHO
- US FDA
- ICH
- EDQM/EMEA
- MHRA (UK)
- TGA
- Health Canada

III. Regulatory Document

- Common Technical Document (CTD)
- Electronic Common Technical Document (eCTD)
- Asian Common Technical Document (ACTD)
- Country Specific Dossiers
- Detailed study of other supportive documents
 - a. Certificate of product permission and other licences
 - b. Approval of Artwork
 - c. Product development Report
 - d. Batch manufacturing and Packing Record
 - e. Analytical method validation
 - f. Process validation Record

IV. Non Clinical Study Reports (M4S)

- Pharmacology Written and tabulated Summary
- Pharmacokinetics Written and tabulated Summary
- Toxicology Studies

V. Clinical Trials (E3)

- Clinical Trial Design
- Independent Ethics Committee (IEC)
- Good Clinical Practice
- Patient information and Consent
- Investigational plan and study protocol
- Efficacy and Safety Evaluation
- Initiation of Clinical trial its overall monitoring and Archival
- Authorities for Clinical Trial Application
- Patient data listing and Case report forms
- Bioavailability and Bioequivalence

VI. Governing Regulatory Bodies across the globe and procedures.

- U.S Food & Drug Administration USDMF/NDA/ANDA/BLA
- Canada Therapeutic Product Directorate DMF
- Europe
 - g. European Medicines Agency(EMA/ National Authorities) EDMF
 - h. European Directorate for Quality of Medicines CEP/COS & Health Care Products
- Product Filing
- Responding Regulatory Deficiencies
- Final Approval Procedure, Review of Dossier
- Regulatory Audits
- DCGI and WHO Submissions

VII. Current Good Manufacturing Practice (cGMP)

- Importance of GMP Compliance
- QA/QC Documentation
- Active Pharmaceutical ingredient and Finished Product
- Validation
- Annual product Quality Review
- Complaints and Recall
- Change Control