SYLLABUS
DAY 1

Module 1: Understanding the Key aspects of the CTD Global Dossier & How to Think for Biological Medicines

- Origin of the CTD Format and impacts on global regulatory activities
- Understanding the Key aspects of the CTD Global Dossier
- Understanding differences between Small and Large Molecules
- What is a QTPP
- Key Terminology
- CMC Linkage

Module 2: Introduction and Understanding the development and manufacturing of Drug Substances

- Regulations and Guidelines
- Critical Quality Attributes, Specifications, Analytical Methods and Validation for small and large molecules
- Understanding Q11 – Basic Rules
- Linkage to Drug Product Section
- EU and US DMFs explained
- CEPs explained

Module 3: Structure and Content of the CMC Sections of Active Substance

- Structure and Content of the CMC Sections – CTD Roadmap
- Introduction to Drug Substance Sections for Small Molecules and Biologics
- Presentation of different DS related reference documents (ASMF, CEP)
- GMP Requirements of active substance
- Tips: Essential information required from API suppliers
- How to present CMC Sections with optimum level of detail to minimize variations

SYLLABUS
DAY 2

Module 4: Understanding the Reviewers Perspective – The CTD Drug Substance Sections

This section examines in detail the regulation and development expectations of reviewers on active substance part of the dossier

- Different types of active substance
- Dossier requirements expected by reviewers
- Examples on deficiencies related with active substance sections
- Tips on presentation of Module 3.2.S and QOS sections properly to get approval faster and to minimize variations

Module 5: Understanding the development and manufacturing of Drug Product

This section examines in detail the development of pharmaceutical drug product

- Regulations and guidelines
- Target Product Profile Requirements
- CQAs and CPPs explained
- PAT Explained

Module 6: Overview of Drug Product Sections of the Dossier

These sections review each of the individual sections P.1 to P.8 of the 3.2.P section of the CTD, and key aspects for 3.2.R and 3.2.A sections.

It addresses differences in data levels for different product types.

It examines critical section 3.2.P.5 and uses analytical data to demonstrate linkage and reviewer expectations. Critically, it highlights the need for writing great justifications.

- How to present CMC Sections with optimum level of detail
- Tips on presentation of Module 3.2.P and QOS sections properly to get approval faster and to minimize variations

SYLLABUS
DAY 3

Module 7: Understanding the Reviewers Perspective – The CTD Equation and Importance of Development Pharmaceutics

This section examines in detail the development pharmaceutical sections of the dossier and highlights key mechanistic ways of ensuring we answer the reviewers questions.

- The equation of Drug Product CTD Section
- Data requirements for drug product development for different types of products
- Scale-up and technical transfer
- CMC Linkage

Module 8: Understanding Source Documents – Reviewers Perspectives

- Understanding Source Documents – Reviewers Perspectives highlights the needs of internal teams versus external reviewers
- Documents writing and approval cycles, templates, management systems, responsibilities – basic rules
- Tips on the QOS requirements
- Reviewers Questions to be answered

Module 9: Global Dossier and Importance of Dossier Redaction

- Regulatory Strategy on global lifecycle management
- Change Control Management and the Impact of your Dossier
- Global Dossier Roll Out for ROW countries
- Structure global & local submission teams to ensure compliance
- Final tips on global dossier writing and management