Course Agenda

Drug Development Immersion Course

Drug Development Immersion is a two-day course concentrating on the regulatory, commercial, and scientific considerations required to successfully bring a drug to market. Discussion points will feature both small molecule and biologic products. Numerous personal accounts and war stories are used to illustrate the decision-making process companies use, giving participants a working knowledge of strategic development.

Day One

Drug Development Overview *9:00–10:00*
Success Metrics & Chances of Success
Timelines and Costs
FDA Approvals

Drugs Defined *10:00–10:45*
Types of Drugs
Product and Data Exclusivity
Approval Process for Biosimilars: FDA & EMA

Break *10:45–11:00*

Drug Discovery *11:00-12:00*
Target Identification
Potential Targets: Pharmacology
Target Validation
Assay Development
Screening
Animal Models
Lead Optimization
Case Study: Multiple Sclerosis

Lunch *12:00–1:00*

Strategic Development *1:00-2:15*
Integrated Development Process
Project Teams
Stage Gates
Draft Label
Therapeutic Target Profile
Draft Label Activity

Break *2:15–2:30*

The FDA & EMA Regulatory Process *2:30-4:15*
FDA and EMA Mission and Organization
PDUFA and REMS
FDA and EMA Formal Meetings with Sponsors
Briefing Pack
Special Protocol Assessment (SPA)
Regulatory Interactions and Tools
Generics, Biosimilars, Orphan Drugs
Regulatory Compliance
Key Risk Factors Activity

Q&A|Review *4:15-4:30*

Day Two

Product Design & Manufacturing *9:00-10:15*
Chemical Manufacturing Controls
Biomanufacturing Overview
Cell Line and Cell Bank Development
Upstream and Downstream Bulk Processing
Formulation, Fill, and Finish
Stability and Analytical Testing of Protein Products
Small Molecule Manufacturing Overview
Small Molecule Formulation
Label, Package, and Distribution

Break *10:15-10:30*

Preclinical Development *10:30–12:00*
Preclinical Development Pre-IND|CTA
Mutagenicity and Carcinogenicity Testing
Toxicology and Safety Pharmacology
Absorption, Distribution, Metabolism, Excretion
Preclinical Development Post IND|CTA

Lunch 12:00–1:00

Clinical Development 1:00–4:15
Clinical Trials Personnel
    Site Staff, Sponsor Staff, Regulatory Staff
Ethical Considerations
Clinical Protocols
Investigator Sites
Endpoint: Clinical vs Surrogate
Study Design Considerations and Choices
Parallel and Crossover Study Design
Basket and Umbrella Study Design

Adaptive Design
Phase I
Pharmacokinetics and Pharmacodynamics
Phase IIA and IIB
Phase IIIA and IIIB
Study Design and Feasibility
Study Planning and Start-Up
Study Conduct and Study Closeout
Statistical Considerations
FDA and EU Approval Process
Phase IV, Drug Safety and Pharmacovigilance

Q&A|Review 4:15–4:30