Drug Development Immersion

Live, Online | Level One

Drug Development Immersion is a two-day, interactive course that explores the regulatory, commercial, and scientific factors that enable a drug to be successfully brought to market. Discussion features both small molecule drugs and biologics. Our instructors illustrate the corporate decision-making process with personal accounts, giving participants unique insight into strategic development. Learn from an industry expert what it takes to get a molecule from the bench into the marketplace.

Drug Development Immersion was developed for the non-science professional who works within or services the biopharma industry.

Five Takeaways

1. Fluency in essential terminology and acronyms used in clinical development
2. In-depth look at the FDA and EMA regulatory process and sponsor interactions
3. Criteria for preclinical studies to support first in human clinical trials
4. Rationale, special considerations, and study design for both traditional and non-traditional clinical trial phases
5. Understanding of the launch process, life cycle management, and post-approval drug safety monitoring

Agenda

Day One

Introductions *9:00-9:15*

Setting the Stage *9:15-10:30*
Small and large molecule drug characteristics
Desirable drug characteristics
Agonist and antagonist drugs
Route of administration based on drug type
Traditional drug development pathway
Gene and cell therapy development pathway
Drug development metrics
Chances of success, timelines and costs

Break 10:30-10:45

The Business of Drug Development
10:45-12:00
Integrated drug development process
Stage gates- go/no go decisions
Target product profile
Draft label
Breakout room: draft label activity
US patents and market exclusivity

Lunch *12:00-12:45*

The Regulatory Process *12:45-2:00*
Regulatory agencies and compliance worldwide
PDUFA, GDUFA, BsUFA
Generics and biosimilars approval pathways
FDA/sponsor meeting timeline
FDA expedited programs
Voucher system
FDA and EMA orphan drug designation
EMA user fees and review times
EMA expedited reviews and designations
FDA and EMA approval process
Regulatory Compliance

Break *2:00-2:15*

Preclinical Development *2:15-3:15*
Preclinical development pre-IND/CTA
Preclinical data objectives
Safety testing terms
Nonclinical studies
  Toxicology, pharmacology, pharmacokinetics
IND/CTA filings
Authorization to proceed to clinical trials

Wrap-Up *3:15-3:30*

Day Two

The Players: Who is involved? *9:00-10:00*
Subjects, sponsors, investigators
Ethics committees/investigational review board
Informed consent
Contract research organizations
Patient advocacy groups
Data monitoring committees (DMC)
How DMC impacts clinical trials

Break *10:00-10:15*

General Principles: Ethics and Risk *10:15-11:00*
Risk assessment and management
Bias and data integrity
Controlling bias: blinding and randomization

Conduct of Clinical Trials *11:00-12:00*
Clinical research purpose
Introduction to study design elements
Endpoints
Inclusion/exclusion criteria
Placebos and control groups
Adverse events and safety reports
Clinical trial documentation
Data management and trial master files

Lunch *12:00-12:45*

Clinical Development Phase I *12:45-1:30*
Purpose of Phase I
Design and conduct of Phase I
Selection of dose: MAD and SAD
Phase IA and IB
Bioequivalence trials
Combined Phase I/II studies
Combining Phase I/II trials

Clinical Development Phase II *12:45-1:30*
Purpose of Phase II
Phase IIA and IIB
Randomized control trials
Statistical considerations
  Null hypothesis, P value, type 1 and 2 errors
Breakout Room: intro to clinical statistics activity

Break *1:30-1:45*

Clinical Development Phase III *1:45-2:45*
Purpose of Phase III
Phase IIIB
Trial designs: parallel, crossover, adaptive
Database cleaning, lock and unblinding
Regulatory application submittal

Clinical Development Phase IV *2:45-3:15*
Real-world evidence initiatives
Launch and life cycle management
Drug safety and pharmacovigilance