# 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

**Setting the Stage** *75 minutes*
Small and large molecule drug characteristics
Desirable drug characteristics
Route of administration based on drug type
Evidence-based medicine and translational science
Traditional drug development pathway
Gene and cell therapy development pathway
Drug development metrics
  Chances of success, timelines and costs
Patents and exclusivity explained

**Discussion/Break** *15 minutes*

**The Business of Drug Development** *45 minutes*
Draft label
Target product profile
Integrated development plan
Stage gates- go/no go decisions
*Breakout room: draft label activity*

**Discussion/Break** *15 minutes*

**The Players: Who is involved?** *45 minutes*
Subjects, sponsors, investigators
Ethics committees/investigational review board
Contract research organizations
Data safety monitoring boards

**Lunch Break** *45 minutes*

**General Principles: Ethics and Risk** *45 minutes*
Good clinical practices
Risk assessment and management
  FDA Risk Evaluation and Mitigation Strategy (REMS)
Bias
Trial blinding and randomization
Data Integrity

**Discussion/Break** *15 minutes*

**The Regulatory Process** *75 minutes*
Regulatory agencies and compliance worldwide
PDUFA, GDUFA, BsUFA
Generics and biosimilars approval pathways
FDA/sponsor meeting timeline
FDA expedited programs
Voucher system explained
Rare disease and orphan drugs
EMA user fees and review times
EMA expedited reviews and designations
FDA and EMA approval process
FDA Risk evaluation and mitigation strategy
*Breakout Room: Key Risk Factors Activity*

**Wrap-Up** *15 minutes*

## Day Two

**Preclinical Development** *45 minutes*
Preclinical development pre-IND/CTA
Nonclinical studies
  Toxicology, pharmacology, pharmacokinetics
IND/CTA filings
Authorization to proceed to clinical trials

**Discussion/Break** *15 minutes*

**Conduct of Clinical Trials** *45 minutes*
Introduction to study design elements
Endpoints
Inclusion/exclusion criteria
Placebos and control groups
Natural history studies
Data management and trial master files

**Discussion/Break** *15 minutes*

**Clinical Development Phase I** *60 minutes*
Purpose of Phase 0 and I
Selection of dose: MAD and SAD
Bioequivalence trials
Design and conduct of Phase I
Phase IA and IB
Study subjects
Phase I sample size
Phase I endpoints
Pharmacokinetics
  Preliminary assessment of drug activity
Analysis and reporting
Combining Phase I/II trials

**Lunch** *45 minutes*

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

**Discussion/Break** *15 minutes*

**Clinical Development Phase III** *60 minutes*
Purpose of Phase III
Phase IIIA and IIIB
Trial Designs
  Parallel, crossover, basket, umbrella, adaptive
Phase III endpoints and approved labeling claims
Database cleaning, lock and unblinding

**Clinical Development Phase IV** *30 minutes*
Launch and life cycle management
Drug safety and pharmacovigilance
Real-world evidence initiatives

**Wrap-Up** *15 minutes*