

# Training Course

## **Drug Discovery and Development From Discovery to Marketing Application**

### **Who Should Attend**

This course is designed for personnel in the pharmaceutical and biotechnology industries and contract research organizations (CROs) who are involved in drug discovery, nonclinical and clinical drug development, and manufacturing and characterization of drug substances and drug products and who want to have an overview understanding of all of the various scientific disciplines that are involved in these processes. Participants should have some knowledge of one or more of the drug discovery and development disciplines and desire to learn more about how these research efforts are integrated into an overall discovery and development research plan and effort. Scientists, managers, and project team leaders at pharmaceutical companies and CROs will gain an overview understanding of the types of studies that are conducted to effectively select discovery leads and develop discovery leads into therapeutic products.

### **Learning Objectives**

Upon completing this course, participants will have been provided with an overview of the entire drug discovery and development processes for effectively characterizing drug candidates and for determining which research studies are recommended for supporting regulatory agency submissions for first-in-human clinical trials and marketing applications for either small organic molecules (NCEs) or macromolecules (i.e., biologicals).

### **Course Description**

The content of this course will assist pharmaceutical, biotechnology, and CRO researchers and managers in understanding the requirements for selecting and then developing drug candidates and for designing development plans that include the necessary research studies for supporting regulatory agency submissions. The various types of experiments, which include drug discovery for drug candidate selection, preclinical safety studies for supporting first-in-human clinical trials, clinical studies to evaluate the safety and efficacy in humans, additional nonclinical safety studies, and manufacturing efforts to develop and characterize the drug substance and drug product, will be described and discussed. Some study designs with results and possible interpretations will be presented. A workshop will provide participants with the opportunity to design logic plans for drug candidates with different developmental requirements.

## **COURSE AGENDA**

### **DAY ONE**

#### **Session 1: (Day 1, 8:30 – 10:00 AM)**

##### **Introduction**

Purpose and Goals  
Drug Discovery and Development Logic Plans  
Overview on Regulatory Agency Submissions

#### **Session 2: (Day 1, 10:30 AM – noon)**

##### **Drug Discovery and Developability Assessment**

Drug Discovery Aspects  
Target Identification  
*In Vitro* Pharmacology Screen  
Discovery Lead Generation  
'Leads' to 'Hits'  
Structural Activity Relationships  
*In Vivo* Pharmacology Screen  
Developability Assessment Overview  
Scientific Disciplines Involved  
Logic Plan for Discovery Lead Selection

#### **Session 3: (Day 1, 1:00 – 2:30 PM)**

##### **Early Formulation Evaluations**

Analytical Chemistry Method Development and Characterization  
Early Formulation Definition and Assessments  
Stability and Solubility Requirements

#### **Session 4: (Day 1, 3:00 – 4:30 PM)**

##### **Preclinical/Nonclinical Drug Development or CTD Safety**

Safety Pharmacology  
Pharmacokinetics and Drug Metabolism  
Toxicology  
Acute, Subchronic, Chronic  
Genotoxicity  
Reproductive and Developmental Toxicology  
Carcinogenicity  
Special Toxicology Studies

## DAY TWO

### **Session 5: (Day 2, 8:30 – 10:00 AM) Clinical Drug Development or CTD Efficacy**

Human Pharmacology (Phase 1)  
Therapeutic Exploratory (Phase 2)  
Therapeutic Confirmation (Phase 3)  
Therapeutic Use (Phase 4)

### **Session 6: (Day 2, 10:30 AM – noon) Chemistry, Manufacturing, and Control (CMC) or CTD Quality**

Drug Substance Characterization and Development  
Drug Product Characterization and Development

### **Session 7: (Day 2, 1:00 – 2:30 PM) Regulatory Agency Submissions**

Pre-IND Package  
IND or First-in-Human Clinical Trial  
End of Phase 2  
NDA or BLA in CTD Format

### **Session 8: (Day 2, 3:00 – 4:30 PM) Workshop to Design and Discuss Participant Prepared Drug Development Logic Plans**

#### **For more information contact:**

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