

Training Course

Drug Discovery and Development From Discovery to Marketing Application

June 16th and 17th 2008
London, United Kingdom

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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