deBasic Drug Development: Overview of Biopharmaceutical R&D

January 2020 San Francisco, CA

Program Day One		***Session No.***
8:15 – 8:30 AM	***Registration & Continental Breakfast***	
8:30 – 8:45 AM	**PERI Welcome and Introductions** • Participant introductions • Faculty Introductions • Course Goals	
8:45 – 9:45 AM	**Overview of Drug Development, Metrics and Top Issues** Allan J. Weinstein, MD • Overview of product development process - From candidate to market • Drug development metrics • Top 10 Issues in Drug Development • Current Industry Trends	***1***
9:45 – 10:45 AM	**Begin with the End in Mind: Label Driven Drug Development** Allan J. Weinstein, MD • What is in a submission for market authorization? • Target Product profile (TPP) - Have a structured way to develop a target product profile - Looking at competitors - Landscape - Commercial involvement	***2***
10:45 – 11:00 AM	***Morning Break***	
11:00 AM – 12:15 PM	**Drug Discovery** Noel J. Cusack, PhD • Sources of new drug candidates • Objectives of early product discovery • Strategies to get from target to product • Disease models • Selected case studies	***3***

Program Day One … continued		***Session No.***
12:15 – 12:45 PM	***Lunch Break***	
12:45 – 2:00 PM	**Pharmacokinetics: Issues and Considerations** Noel J. Cusack, PhD • Refresher: Key Concepts in PK, PD & ADME • PK support during drug development • Comparison of biologics with small molecules • Selected Case Studies	***4***
2:00 – 2:15 PM	***Afternoon Break***	
2:15 – 3:30 PM	**Key Concepts in Nonclinical Safety and Toxicology** Noel J Cusack, PhD • Objectives of Nonclinical Safety for Clinical Trial Planning • Nonclinical safety assessment (Risk) • Dose selection for First-in-Human clinical trial • Safety support during drug development • Selected Case Studies	***5***
3:30 – 4:45 PM	**Portfolio Management Workshop 1: "Early Development Decision Making"** Faculty • Participants assume the role of a "Portfolio Planning Committee" • The assignment: select 4 candidates to advance based on the pre-clinical information provided for a list of 10 compounds/therapies • Group discussion of findings and decision-making rationale	***6***
4:45 – 5:00 PM	**End of Day Wrap-up/Questions and Answers** Faculty	

Program Day Two		***Session No.***
8:15 – 8:30 AM	***Registration & Continental Breakfast***	

8:30 – 9:30 AM	**Regulatory Overview**
	Allan J. Weinstein, MD
	• Regulations for new drug and biologic approval
	  – Overview of regulatory process
	  – Understanding the regulatory agencies' role in clinical development: US, EU, Japan
	  – Regulatory Update: changes in last 10 years
	• Emerging Regulatory Landscape (PDUFA VI)
		7

Program Day Two … continued		***Session No.***
9:30 – 9:45 AM	***Morning break***	

9:45 – 11:00 AM	**Chemistry, Manufacturing and Controls (CMC)**
	Noel J. Cusack, PhD
	• Drug Substance manufacture
	  – Small molecules
	  – Biologics
	• Drug Product manufacture
	  – Rationale for formulation
	  – Small molecules
	  – Biologics
		8

11:00 AM – 12:15 PM	**Clinical Development Plan Considerations – Part 1** Allan J. Weinstein, MD • Goals of a clinical development program • Expectations of regulatory agencies • Phases and expectations of clinical research • Strengths and weaknesses of clinical Trials • Adaptive design • Bayesian statistics • Big Data	***9***
12:15 – 12:45 PM	***Lunch Break***	
12:45 – 2:00 PM	**Clinical Development Plan Considerations – Part 2** Allan J. Weinstein, MD • Study designs • Challenges of global development • The protocol • Epidemiology of disease • Good clinical practices • Ethical considerations	***10***
2:00 – 2:15 PM	***Afternoon Break***	

Program Day Two … continued ***Session No.***

2:15 – 3:30 PM **Portfolio Management Workshop 2: "Advancing Compounds"** ***11***
Faculty

- "Portfolio Planning Committee" assignment (continued)
- Select 2 compounds to advance based upon recently generated pre-clinical information provided
- Decide the fate of all 10 candidates
  - Develop, out-license, put on shelf, or kill
- Group discussion of findings and decision-making rationale

3:30 – 3:45 PM ***Stretch Break***

3:45 – 4:30 PM **Pharmacoeconomics and Market Access** ***12***
Allan J. Weinstein, MD

- Pharmacoeconomics & Healthcare Outcomes Research
- Measuring the value of pharmaceutical therapy
- Healthcare Informatics: QoL, QALY
- Pricing & payer reimbursement issues
- Cost-minimization, benefit, utility, comparative effectiveness
- Reimbursement linked to outcomes
- PROs: Patient Reported Outcomes
- Value evidence data generation

4:30 – 5:00 PM **Product Launch and Pharmacovigilance** ***13***
Allan J. Weinstein, MD

- Pre-launch necessities: regulatory and business requirements
- Developing the launch plan
  - Launch team, distribution strategy, metrics for success
  - Product lifecycle
- Overview of Pharmacovigilance
  - Pharmacovigilance and signaling
  - REMS and Benefit / Risk Management

5:00 PM **End of Course**

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Course Overview

PERI's fundamental education course provides an overview of the pharmaceutical development process, from drug discovery, nonclinical and clinical development, and manufacturing, culminating in product launch and marketing. The course focuses on the decisions that need to be made throughout the therapeutic development process and the criteria influencing these decisions. In addition to face-to-face training, the Decision Points in Pharmaceutical Development online component introduces the phases of development and the key concepts explored during the live course.

Key Course Topics:

- Label-Driven Drug Development
- Sources of New Drugs
- Pharmacokinetics & Pharmacodynamics
- Safety & Toxicology
- Regulatory Landscape: US, EU, Japan
- Chemistry, Manufacturing, and Control
- Clinical Development: Phases and Protocols
- Pharmacoeconomics
- Pharmacovigilance

Course Objectives

Upon completion of this course, participants should be able to:

- State the basic steps in the drug development process
- Explain the difference between research and development
- Analyze the key decision points in the drug development process
- Evaluation the implications of label-based drug development
- Discuss the role of interaction with FDA and other regulatory agencies

Course Faculty

Noel J. Cusack, PhD
Independent Non-Clinical Consultant
njcphd@aol.com

Allan J. Weinstein, MD
Clinical Research & Regulatory Affairs Consultant
ajwmd@sbdglobal.com