Basic Drug Development:
Overview of Biopharmaceutical R&D

Virtual Training Program
February 15 – 17, 2022

Program Day One: February 15, 2022

Session No.

All times listed EST

11:45 AM — ***Online Classroom Opens***

12:00 – 12:15 PM — **PERI Welcome and Introductions**

- Participant introductions
- Faculty Introductions
- Course Goals

12:15 – 1:15 PM — **Overview of Pharmaceutical Development, Metrics and Top Issues** — ***1***
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

1:15 – 1:30 PM — ***Stretch Break #1***

1:30 – 2:30 PM — **Begin with the End in Mind: Label Driven Drug Development** — ***2***
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

2:30 – 2:40 PM — ***Stretch Break #2***

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

2:40 – 3:55 PM **Drug Discovery** ***3***
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

3:55 PM – 4:35 PM ***Extended Break***

4:35 – 5:50 PM **Pharmacokinetics: Issues and Considerations** ***4***
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

5:50 – 6:00 PM **Course Day 1 Wrap-up, Preview Day 2**

Program Day Two: February 16, 2022 **Session No.**

All times listed EST

11:45 AM ***Online Classroom Opens***

12:00 – 12:10 PM **PERI Welcome: Day Two Preview**

12:10 – 1:25 PM **Key Concepts in Nonclinical Safety and Toxicology** ***5***
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

1:25 – 1:40 PM ***Stretch Break #1***

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

1:40 – 2:55 PM **Chemistry, Manufacturing and Controls (CMC)** ***6***
Noel J Cusack, PhD

- Drug Substance manufacture
  - Small molecules
  - Biologics
- Drug Product manufacture
  - Rationale for formulation
  - Small molecules
  - Biologics

2:55 – 3:30 PM ***Extended Break***

3:30 – 4:45 PM **Portfolio Management Workshop 1: "Early Development Decision Making"** ***7***
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

4:45 – 4:55 PM ***Stretch Break #2***

4:55 – 5:55 PM **Regulatory Overview** ***8***
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

5:50 – 6:00 PM **Course Day 2 Wrap-up, Preview Day 3**

Program Day Three: February 17, 2022

All times listed EST

Session No.

11:45 AM — ***Online Classroom Opens***

12:00 – 12:05 PM — **PERI Welcome: Day Three Preview**

12:05 – 1:05 PM — **Clinical Development Plan Considerations – Part 1** — ***9***

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

1:05 – 1:15 PM — ***Stretch Break #1***

1:15 – 2:45 PM — **Clinical Development Plan Considerations – Part 2** — ***10***

Allan J. Weinstein, MD

- Study designs
- Challenges of global development
- The protocol
- Epidemiology of disease
- Good clinical practices
- Ethical considerations

2:45 – 3:15 PM — ***Extended Break***

3:15 – 4:35 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

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

4:35 – 4:45 PM ***Stretch Break #2***

4:45 – 5:25 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

5:25 – 6:00 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

6:00 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.

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

Allan J. Weinstein, MD
Clinical Research & Regulatory Affairs Consultant

Continuing Education Credit

Pharmaceutical Education & Research Institute, Inc. (PERI) is pleased to make continuing education credit available to you for attendance at this program. To receive credit, you must attend the entire program and submit both the Continuing Education Application form and the program evaluation directly to a PERI course manager. Additional $35 fee applies for students who are applying for continuing education credit.

Additional continuing education information forthcoming.

ACPE Statement for Pharmacy Education:

Pharmaceutical Education & Research Institute, Inc. (PERI) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

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