Basic Drug Development:
Overview of Biopharmaceutical R&D

March 3 - 4, 2025
iQ Smart Center • San Diego, CA

Program Day One: Monday, March 3, 2025 ***Session No.***
All times listed PST

8:15 AM ***Classroom Opens, Continental Breakfast***

8:30 – 8:45 AM **PERI Welcome and Introductions**

- Participant introductions
- Faculty Introductions
- Course Goals

8:45 – 9:45 AM **Overview of Pharmaceutical Development, Metrics and Top Issues** ***1***
Allan J. Weinstein, MD
Clinical Research and Regulatory Affairs Consultant

- Overview of Development Process - From Candidate to Market
- Drug Development Metrics
- Key Development Questions – Go/No Go Decision Points
- Current Industry Trends & Future Developments
- Pharmaceutical Spending: Global Development
- Success Rates in Development

9:45 – 10:30 AM **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, market landscape
- Commercial involvement

10:30 – 10:45 AM ***Stretch Break #1***

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10:45 AM – 12:00 PM **Drug Discovery** ***3***
Noel J. Cusack, PhD
Independent Consultant, Nonclinical Development

- Targets for drug intervention
- Sources of new drug candidates
- Optimization of drug candidates
- Drug candidate validation
- Drug discovery exercise

12:00 – 12:45 PM ***Catered Lunch Break***

12:45 – 1:45 PM **Pharmacokinetics: Issues and Considerations** ***4***
Noel J. Cusack, PhD

- Refresher: Key Concepts in PK & ADME
- PK support during drug development
- Comparison of biologics with small molecules
- Case studies

1:45 – 2:45 PM **Portfolio Management Workshop 1: "Early Development Decision Making"** ***5***
Course 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

2:45 – 3:00 PM ***Afternoon Break***

3:00 – 4:00 PM **Key Concepts in Nonclinical Safety and Toxicology** ***6***
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
- Case studies

Program Day One, continued ***Session No.***
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4:00 – 4:05 PM ***Stretch Break***

4:05 – 4:50 PM **Chemistry, Manufacturing and Controls (CMC)** ***7***
Noel J. Cusack, PhD

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

4:50 – 5:00 PM **Course Day 1 Wrap-up, Preview Day 2** ***6.75***

Program Day Two: Tuesday, March 4, 2025 ***Session No.***
All times listed PST

8:15 AM ***Classroom Opens, Continental Breakfast***

8:30 – 8:35 AM **PERI Welcome: Day Two Preview**

8:35 – 9:45 AM **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

Program Day Two, continued ***Session No.***
All times listed PST

9:45 – 9:50 AM ***Stretch Break #1***

9:50 – 10:50 AM **Portfolio Management Workshop 2: "Advancing Compounds"** ***9***
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

10:50 – 11:00 AM ***Stretch Break #2***

11:00 AM – 12:15 PM **Clinical Development Plan Considerations – Part 1** ***10***
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

12:15 – 1:00 PM ***Catered Lunch Break***

1:00 – 2:15 PM **Clinical Development Plan Considerations – Part 2** ***11***
Allan J. Weinstein, MD

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

Program Day Two, continued ***Session No.***
All times listed PST

2:15 – 3:15 PM **Portfolio Management Workshop 3 – "Selecting Development Strategy"** ***12***
Faculty

- Limited clinical trials conducted on 4 of the drug candidates
- Only two candidates considered for further development
- Nonclinical safety and CMC data obtained for the 2 candidates
- What could a sales force use as a "handle" for eventual marketing?

3:15 – 3:30 PM ***Afternoon Break***

3:30 – 4:15 PM **Pharmacoeconomics and Market Access** ***13***
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
- PROs: Patient Reported Outcomes
- Value evidence data generation

4:15 – 4:45 PM **Product Launch** ***14***
Allan J. Weinstein, MD

- Pre-launch necessities: regulatory and business requirements
- Developing the launch plan
  - Launch team, distribution strategy, metrics for success
  - Product lifecycle

4:45 PM **Course Conclusion**

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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
- Discuss the role of interaction with FDA and other regulatory agencies

Course Faculty

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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.

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Pharmaceutical Education & Research Institute, Inc. (PERI) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. ACPE Universal Activity Number is 0708-0000-25-001-L01-P. 1.375 continuing education units (CEUs) are available for this program. Initial Release Date: 03/03/2025. This is an application-based CPE Activity.

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