



**Basic Drug Development:
Overview of Biopharmaceutical Research & Development**

**Virtual Training Program
August 4 - 6, 2025**

Monday, August 4, 2025 – Program Day 1

All Times Listed EDT

**Session
No.**

10:00 – 10:15 AM

PERI Welcome & Course Overview

Jo Ann Zoul, Course Manager

The Pharmaceutical Education and Research Institute, Inc.

10:15 – 11:15 AM

**Overview of Pharmaceutical Development, Metrics and
Top Issues**

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

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11:15 – 11:30 AM

Stretch Break

11:30 AM – 12:15 PM

Drug Discovery

Noel J. Cusack, PhD

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

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12:15 – 1:00 PM

Extended Break

1:00 – 2:00 PM

Portfolio Management Workshop 1: Early Development Decision Making

Faculty and Participants

- 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

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Monday, August 4, 2025 – Program Day 1...continued

All Times Listed EDT

**Session
No.**

2:00 – 2:15 PM

Stretch Break

2:15 – 3:05 PM

Pharmacokinetics: Issues and Considerations

Noel J. Cusack, PhD

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

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3:05 – 3:10 PM

Quick Break

3:10 – 4:00 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
- Case studies

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4:00 PM

End of Day One

Tuesday, August 5, 2025 – Program Day 2

Tab No.

All Times Listed EDT

10:00 – 10:10 AM	<u>Day Two Overview, Welcome</u> <i>Jo Ann Zoul, Course Manager</i> The Pharmaceutical Education and Research Institute, Inc.	
10:10 – 11:15 AM	<u>Begin with the End in Mind: Label Driven Drug Development</u> Allan J. Weinstein, MD <ul style="list-style-type: none">• What is in a submission for market authorization?• Target Product profile (TPP)<ul style="list-style-type: none">○ Have a structured way to develop a target product profile○ Looking at competitors, market landscape• Commercial involvement	6
11:15 – 11:30 AM	<i>Stretch Break</i>	
11:30 AM – 12:30 PM	<u>Clinical Development Plan Considerations – Part 1</u> <i>Allan J. Weinstein, MD</i> Clinical Research and Regulatory Affairs Consultant <ul style="list-style-type: none">• 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	7
12:30 – 1:15 PM	<i>Extended Break</i>	
1:15 – 2:30 PM	<u>Clinical Development Plan Considerations – Part 2</u> <i>Allan J. Weinstein, MD</i> <ul style="list-style-type: none">• Study designs• Challenges of global development• The protocol• Epidemiology of disease• Good clinical practices• Ethical considerations	8
2:30 – 2:45 PM	<i>Extended Break</i>	

Tuesday, August 5, 2025 – Program Day 2...continued

All Times Listed EDT

**Session
No.**

2:45 – 3:45 PM

Portfolio Management Workshop 2: Advancing Compounds

Faculty and Participants

- 1:15 – 1:20 PM Overview
- 1:20 – 1:50 PM Individual Work
- 1:50 – 2:10 PM Voting/Discussion
- 2:10 – 2:15 PM Final Discussion

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3:45 - 4:00 PM

Wrap Up Day Two – Preview Day Three

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Wednesday, August 6, 2025 – Program Day 3

All Times Listed EDT

Tab No.

10:00 – 10:10 AM	<u>Day Three Overview, Welcome</u> <i>Jo Ann Zoul, Course Manager</i> The Pharmaceutical Education and Research Institute, Inc.	
10:10 – 11:30 AM	<u>Applying Project Management Principles to Drug Development</u> David Fritsch, MBA Principal, Biotechnology Operations Consultant Fritsch Consulting, LLC <ul style="list-style-type: none">• Areas of Project Management<ul style="list-style-type: none">○ Development – Clinical to Commercial○ Sustaining and Continuous Improvement○ Product Life Cycle• Working with Project Teams<ul style="list-style-type: none">○ Introduction of the Project Sherpa○ Hard and Soft Skills/Communication Skills○ Effective Communication: Message Mapping○ Understanding Type – Personalities and Behaviors	10
11:30 – 11:40 AM	<u>Stretch Break</u>	
11:40 AM – 1:00 PM	<u>Regulatory Overview</u> Allan J. Weinstein, MD <ul style="list-style-type: none">• Regulations for new drug and biologic approval<ul style="list-style-type: none">○ 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	11
1:00 – 1:45 PM	<u>Extended Break</u>	
1:45 – 2:45 PM	<u>Safety in Drug Development</u> <i>Min Chen, M.S., R.PH.</i> Pharmacovigilance Consulting, LLC	12
2:45 – 3:00 PM	<u>Stretch Break</u>	

3:00 – 3:45 PM

Pharmacoeconomics and Market Access

Allan J. Weinstein, MD

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- 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

3:45 – 4:00 PM

Program Wrap-up / End of Course

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