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

**Virtual Training Program**
**November 19 - 21, 2025**

***Wednesday, 19, 2025 – Program Day 1***
All Times Listed EDT

| | | Session No. |
|---|---|---|
| 10:00 – 10:15 AM | ***PERI Welcome & Course Overview***<br>*Jo Ann Zoul, Course Manager*<br>The Pharmaceutical Education and Research Institute, Inc. | |
| 10:15 – 11:15 AM | **Overview of Pharmaceutical Development, Metrics and Top Issues**<br>*Allan J. Weinstein, MD*<br>Clinical Research and Regulatory Affairs Consultant<br>• Overview of Development Process - From Candidate to Market<br>• Drug Development Metrics<br>• Key Development Questions – Go/No Go Decision Points<br>• Current Industry Trends & Future Developments<br>• Pharmaceutical Spending: Global Development<br>• Success Rates in Development | *1* |
| 11:15 – 11:30 AM | ***Stretch Break*** | |
| 11:30 AM – 12:15 PM | **Drug Discovery**<br>*Noel J. Cusack, PhD*<br>• Targets for drug intervention<br>• Sources of new drug candidates<br>• Optimization of drug candidates<br>• Drug candidate validation | *2* |
| 12:15 – 1:00 PM | ***Extended Break*** | |
| 1:00 – 2:00 PM | **Portfolio Management Workshop 1: Early Development Decision Making**<br>*Faculty and Participants*<br>• Participants assume the role of a “Portfolio Planning Committee”<br>• The assignment: select 4 candidates to advance based on the pre-clinical information provided for a list of 10 compounds/therapies<br>• Group discussion of findings and decision-making rationale | *3* |

***Wednesday, 19, 2025 – Program Day 1…continued*** — ***Session No.***

All Times Listed EDT

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|---|---|---|
| 2:00 – 2:15 PM | ***Stretch Break*** | |
| 2:15 – 3:05 PM | **Pharmacokinetics: Issues and Considerations**<br>*Noel J. Cusack, PhD*<br>• Refresher: Key Concepts in PK & ADME<br>• PK support during drug development<br>• Comparison of biologics with small molecules<br>• Case studies | ***4*** |
| 3:05 – 3:10 PM | ***Quick Break*** | |
| 3:10 – 4:00 PM | **Key Concepts in Nonclinical Safety and Toxicology**<br>*Noel J Cusack, PhD*<br>• Objectives of Nonclinical Safety for Clinical Trial Planning<br>• Nonclinical safety assessment (Risk)<br>• Dose selection for First-in-Human clinical trial<br>• Safety support during drug development<br>• Case studies | ***5*** |
| 4:00 PM | ***End of Day One*** | |

***Thursday, November 20, 2025 – Program Day 2*** **_Tab No._**

All Times Listed EDT

10:00 – 10:10 AM **Day Two Overview, Welcome**
*Jo Ann Zoul, Course Manager*
The Pharmaceutical Education and Research Institute, Inc.

10:10 – 11:15 AM **Begin with the End in Mind: Label Driven Drug Development** **6**
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

11:15 – 11:30 AM ***Stretch Break***

11:30 AM – 12:30 PM **Clinical Development Plan Considerations – Part 1** ***7***
*Allan J. Weinstein, MD*
Clinical Research and Regulatory Affairs Consultant

- 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

12:30 – 1:15 PM ***Extended Break***

1:15 – 2:30 PM **Clinical Development Plan Considerations – Part 2** ***8***
*Allan J. Weinstein, MD*

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

2:30 – 2:45 PM ***Extended Break***

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| 2:45 – 3:45 PM | **Portfolio Management Workshop 2: Advancing Compounds**<br>*Faculty and Participants* | ***9*** |

- 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** |

***Friday, November 21, 2025 – Program Day 3*** **Tab No.**

All Times Listed EDT

10:00 – 10:10 AM **Day Three Overview, Welcome**
*Jo Ann Zoul, Course Manager*
The Pharmaceutical Education and Research Institute, Inc.

10:10 – 11:30 AM **Applying Project Management Principles to Drug Development** ***10***
David Fritsch, MBA
Principal, Biotechnology Operations Consultant
Fritsch Consulting, LLC

- Areas of Project Management
    - Development – Clinical to Commercial
    - Sustaining and Continuous Improvement
    - Product Life Cycle
- Working with Project Teams
    - Introduction of the Project Sherpa
    - Hard and Soft Skills/Communication Skills
    - Effective Communication: Message Mapping
    - Understanding Type – Personalities and Behaviors

11:30 – 11:40 AM ***Stretch Break***

11:40 AM – 1:00 PM **Regulatory Overview** ***11***
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

1:00 – 1:45 PM ***Extended Break***

1:45 – 2:45 PM **Safety in Drug Development** ***12***
*Min Chen, M.S., R.PH.*
Pharmacovigilance Consulting, LLC

2:45 – 3:00 PM ***Stretch Break***

3:00 – 3:45 PM **<u>Pharmacoeconomics and Market Access</u>** ***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

3:45 – 4:00 PM ***Program Wrap-up / End of Course***