Basic Drug Development:
Overview of Biopharmaceutical Research & Development

Virtual Training Program
May 14 – 16, 2025

Wednesday, May 14, 2025 – Program Day 1 ***Session No.***
All Times Listed EDT

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 the Biopharmaceutical Research & Development Process** ***1***
Noel J. Cusack, PhD
Independent Consultant
Nonclinical Development

- An overview of the major decision points/phases of the biopharmaceutical development and approval processes

11:15 – 11:30 AM ***Stretch Break***

11:30 AM – 12:15 PM **Drug Discovery** ***2***
Noel J. Cusack, PhD

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

12:15 – 1:00 PM ***Extended Break***

1:00 – 2:00 PM **Portfolio Management Workshop 1: Early Development Decision Making** ***3***
Faculty and Participants

- 1:00 – 1:10 PM Overview
- 1:10 – 1:30 PM Individual Work
- 1:30 – 1:35 PM Voting
- 1:35 – 1:45 PM Discussion
- 1:45 – 1:50 PM Revote/Final Discussion

2:00 – 2:15 PM ***Stretch Break***

Wednesday, May 14, 2025 – Program Day 1…continued ***Session No.***
All Times Listed EDT

2:15 – 3:05 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

3:05 – 3:10 PM ***Quick Break***

3:10 – 4:00 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
- Case studies

4:00 PM ***End of Day One***

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Wednesday, May 15, 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 **Overview of Regulatory Process – IND and Early-Stage Drug Development** **5**
Carolyn Finkle, MSc
Independent Consultant

- Drug development pathway and key milestones
- FDA and Historical regulatory events
- Investigational New Drug Applications
- Early Clinical Development
- Expedited Programs
- Regulatory Strategies

11:15 – 11:30 AM ***Stretch Break***

11:30 AM – 12:30 PM **Clinical Development Plan Considerations – Part 1** ***6***
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** ***7***
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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Wednesday, May 15, 2025 – Program Day 1…continued ***Session No.***

All Times Listed EDT

2:45 – 3:45 PM **Portfolio Management Workshop 2: Advancing Compounds** ***8***

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

3:45 - 4:00 PM **Wrap Up Day Two – Preview Day Three**

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Friday, May 16, 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 – 11:15 AM **Drug Product Manufacturing: Synthetic and Biologic Products** ***9***
Carolyn Finkle, MSc

- Describe CMC development process
- Describe formulation development and decision points
- Presentation of case studies
- Gain an appreciation for the complexity of therapeutic protein development
- Understand the CMC regulatory process

11:15 – 11:30 AM ***Stretch Break***

11:30 AM – 12:30 PM **Successful Interactions with Regulatory Agencies** ***10***
Carolyn Finkle, MSc

- Why, when and how to interact with FDA
- Why, when and how to interact with EMA
- What defines a successful Agency meeting?

12:30 – 1:15 PM ***Extended Break***

1:15 – 2:15 PM **Safety in Drug Development** ***11***
Min Chen, M.S., R.PH.
Pharmacovigilance Consulting, LLC

2:15 – 2:30 PM ***Afternoon Break***

2:30 – 3:45 PM **Getting the Product to Market – the New Drug Approval Process** ***13***
Carolyn Finkle, MSc

- Data Requirements
- New Drug Applications
- Expedited Programs and Accelerated Approval
- FDA Risk/Benefit Considerations
- Examples of Recent Approvals
- Post-Approval Commitments

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

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