Basic Drug Development:
Overview of Biopharmaceutical Research & Development

Virtual Training Program
May 15 – 17, 2024

Wednesday, May 15, 2024 – Program Day 1 ***Tab 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 – 11:00 AM **Overview of the Biopharmaceutical Research & Development Process** ***1***
Noel J. Cusack, PhD Course Co-Director
Independent Consultant
Nonclinical Development

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

11:00 – 11:15 AM ***Morning Break***

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

- Drug discovery rationale
- Targets for drug intervention
- Optimization of drug candidates
- Pharmacology of drug candidates
- Pharmacokinetics refresher: Key concepts
- Pharmacokinetics support during drug development
- Comparison of biologics with small molecules

12:15 – 1:00 PM ***Lunch Break***

1:00 – 1:50 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

1:50 – 2:05 PM ***Afternoon Break***

Wednesday, May 15, 2024 – Program Day 1…continued **Tab No.**

All Times Listed EDT

2:05 – 2:55 PM **Overview of Nonclinical Biopharmaceutical Development** ***4***

Noel J. Cusack, PhD

- Objectives of nonclinical safety studies
- Safety and toxicity assessment (risk)
- Dose selection for First in Human clinical trial
- Nonclinical studies to support drug NDA/BLA and marketing approval

2:55 – 3:00 PM ***Stretch Break***

3:00 – 4:00 PM **Overview of Regulatory Process – IND and Early Stage Drug Development** **5**

Carolyn Finkle, MSc Course Co-Director
Independent Consultant

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

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

Thursday, May 16, 2024 – 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 – 11:10 AM **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

11:10 – 11:25 AM ***Morning Break***

11:25 – 12:30 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

12:30 – 1:15 PM ***Lunch Break***

1:15 – 2:15 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

2:15 – 2:30 PM **Afternoon Break**

Thursday, May 16, 2024 – Program Day 2 (continued) ***Tab No.***

All Times Listed EDT

2:30 – 3:15 PM	**A Review of Safety in Drug Development** *Asif Mahmood, MD, MPH, MBA* Vice President Medical Safety & Pharmacovigilance, AskBio	***9***
3:15 – 4:00 PM	**Successful Interactions with Regulatory Agencies** *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?	***10***
4:00	**End of Day Two**	

Friday, May 17, 2024 – 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 AM – 12:30 PM **FDA Presentations & Panel Discussion** ***11***

10:10 – 10:40 AM *Amy Ellis, PhD*
Pharmacologist
Division of Anti-Infective Products
CDER/OND/OAP

10:40 – 11:10 AM *Kamal Tiwari*
Quality Assessment Lead (Acting)
Division of Process Assessment III, Branch IX
CDER/OND/OAP

11:10 – 11:20 AM ***Stretch Break***

11:20 AM – 12:30 PM *FDA Panel Discussion*
Moderator - Carolyn Finkle, MSc

12:30 – 1:15 PM ***Lunch Break***

1:15 – 2:15 PM **Drug Product Manufacturing: Synthetic and Biologic Products** ***12***
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

2:15 – 2:30 PM ***Afternoon Break***

Friday, May 17, 2024 – Program Day 3…continued ***Tab No.***

All Times Listed EDT

2:30 – 3:45 PM	**Getting the Product to Market – the New Drug Approval Process** Carolyn Finkle, MSc • Data Requirements • New Drug Applications • Expedited Programs and Accelerated Approval • FDA Risk/Benefit Considerations • Examples of Recent Approvals • Post-Approval Commitments	***13***
3:45 – 4:00 PM	***Program Wrap-up / End of Course***	