Virtual Training Program
May 17 – 19, 2023

Wednesday, May 17, 2023 – 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 – 01:00 PM ***Lunch Break***

1:00 – 1:45 PM **A Review of Safety in Drug Development** **3**
Asif Mahmood, MD, MPH, MBA
Vice President, Global Safety and Pharmacovigilance

1:45 – 2:00 PM ***Afternoon Break***

2:00 – 3:00 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

3:00 – 4:00 PM

Portfolio Management Workshop1: Early Development Decision Making **5**

Faculty and Participants

- 2:00 – 2:10 PM Overview
- 2:10 – 2:30 PM Individual Work
- 2:30 – 2:40 PM Voting
- 2:40 – 2:50 PM Discussion
- 2:50 – 3:00 PM Revote/Final Discussion

End of Day One

Thursday, May 18, 2023 – Program Day 2 ***Tab No.***
All Times Listed EDT

10:00 – 10:15 AM **Day Two Overview, Welcome**
Jo Ann Zoul, Course Manager
The Pharmaceutical Education and Research Institute, Inc.

10:15 – 11:15 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
- Big Data

11:15 – 11:30 AM ***Morning Break***

11:30 – 12:30 AM **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 – 1:30 PM ***Lunch Break***

1:30 – 2:30 PM **Portfolio Management Workshop 2: Advancing Compounds** ***8***
Faculty and Participants

- 1:30 – 1:35 PM Overview
- 1:35 – 2:05 PM Individual Work
- 2:05 – 2:25 PM Voting/Discussion
- 2:25 – 2:30 PM Final Discussion

2:30 – 2:45 PM **Afternoon Break**

2:45 – 4:00 PM

Overview of Regulatory – Overview of Regulatory Process – IND and Early Stage Drug Development ***9***

Carolyn Finkle, MSc Course Co-Director
Senior VP and Head of Regulatory Affairs, Precigen

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

End of Day Two

Friday, May 19, 2023 – Program Day 3 **Tab No.**
All Times Listed EDT

10:00 – 10:15 AM **Day Three Overview, Welcome**
Jo Ann Zoul, Course Manager
The Pharmaceutical Education and Research Institute, Inc.

10:15 – 11:00 AM **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?

11:00 – 11:15 AM ***Morning Break***

11:15 AM – 12:45 PM **FDA Presentations & Panel Discussion** ***11***

11:15 AM – 11:40 AM *Amy Ellis, PhD*
Pharmacologist
Division of Anti-Infective Products
CDER/OND/OAP

11:40 AM – 12:00 PM *Kamal Tiwari, PhD*
Quality Assessment Lead (Acting)
Division of Process Assessment III, Branch IX
CDER/OND/OAP

12:00 AM – 12:45 PM *FDA Panel Discussion*

Moderator
Carolyn Finkle, MSc

12:45 – 1:45 PM ***Lunch Break***

1:45 – 2:45 PM **Getting the Product to Market – the New Drug Approval Process** ***12***
Carolyn Finkle, MSc

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

- Post-Approval Commitments

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Friday, May 19, 2023 – Program Day 3…continued
All Times Listed EDT

2:45 – 3:45 PM

Drug Product Manufacturing: Synthetic and Biologic Products ***13***
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

3:45 – 4:00 PM

Program Wrap-up / End of Course