Basic Drug Development:
Overview of Biopharmaceutical Research & Development

Virtual Training Program
November 17 - 19, 2021

Wednesday, November 17 - 19, 2021 – Program Day 1 ***Tab No.***

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

10:15 – 11:00 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 **Overview of Nonclinical Biopharmaceutical Development** ***2***
Noel J. Cusack, PhD

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

12:15 – 1:00 PM ***Lunch Break***

1:00 – 1:45 PM **Pharmacovigilance Through The Product Lifecycle** ***3***
Asif Mahmood, MD, MPH, MBA
Vice President, Global Safety and Pharmacovigilance

1:45 – 2:00 PM ***Afternoon Break***

2:00 – 3:00 PM **Portfolio Management Workshop1: Early Development Decision Making** ***4***

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

Wednesday, November 17, 2021 – Program Day 1…continued

2:00 – 3:15 PM ***Stretch Break***

3:15– 4:15 PM **Clinical Development Plan Considerations – Part 1** ***5***

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

End of Day One

Thursday, November 18, 2021 – Program Day 2

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 2** ***6***
Allan J. Weinstein, MD

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

11:15 AM – 11:30 AM ***Morning Break***

11:30 AM – 12:30 PM **Portfolio Management Workshop 2: Advancing Compounds** ***7***
Faculty and Participants

- 11:30 – 11:35 AM Overview
- 11:35 AM– 12:05 PM Individual Work
- 12:05 – 12:25 PM Voting/Discussion
- 12:25 – 12:30 AM Final Discussion

12:30 – 1:30 PM ***Lunch Break***

1:30 – 2:45 PM **Overview of Regulatory – Overview of Regulatory Process – IND and Early Stage Drug Development** ***8***
Carolyn Finkle, MSc Course Co-Director
Chief Operating Officer, Medicago

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

2:45 – 3:00 PM ***Afternoon Break***

Thursday, November 18, 2021 – Program Day 2…continued

3:00 – 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?	***9***
	End of Day Two	***.***

Friday, November 19, 2021 – Program Day 3

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 **Drug Product Manufacturing: Synthetic and Biologic Products** ***10***
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

11:00 – 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 *Nallaperumal Chidambaram, PhD*
Branch Chief
Pharmaceutical Manufacturing & Division of Pharmaceutical Manufacturing
Office of Pharmaceutical Manufacturing Assessment

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

Moderator
Carolyn Finkle, MSc

12:45 – 1:45 PM ***Lunch Break***

Friday, November 19, 2021 – Program Day 3…continued

1:45 – 2:45 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	***12***
2:45 – 3:45 PM	**Workshop 3: Case Studies in Biopharmaceutical Development** Faculty and Participants • Regulatory • CMC/Regulatory issues • Clinical Development	***13***
3:45 – 4:00 PM	***Program Wrap-up / End of Course***	