Fundamentals of Biotech Development: Biologics, Vaccines, Cells & Gene Therapy
Virtual Training Program
February 27 – 28, 2025

Thursday, February 27, 2025 – Program Day 1 ***Session No.***
All Times Listed ET

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

10:15 AM – 11:15 AM **Exploring the Past, Present, and Future of Biologics** ***1***
Martin Green, PhD
Supervisory Toxicology
Division of Clinical and Toxicology Review
CBER, FDA

- Scientific and Regulatory Distinctions Between Drugs and Biological Products
- History of the Events and Laws Governing Biological Product Regulation
- Future of Biologics

11:15 – 11:30 AM ***Stretch Break***

11:30 AM – 12:30 PM **Preclinical Development of Biologics – A Scientific and Regulatory Perspective** ***2***
Christopher Ellis, PhD
Supervisory Pharmacologist
Division of Anti-Viral Products
CDER, FDA

- Properties of Biologics & Biosimilars – A Brief Review
- Successfully Planning Preclinical Safety Studies for Biologics
- Immunogenicity and Preclinical Studies
- Strategy for Successful Preclinical Development

12:30 – 1:15 PM ***Extended Break***

1:15 PM – 2:15 PM **Vaccines: Development and Regulatory Considerations** ***3***
Matthew Steele, PhD
Team Leader for Biologics Medical Countermeasures
OS/ASPR/BARDA

- Vaccine Development
- Special Populations
- Regulatory Pathways and Considerations

2:15– 2:30 PM	***Stretch Break***	
2:30 – 3:45 PM	**Manufacturing Challenges and Considerations for Biotherapeutic Products** *David Fritsch, MBA* Principal, Biotechnology Operations Consultant Fritsch Consulting, LLC • Manufacturing Needs for Various Biologics and Biotherapeutics • Working with CMOs and CDMOs • Tech Transfer Requirements and Considerations	***4***
3:45 – 4:00 PM	***End of Day One***	

Friday, February 28, 2025 – Program Day 2 ***Session No.***
All Times Listed ET

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 **Perspective on Pharm/Tox Assessment for Cell and Gene Therapy Products** ***5***
Melanie T. Hartsough, PhD
Independent Consultant

- Definition of Cell & Gene Therapy
- Potential Challenges in toxicology program design

11:15 – 11:30 AM ***Stretch Break***

11:30 AM – 12:30 PM **Topic to be Announced** ***6***

12:30 – 1:15 PM ***Extended Break***

1:15 – 2:30 PM **Clinical Development Plan Considerations** ***7***
Allan J. Weinstein, MD
Clinical Research and Regulatory Affairs Consultant

- Combined study phases
- Adaptive Designs
- Enrichment Strategies
- Small Clinical Trials for Rare Diseases
- Exploratory Clinical Studies

2:30 – 2:45 PM ***Stretch Break***

2:45 – 3:45 PM	**Regulatory Pathways and Guidance for Biologics and Biosimilars** *Gillian Woollett, MA, DPhil* *Vice President, Head Regulatory Strategy, and Policy US* *Samsung Bioepis* • Global Context for Biologic Regulations • Alternative Biologics vs. Biosimilars • Global Product Development • Pharmacovigilance in a Multisource Environment	***8***
3:45 – 4:00 PM	**Course wrap-up and adjournment**	