Monday, March 4, 2019

8:00 – 8:30 AM  Registration and Continental Breakfast

8:30 – 8:45 AM  PERI Welcome & Introduction of Course
Jo Ann Zoul
Course Manager
Pharmaceutical Education & Research Institute, Inc. (PERI)

8:45 – 9:45 AM  The History of Biologics
- Scientific and Regulatory Distinctions Between Drugs and Biological Products
- History of the Events and Laws Governing Biological Product Regulation

9:45 – 10:45 AM  Regulatory Aspects of Biologics, Follow-on Biologics & Their Regulatory Pathway

10:45 – 11:00 AM  Morning Break

11:00 – 12:00 PM  Preclinical Development of Biologics – A Scientific and Regulatory Perspective
- Properties of Biologics & Biosimilars – A Brief Overview
- Successfully Planning Preclinical Safety Studies for Biologics
- Immunogenicity and Preclinical Studies
- Strategy for Successful Preclinical Development

12:00 – 1:00 PM  Lunch on your Own
**Monday, March 4, 2019  (continued)**

1:00 – 2:00 PM  **Perspective on Pharm/Tox Assessment for Cell and Gene Therapy Products**

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

2:00 – 3:00 PM  **Pharmacokinetics: How the Body Handles Biologics**

- Pharmacokinetics (PK) refresher
- PK aspects unique to Biologics
- Considerations in supporting FIH studies
- Consideration during clinical development
- Considerations for BLA Submissions

3:00 – 3:15 PM  **Afternoon Break**

3:15 – 4:15 PM  **How are Biologics Manufactured? Chemistry, Manufacturing and Controls**

- Drug Substance (Active Pharmaceutical Ingredient)
- Drug Product (formulated Drug Substance)
- How manufacture and product design fits into the overall development
- Considerations for BLA submissions

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**Tuesday, March 5, 2019**

8:00 – 8:30 AM  **Continental Breakfast**

8:30 – 9:30 AM  **Overview of Clinical Trial Design**

- Characteristics of biologics in clinical development
- Overview of study phases
- Description of some study designs
- Controls used in clinical studies
Tuesday, March 5, 2019  (continued)

9:30 – 10:30 AM  Clinical Strategies in Biologics Development

•  Adaptive Designs
•  Exploratory Clinical Studies
•  Orphan Diseases
•  Biomarkers and Accelerated Approval

10:30 – 10:45 AM  Morning Break

10:45 – 11:45 AM  BLA Simulation Workshop Part 1: Introduction to BLA Simulation

Participants and Faculty
•  Team building and roll playing
•  FDA as interactive participants
•  Decision-making in the drug development process
•  The evolving product label

11:45 AM – 12:45 PM  Lunch on your Own

12:45 – 2:45 PM  BLA Simulation Workshop Part 2: BLA Assembly and FDA Interactions

Participants and Faculty
•  FDA as interactive participants
•  Decision-making in the drug development process
•  The evolving product label

2:45 – 3:00 PM  Afternoon Break

3:00 – 3:45 PM  BLA Simulation Workshop Part 3: Label Submission to “FDA”

•  Participants and Faculty
•  BLA presentations from “Company” Teams to the “FDA” Panel
•  Lessons Learned

3:45 – 4:45 PM  Post BLA Considerations

•  Product launch and marketing

4:45 – 5:00 PM  Course wrap-up and adjournment