The Pharmaceutical Education & Research Institute, Inc.

Biologics and Biosimilars: An Integrated Overview of Product Development

March 4 - 5 ✦ Fairfax, Virginia

Monday, March 4, 2019 **Tab No.**

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 – 10:00 AM **The History of Biologics** 1
Martin Green, PhD
Supervisory Toxicology
Division of Vaccines and Related Product Applications
CBER, FDA

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

10:00 – 11:00 AM **Preclinical Development of Biologics – A Scientific and Regulatory Perspective** 2
Christopher Ellis, PhD
Pharmacologist
Division of Anti-Viral Products
CDER, FDA

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

11:00 – 11:15 AM ***Morning Break***

11:15 AM – 12:15 PM **Perspective on Pharm/Tox Assessment for Cell and Gene Therapy Products** 3
Melanie T. Hartsough, PhD
Independent Consultant

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

12:15 – 1:15 PM ***Lunch on your Own***

1:15 – 2:00 PM	**Rare Disorders** *Orest Hurko, MD* *Alnylam Pharmaceuticals* *Tufts Center for Study of Drug Development* • Definitions of Rare Disorders • Relationship of Biologicals to Rare Disorders • Etiologies of Rare Disorders • Clinical Development for Rare Disorders	4
2:00 – 3:00 PM	**How the Body Handles Biologics: Pharmacokinetics** *Noel J. Cusack, PhD* *Independent Consultant* *Nonclinical development* • Pharmacokinetics (PK) refresher • PK aspects unique to biologics • Considerations in supporting FIH clinical studies • Considerations during clinical development	5
3:00 – 3:15 PM	***Afternoon Break***	
3:15 – 4:15 PM	**How are Biologics Manufactured? Chemistry, Manufacturing and Controls** *Noel J. Cusack, PhD* • Drug Substance (Active Pharmaceutical Ingredient) • Drug Product (formulated Drug Substance) • How manufacture and product design fits into the overall development	6

Tuesday, March 5, 2019

8:00 – 8:30 AM	***Continental Breakfast***	
8:30 – 9:30 AM	***Regulatory Aspects of Biologics, Follow-on Biologics & Their Regulatory Pathway*** *Gillian Woollett, MA, DPhil* *V.P. FDA Regulatory Policy* *Avalere Health*	7
9:30 – 10:30 AM	**Overview of Clinical Trial Design** *Orest Hurko, MD* • Overview of study phases • Description of some study designs • Controls used in clinical studies • Special Safety Concerns for Biologics	8
10:30 – 10:45 AM	**Morning Break**	
10:45 – 11:45 AM	**Clinical Strategies in Biologics Development** *Orest Hurko, MD* • Combined study phases • Adaptive Designs • Enrichment Strategies • Small Clinical Trials for Rare Diseases • Exploratory Clinical Studies	9
11:45 – 12:45 PM	**Lunch on your Own**	
12:45 – 1:30 PM	**BLA Simulation Workshop Part 1: Introduction to BLA Simulation** *Noel J. Cusack, PhD - Participants and Faculty* • Team building and roll playing • FDA as interactive participants • Decision-making in the drug development process • The evolving product label	10
1:30 – 3:30 PM	**BLA Simulation Workshop Part 2: BLA Assembly and FDA Interactions** *Noel J. Cusack, PhD* - Participants and Faculty • FDA as interactive participants • Decision –making in the drug development process • The evolving product label	11

3:30 – 4:00 PM	**BLA Simulation Workshop Part 3: Label Submission to "FDA"** *Noel J. Cusack, PhD - Participants and Faculty* • FDA presentations from "Company" Teams to the "FDA" Panel • Lessons Learned	12
4:00 – 4:45 PM	**Post BLA Considerations** *Noel J. Cusack, PhD* • Product launch and marketing	13
4:45 – 5:00 PM	**Course wrap-up and adjournment**	

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