Day One: Wednesday, September 18, 2019

8:00 a.m.  Registration & Coffee

8:30 a.m.  USP Welcome
Jaap Venema
Chief Science Officer, USP

8:40 a.m.  Workshop Overview
Jill Crouse-Zeineddini
Chair, USP Bioassay Workshop Steering Committee; Member, USP BIO2 Expert Committee; Chair, USP Fc Function Assays Expert Panel

8:50 a.m. – 11:40 a.m. Session I – Regulatory and Pharmacopeial Considerations
Session Chair: Tim Schofield
USP Bioassay Workshop Steering Committee and Member, USP Statistics Expert Committee

8:55 a.m.  Regulatory Considerations for Characterization and Comparability of Cell-Based Products for Animal Use
Michael Brewer and Jacob Michael Froehlich
CVM, FDA

9:20 a.m.  Request sent to CDER
Speaker
Affiliation

9:45 a.m.  Request sent to CBER for CGT
Speaker
Affiliation

Hiroko Shibata, Akiko Ishii-Watabe
NIHS, Japan

10:35 a.m.  Morning Break

11:00 a.m.  A New USP Chapter <1108> Assays to Evaluate Fragment Crystallizable (Fc)-mediated Effector Function
Jill Crouse-Zeineddini
USP Fc Function Assays Expert Panel Chair

11:25 a.m.  Panel Discussion / Q&A
11:40 a.m.–2:10 p.m.  Session II –Reference Standards to Support Bioassays  
Session Chair:  Jan Amstrup  
USP Bioassay Workshop Steering Committee and Member, USP Insulins Expert Panel and USP Bioassay General Chapters Expert Panel

11:45 a.m.  Principles and Practices for Reference Standards  
Tim Schofield  
CMC Sciences, LLC

12:10 p.m.  Development of the First World Health Organization (WHO) International Standard for Gene Therapy  
Yuan Zhao  
NIBSC

12:35 p.m. – 1:30 p.m.  Lunch

1:30 p.m.  Ensuring Biosimilar Monoclonal Antibody Product Consistency Through New Publically Available Bioassay International Standards  
Sandra Prior  
NIBSC

1:55 p.m.  Panel Discussion / Q&A

2:10 p.m. – 3:45 p.m.  Session III– Assessment of Potency for Cell, Gene and Immuno Therapies  
Session Chair: Gaël Debauve  
USP Bioassay Workshop Steering Committee

2:15 p.m.  Development of In Vitro Functional Bioassays for Potency and Immunogenicity screening of Cell and Gene Therapy products: challenges and opportunities  
Séverine Giltaire, Jana Schockaert, Sofie Pattijn  
ImmunXperts SA

2:40 p.m.  Strategies for the Successful Transfer of Potency Assays for Gene Therapy Products  
Nathan Weinstock  
Biogen

3:05 p.m.  Determination of Potency for a Plasmid Immunotherapy Product  
Peder Lisby Nørby and Jan Amstrup  
Novo Nordisk A/S

3:30 p.m.  Panel Discussion / Q&A

3:45 p.m.  Networking Reception

5:00 p.m.  End Day 1
Day Two: Thursday, September 19, 2019

8:00 a.m.  Registration & Coffee

8:30 a.m. – 10:30 a.m.  Session IV – Bioassays to Evaluate Complex Structure-Function Assessments of Protein Therapeutics
Session Chair: Teresa Surowy
USP Bioassay Workshop Steering Committee; Member, USP Fc Function Assays Expert Panel

8:35 a.m.  Challenges of Bioassay Development and Specification Assessment for Biosimilar Product with Multiple Mechanisms of Action
Ling Gu
Pfizer

9:00 a.m.  Monitoring Fc Glycan Modifications and Their Impact on Biological Activity in Monoclonal Antibodies
Allyson Masci
Biogen

9:25 a.m.  Panel Discussion / Q&A

9:45 a.m.  Morning Break

10:15 a.m. –11:40 a.m. p.m.  Session V – Breakout sessions
Session Chair: Maura Kibbey
USP

First 5 minutes: Go to rooms and instructions
Break into 3 groups for 25’ each, discuss (attendees in different rooms, facilitators rotate to rooms; USP Staff will take notes in each room)
Group A: Novel Approaches for Gene Therapy Products (Facilitators: Svetlana Bergelson and Jan Amstrup)
Group B: Structure Function Relationships (Facilitators: Teresa Surowy and Max Tejada)
Group C: Reference Standards (Facilitators: Steve Walfish and Perceval Sondag)

11:40 a.m.  Lunch

12:40 p.m.  Reports from Breakout Sessions
1:00 p.m. – 3:00 p.m. Session VI – Driving the Bioassay Life Cycle
Session Chair: Robert Singer
USP Bioassay Workshop Steering Committee and Chair, USP Statistics Expert Committee

1:05 p.m. Best Practices in Bioassay Development to Support Registration of Biopharmaceuticals
John R. White
GSK

1:30 p.m. Uh oh, Our Primary Standard isn’t Stable; What Do We Do Now?
David Lansky
Precision Bioassay, Inc.

1:55 p.m. What does it take to Calculate Potency and Which Data Do You Need?
Jan Amstrup
Novo Nordisk A/S

2:20 p.m. Analytical Bridging: How to Cross on the Wire Stretched Between Two Bioassay Methods? A Case Study
Gaël Debauve
UCB

2:45 p.m. Setting the Acceptance Limits for Bioassay Validation
Perceval Sondag
Merck Center for Mathematical Sciences

3:10 p.m. Panel Discussion / Q&A

3:25 p.m. Workshop Wrap-up
Jill Crouse-Zeineddini, Ph.D., Amgen
Chair, USP Bioassay Steering Committee and Member, USP BIO2 Expert Committee

3:35 p.m. Workshop Concludes