Day One: Monday, September 25, 2017

8:00 a.m. Registration & Coffee

8:30 a.m. USP Welcome
Fouad Atouf, Ph.D.
Vice President, Global Biologics, USP

8:40 a.m. Workshop Overview
Michael Mulkerrin, Ph.D., ADC Therapeutics
Chair, USP BIO2 – Proteins Expert Committee

8:50 a.m. – 10:25 a.m. Session I – Overview of Life Cycle Approach
Chair: Ken Miller, Ph.D., Medimmune
Member, USP GCBA Expert Committee

8:50 a.m. A Lifecycle Approach to Bioassay Validation
Timothy Schofield, M.A, GlaxoSmithKline
Member, USP General Chapters - Statistics Expert Committee

9:15 a.m. Regulatory Perspective on the Development and Validation of Bioassays
Chikako Torigoe, Ph.D, CMC Reviewer, OBP, CDER, FDA

9:40 a.m. European Regulatory Perspectives and Expectations
Peter Rigsby, MSc, National Institute for Biologics Standards & Control (NIBSC)
Member, USP General Chapters - Statistics Expert Committee

10:05 a.m. Panel Discussion / Q&A (20 min)

10:25 a.m. Morning Break

10:45 a.m. – 1:45 p.m. Session II – Stage 1, Method Design and Development
Chair: Jill Crouse-Zeineddini, Ph.D., Amgen
Member, USP BIO2 – Proteins Expert Committee

10:45 a.m. Case Study: Get to Know Your Bioassay From Clinical to Commercialization
Speaker: Catherine Cruz Ph.D., Genentech

11:10 a.m. Strategic/Modular Bioassay Design and Analysis
Speaker: David Lansky, Ph.D., Precision Bioassay, Inc
Member, USP General Chapters - Statistics Expert Committee

11:35 a.m. Regulatory Perspective on Setting Biological Product Specifications
Speaker: Detlef Bartel, Ph.D, Paul-Ehrlich-Institut

12:00 p.m. – 1 p.m. Lunch/Poster Presentation
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| 1:00 p.m.  | **Challenges in Establishing a Research Bioassay as a Robust QC Lot Release Assay**  
|            | Speaker: Ashley Mullan, MedImmune LLC                                                                                 |
| 1:25 p.m.  | Panel Discussion / Q&A (15 min)                                                                                       |
| 1:40 p.m.  | **Session III – Stage 2, Procedure Performance Qualification**  
|            | Chair: David Lansky, Ph.D., Precision Bioassay, Inc  
|            | Member, USP General Chapters - Statistics Expert Committee                                                           |
| 1:40 p.m.  | **Lifecycle Of A Bioassay: From Development To Implementation In Commercial Qc Passing By Assay Bridging**  
|            | Speaker: Gaël Debauve, Ph.D., UCB Pharma S.A                                                                            |
| 2:05 p.m.  | **Using Both USP <1210> and USP <1033> for Stage 2 Bioassay Qualification**  
|            | Speaker: Richard Burdick, Ph.D., Elion Labs  
|            | Member, USP General Chapters - Statistics Expert Committee                                                           |
| 2:30 p.m.  | **Afternoon Break**                                                                                                    |
| 2:55 p.m.  | **Life Cycle Approach Stages 1 and 2 versus Traditional Qualification and Validation**  
|            | Speaker: Freyja Williams, Biologist - CBER DBPAP- U.S. FDA                                                           |
| 3:20 p.m.  | **Lifecycle management of a commercial potency assay at Biogen**  
|            | Speaker: Tilanthi Jayawardena, Biogen                                                                                 |
| 3:45 p.m.  | Panel Discussion / Q&A (15 min)                                                                                       |
| 4:00 p.m.  | **Poster Presentation & Networking Reception**                                                                        |
| 5:00 p.m.  | **End Day 1**                                                                                                         |

**Day Two: Tuesday, September 26, 2017**

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<td>8:00 a.m.</td>
<td><strong>Registration &amp; Coffee</strong></td>
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| 8:30 a.m.  | **Session IV – Stage 3, Continued Procedure Performance Verification**  
|            | Chair: David LeBlond                                                                                                 |
| 8:30 a.m.  | **Biosimilar Potency Assessment: Application of Continuous Improvement to Bioassay Development**  
|            | Speaker: Andrew D. Wallace Ph.D., Catalent Pharma Solutions                                                          |
| 8:55 a.m.  | **General Framework for Bioassay Equivalence Testing Over a Range of Outcomes**  
|            | Speaker: Lingmin Zeng, Ph.D., Medimmune                                                                            |
USP’s 7th Bioassay Workshop – Bioassay Life Cycle Approach
September 25-26, 2017
USP Headquarters, Rockville, Maryland, USA

Preliminary Agenda
(As of September 6, 2017 / Subject to Change)

9:20 a.m.    FDA Perspective on Stage 3, Continued Procedure Performance Verification
Speaker: Alfred V. Del Grosso, Ph.D, FDA-CBER-OCBQ

9:50 a.m.    Morning Break

10:20 a.m.   “Can You Hear the Echo®? Acoustic Droplet Ejection Technology Improves Assay Precision”
Speaker: Jill Crouse-Zeineddini, Ph.D., Amgen
Member, USP BIO2 – Proteins Expert Committee

10:45 a.m.   Panel Discussion / Q&A (15 min)

11:00 a.m. – 12:05 p.m. Session V – Breakout sessions
Chair: Timothy Schofield, M.A.GlaxoSmithKline
Member, USP General Chapters - Statistics Expert Committee

First 5 minutes: Instructions

Break into 3 groups for 20’ each, discuss
Group A: Stage 1, Method Design and Development (Facilitator: Ken Miller, Ph.D., scribe: USP staff)
Group B: Stage 2, Method Procedure Performance Qualification (Facilitator: Jill Crouse-Zeineddini, Ph.D., scribe: USP staff)
Group C: Stage 3: Continued Procedure Performance Verification (Facilitator: David LeBlond, scribe: USP staff)

12:05 p.m.   Lunch/Poster presentation

1:00 p.m.    Survey/Evaluation

1:15 p.m.    Reports from Breakout Sessions

1:30 p.m.    Workshop Discussion and Wrap-up
Michael Mulkerrin, Ph.D., ADC Therapeutics
Chair, USP BIO2 – Proteins Expert Committee

2:15 p.m.    Afternoon Break

2:45 p.m. – 4:30 p.m. Session VI: Vendor’s Presentation and Q&A
Chair: Robert Singer, MS., Robert Singer Consulting
Chair, USP General Chapters-Statistics Expert Committee

4:30 p.m.    Workshop Adjourns