USP's 7th Bioassay Workshop – Bioassay Life Cycle Approach
September 25-26, 2017
USP Headquarters, Rockville, Maryland, USA

Final Agenda
(As of September 22, 2017)

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. – 2:30 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

8:00 a.m.	**Registration & Coffee**
8:30 a.m. – 10:00 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

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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**