BEBPA's 3rd Annual

US Bioassay Conference

Best Practices for the Best Potency Assays

March 13-15, 2019

Register for the Conference HERE

Crowne Plaza LA Harbor Hotel

San Pedro, CA

Pre-Conference Workshops, March 13, 2019 (*8:30AM–4:30PM*)

Track 1: Bioassay Town Hall: A Discussion of Practical Issues with Establishing Assay and Test Sample Criteria for Bioassays
Instructors: Laureen Little, President, BEBPA & Nancy Niemuth, Research Leader, Battelle

Track 2: Reference Standard – Challenges and Opportunities
Instructors: Jane Robinson, Consultant, BEBPA, Bassam Hallis, Head, Public Health England, and Sian Estdale, Head, Covance

Day 1, March 14, 2019

8:15 Welcome and Opening Comments by BEBPA President

Session 1: Developing Mechanistically Relevant Potency Assays

Session Chair: Laureen Little, President, BEBPA

8:30 USP Bioassay Chapter Revision Journey
Steven Walfish, Principal Scientific Liaison, USP

9:00 The New Laboratory Paradigm for Pharmaceutical Development
Leonard Blackwell, Principal Scientist, Biogen

9:30 Reporter Cell-Based Assay: Connecting to the Biological Relevance
Guoying Jiang, Director, Genentech

10:00 Appropriate Fc Functionality Assessment - Control of the Effector Functions of Therapeutic Antibodies
Tilman Schlothauer, Group Leader, Roche

10:30-11:00 Morning Break

Session 2: Critical Rare Reagents for Bioassays

Session Chair: Guoying Jiang, Director, Genentech

11:00 **Case Study: Process to Assure Potency from Clinical Phase Through Lifecycle of a Product**
Kimberly Flecke, Senior Scientist, Pfizer Inc.

11:30 **Interactive Survey: Current Practices for Reference Materials**
Laureen Little, President, BEBPA

12:15-1:30 Lunch

1:30 **To Err is Human: Common Errors Observed in Bioassay Development**
Keynote Speaker
Gerald Feldman, Supervisory Biologist, US Food and Drug Administration

Session 3 Continued: Critical Rare Reagents for Bioassays

2:00 Your Statistician is Your Friend: Optimizing Reagent Qualification Using Equivalence Tests
Nancy Niemuth, Research Leader, Battelle

2:30 **Case Study: Characterization and Qualification of Thaw-and-Use Cell Banks for Use in Bioassays**
Jey Cheng, Bioassay Group Leader, Promega

Session 4: Be Kind to Your Data: Appropriate Analysis of Bioassay Results

Session Chair: Stan Deming, President, Statistical Designs

3:00 The Log Transformation: A Biologist's Best Friend
Janice Callahan, President, Callahan Associates

3:30-4:00 Afternoon Break

4:00 Similarity (or Parallelism) Testing is Mandatory Prior to Calculating Relative Potency
Perceval Sondag, Sr. Manager, Pharmalex

4:30 Near-Universal Bounds for Similarity in Bioassays
David Lansky, President, Precision Bioassay, Inc.

5:00 **Introductions to Poster Presenters**
Laureen Little, President, BEBPA

Day 2, March 15, 2019

8:15 Comments by Session Chair

Session 5: Changing and Comparing Bioassays

8:30 Test Method Replacement: A Regulator's Perspective
Keynote Speaker
Leslie Wagner, Chemist, US Food and Drug Administration

9:00 Scientific Considerations and Case Studies on Bioassay Changes
Xu-Rong Jiang, Director, AstraZeneca

9:30 A Bioassay Comparability Assessment Between Two Contract Labs (Case Study)
Anton Stetsenko, Associate Director, ADC Therapeutics

10:00-10:30 Morning Break

Session 6: Improving Your Bioassays

10:30 **Bioassay Transfer and Comparative Testing for a Commercial Antibody**
June Saunders, Specialist, Emergent BioSolutions

11:00 "I CAN Let You Do That, Dave." Solutions for Automation of GMP Assays, Including Bioassays
Mike Sadick, Principal Scientist, Catalent Biologics

11:30 Case Study: Use of Acoustic Droplet Ejection Technology in Development and Regulated Testing Laboratories
Jill Crouse-Zeineddini, Scientific Director, Amgen Inc.

12:00-1:15 Lunch

1:15 **Comments by Session Chair**
Bassam Hallis, Head and General Project Manager, Public Health England

Session 7: Let's Develop Some Bioassays!

1:45 Development of a Reporter Gene Potency Assay for Bispecifics
Joseph Callahan, Technical Development Scientist, Genentech

2:15 Cellular Functional Bioassays for Insulin Analogues-Challenges & Learnings
Atul Tiwari, Associate Director, Syngene International Ltd

2:45-3:15 Afternoon Break

3:15 Statistics for Quantal Assays -- They're Different
Stan Deming, President, Statistical Designs

3:45 Understanding Critical Fold Difference and Its Application in Reporting Assay Precision
Nancy Sajjadi, Independent Consultant

4:15 Development and Qualification of an ACT-101 Competitive Cell-Based Ligand-Binding Assay
Tam Bui, Associate Scientist, Custom Biologics

4:45 Conference Adjourns

3 Ways to Register: Online at BEBPA.org – Phone: 916-747-6205 – Email: cori.schrader@bebpa.org

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Poster Title	Name	Company
Robustness Study Design and Data Analysis_ Case Study of Cell-Based Reporter Assay for a Therapeutic Antibody	Ping Carlson	Celgene
Considerations in Bioassay Method Transfer to a CDMO	Sharon Young	Thermo Fisher
Quantitative Cell-Based Reporter Gene Bioassays to Advance Individual or Combination Cancer Immunotherapy	Jey Cheng	Promega
Measurement of Fc-mediated ADCC and CDC of anti-TNFα and anti-VEGF Therapeutic Antibodies using Reporter-based Bioassays and Engineered TNFα+ and VEGF+ Target Cells	Steven Edenson	Promega
Reproducible MOA-Reflecting Reporter-Based Bioassays to Enable Drug Development of Biosimilars and Biobetters	Jeff Nelson	Promega
How to Optimize Cell-based NAb Assays using the iLite Technology	Therese Segerstein	Svar Life Sciences
A novel method for quantification of ADCC activity based on the use of engineered effector cells and a series of matching target cells.	Therese Segerstein	Svar Life Sciences
Echo® 525 Liquid Handler-enabled Bioassay: Establishing a Miniaturized Humira / TNFα L929 Cytotoxicity Bioassay	Jared Bailey	Labcyte
Development, Qualification and Transfer of a "Thaw-and-Use" Bioassay for a Therapeutic Antibody Drug Conjugate Produced using Sutro's Proprietary XpressCF+™ Cell Free Expression System.	Rajni Kalyandasani	Sutro Biopharma, Inc
Development of a Semi-Automated Bioassay for GMP Use	Christine Zhao	Regeneron Pharmaceuticals

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