BEBPA's 2nd Annual

US Bioassay Conference

Best Practices for the Best Potency Assays

March 7-9, 2018

Register for the Conference HERE

Handlery Hotel

San Diego, CA

Pre-Conference Workshops, March 7, 2018 (*8:30AM–4:30PM*)

Track 1: Workshop AM: **Bioassay Basics—What we (Should) Do in the Lab and Why**
Instructors: Dr. Bassam Hallis, **PHE** & Dr. Jane Robinson, **Consultant**

Workshop PM: **From Continuous to Thaw & Go…….What's in YOUR bioassay?**
Instructors: Mike Merges & Dr. Mike Sadick, **Catalent**

Track 2: All Day Workshop **Introduction to Statistics for Potency Assays**
Instructors: Nancy Niemuth, **Battelle** & Dr. Ann Yellowlees, **Quantics BioStatistics**

Day 1, March 8, 2018

8:15 Welcome to the Conference

8:30 Opening Keynote Talk: Bioassays: the Past, the Present and the Future-
Dr. Jane Robinson, President, **Consultant**

Session 1: Bioassays for BioSimilars

9:00 The Role and Requirement of Bioassays in Assessing Analytical Similarity of Biosimilar Products to Reference Products
Dr. Xu-Rong Jiang, Director & Head of Quality, **AstraZeneca BioVentures**

9:30 Reproducible, MoA-reflecting Reporter Based Bioassays to Enable Drug Development of Biosimilars and Biobetters
Dr. Mei Cong, Director, **Promega**

10:00-10:30 Morning Break

Session 2: Reference Materials

10:30 Reference Materials, A Moving Target?
Cindy Grant, **Janssen R&D**

11:00 Development of a Guinea Pig Potency Assay for a Next-Generation Anthrax Vaccine Candidate: Generation of a Stabilized Vaccine Reference Standard
Dr. Daniel Tishkoff, Principal Scientist, **Emergent Biosolutions**

11:30 Statistical Approaches for Bridging Reference Lots
Dr. Ann Yellowlees, Director, **Quantics Biostatistics**

12:00-1:30 Lunch

Session 3: Pharmacopeia and the BioAssay

1:30 Review of the New USP <1210>: Challenge and Opportunities
Perceval Sondag, Sr. Manager Statistics, **Pharmalex Development Services LLC**

2:00 USP Bioassay Chapters: Changes Afoot
Robert Singer, Principal Consultant, **R. Singer Consulting**

2:30 Introduction to Poster Presenters

3:00-3:30 Afternoon Break

Session 4: BioAssays for Product Characterization

3:30 The Use of Surface Plasmon Resonance for Extended Biological Characterization
Dr. Jeongsup Shim, Scientist, **Genentech**

4:00 Visualization and Assay Simulation Tools for the Verification of Equivalence Test Systems
Dr. Ralf Stegmann, CEO, **Stegmann Systems**

4:30 Does It Or Doesn't It? Only The Assay Control Sample Knows For Sure
Drs. Stan Deming, President, **Statistical Designs** & Mike Sadick, Principal Scientist, **Catalent**

Day 2, March 9, 2018

8:15 Comments by Session Chair

Session 5: Product Specific BioAssays

8:30 An MOA Reflective Bioassay for a Bi-Specific Immono-Oncology Product
Hyun Jun Kim, Sr. Manager, **AstraZeneca BioVentures**

9:00 Potency Assays for Immuno-Oncology Products
Tara Stauffer, Manager, Bristol-Myers Squibb

9:30 Development, Validation, and Implementation of an ELISA for Determining Potency of an Influenza Vaccine
Dr. Michael Murphy, Director and Dan Hastings, **Medicago**

10:00-10:30 Morning Break

Session 6: Bridging Assays

10:30 Strategies for Bridging Late Phase Cell-Based Potency Assays — Amy Teale, Sr Analytical Scientist, **Regeneron Pharmaceuticals**

11:00 Converting an Enzymatic Potency Assay to a Relative Potency Assay
Dr. Yeeting E. Chong, Scientist II, **aTyr Pharma Inc**

11:30 Comparison of Recombinant Human FSH Produced by Ferring (REKOVELLE®) using *In Vivo* Bioassay and *In Vitro* Cell-based Assay
Dr. Avi Zrachya, Senior Research Scientist, **Bio-Technology General Ltd. (BTG-FERRING)**

12:00-1:30 Lunch

Interactive Survey

1:30 Combining Run Results to Calculate Reportable Values
Dr. Laureen Little, President, **BEBPA**

Session 7: New and Improved Technologies

2:00 Application of Droplet Digital PCR in Gene Therapy- A Case Study on Infectious Titer and Residual Host Cell DNA— Yu Wang, Analytical Development, **Biogen**

2:30 AR BioAssay© - Clinically-Enabled Live Cell Assay for Pan-Androgen Measurement
Dr. Fred Schaufele, Co-Founder & Director, **Xcellassay**

3:00-3:30 Afternoon Break

3:30 Thaw-and-Use Target Cells Pre-Labeled with Calcein AM for Antibody Dependent Cell-Mediated Cytotoxicity Assays—Dr. Shan Chung, Principal Scientist/Group Leader, **Genentech**

4:00 Development of Automated Platform Assays for Potency Measurement of Drug Substances: Advantages and Challenges
Dr. Veerendra Koppolu, Scientist, MedImmune

4:30 Seamless Implementation of Qualified Bioassays from Development to QC Lot Release
Dr. Jane Lamerdin, Eurofins US

5:00 Conference Adjourns

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