



BEBPA's 10th Annual

Bioassay Conference

Best Practices for the Best Potency Assays

September 27-29, 2017

Register for the Conference [HERE](#)

[The Radisson Blu](#)
St. Julian's, Malta

Pre-Conference Workshops, September 27 2017

9:00 AM– 5:00PM

Workshop 1: Make Your Bioassay Great...the First Time

Instructors: Mike Merges & Mike Sadick, Catalent

Workshop 2: Introduction to Statistics for Potency Assays

Instructors: Nancy Niemuth, Research Leader, Battelle

Day 1, September 28, 2017

8:15 Welcome to the Conference

Session 1: Assay Development

8:30 Potency Testing: A Landscape Overview

Dr. Marie Gottar-Guillier, Laboratory Head, Novartis

9:00 Challenges in Development & Validation of Early Stage Assays Where Reagents Including Reference & QCs are very Limited

Dr. Kelly Thomas, Sr. Team Leader, Public Health England

9:30 2 in 1: Increasing Efficiency of Potency Assay Optimization via DoE

Dr. Johannes Solzin, Skill Center, Boehringer Ingelheim

10:00-10:30 Morning Break

10:30 Single Donor KILR[®]CD16 Effector Cells to Drive Robust and Reproducible ADCC and T-cell Redirection

Alexander Baumann, DiscoverX

11:00 Can we consign "The Edge Effect" to history?

Dr. Ann Yellowlees, Director, Quantics Biostatistics

11:30 Introduction of Poster Presenters

12:00-1:30 Lunch

Session 2: Bioassays for Antibody Products

1:30: Mechanism of Action Assays to Determine the Fc Effector Function of Palivizumab

Dr. Ulrike Herbrand, Charles River Biopharmaceuticals Services GmbH

2:00 Case Study: Two Stage DoE Development/Optimization

Jasper Jacobs, Associate Scientist, Ablynx nv

2:30 Functional Characterization Strategy for T-cell Bispecific Antibodies

Dr. Julia Krueger, Laboratory Head, Roche

3:00-3:30 Afternoon Break

3:30 Binding and Bioactivity Assays for Biosimilarity Assessment of Adalimumab and Bevacizumab

Dr. Christoph Giese, Director, ProBioGen AG

4:00 Development of Reporter Based Bioassays Capable of Selecting Optimal Human Immunostimulatory Antibodies with Varying Fc Gamma Receptor Dependence

Dr. Mei Cong, Research Manager, Promega

Session 3: Interactive Session

5:00 How do we Calculate a Reportable Values for Multi-plate (Multirun) Potency Assays

Dr. Laureen Little, President, BEBPA

5:30 Conference Adjourns

Day 2, September 29, 2017

8:15 Comments by Session Chair

Session 4: Product Specific Bioassays

8:30 Harnessing BLI Technology for Overcoming the Effects of Protein Aggregates on Fc Receptor Binding

Dr. Marina Feschenko, Principal Scientist, Biogen

9:00 Potency Testing for Hematopoietic Stem Cell Therapies

Dr. Dirk Haubert, Laboratory Head, Novartis

9:30 Potency Assay Development for Cellular Therapeutics

Dr. Stuart Dunn, Bioassay Development Manager, Covance

10:00-10:30 Morning Break

10:30 In-Vitro Functional Bioassays of Candidate Therapeutics in Immuno-Oncology

Dr. Severine Giltair, Senior Scientist, ImmunXperts SA

11:00 Using Affinity Chromatography to Characterize Fc Receptor Interactions

Dr. Florian Cymer, Group Head, Roche

11:30 Development of Combinatorial Potency Assays to Analyze Bi-Specific Protein Therapeutics

Dr. Matthias Naumer, Group Leader, AbbVie Deutschland

12:00-1:30 Lunch

Session 5: Nuts & Bolts of Assay Lifecycle Management

1:30 What's the Best Strategy for Collecting Data to Estimate a Four-Parameter Logistic Curve? A Simulation Study Using Nonlinear Designs in JMP

Dr. Ian Cox, Marketing Manager, SAS

2:00 Alternatives to the 5pl for Asymmetric Data

Dr. Francis Bursa, Quantics BioStatistics

2:30 Automated, Generic Direct Binding ELISA for Potency Measurements

Dr. Petr Obrdlík, Fellow, Novartis

3:00-3:30 Afternoon Break

3:30 VAC2VAC - Vaccine Batch to Vaccine Batch Comparison by Consistency Testing

Dr. Dieter Pullirsch, Sr. Expert, Austrian Medicines and Medical Devices Agency

4:00 Method Comparison Revisited: R Package for Bivariate Least Squares Regression

Dr. Walter Hoyer, Statistic Manager, GSK

4:30 Conference Adjourns