



BEBPA's 6<sup>th</sup> Annual

## US Bioassay Conference

Best Practices for the Best Potency Assays

March 21-24, 2022

Register for the Conference [HERE](#)

Virtual Conference

**\*All Times are in US PACIFIC DAYLIGHT TIME\***

### Day 1: Monday, March 21, 2022

**Session Topic: Stages in the Lifecycle of Bioassays**

**Session Chair: Lauren Little, President, BEBPA**

- 7:30 Welcome Comments by BEBPA's President
- 7:45 Audience Survey
- 8:00 [Switch from an In-Vivo to an In-Vitro Potency Test for QC Market Batch Release](#)  
*Aurora Dadone, Scientist, EMD Serono*
- 8:30 Q & A Session
- 8:45 [Strategy for the Potency Assessment of a Monoclonal Antibody: Development, Harmonization, and Comparison of Three Binding and One Cell-Based Potency Assays](#)  
*Adriana Rimesso, Scientist, Biogen*
- 9:15 Q & A Session
- 9:30 - 9:45 Break**
- 9:45 [Method Transfer and Validation at Multiple Sites](#)  
*Céline Vongsouvanh, Scientist II, Allakos Inc*
- 10:15 Q & A Session
- 10:30 [Principles and Practices for Reference Standards](#)  
*Tim Schofield, Owner & Consultant, CMC Sciences, LLC*
- 11:00 Q & A Session
- 11:15 Panel Discussion

**11:45 Conference Adjourns**

#### Thank You Conference Sponsors!



### Day 2: Tuesday, March 22, 2022

**Session Topic: Bioassays for Novel Cell-Based Therapeutics**

**Session Chair: Kristin Clement, Director of Analytical Development, Aruvant Sciences**

- 7:30 Session Introductions & Audience Survey
- 7:45 [Resetting Expectations for CAR-T Potency Assessment](#)  
*Avinash Chinthala, Scientist II, Precision BioSciences*
- 8:15 Q & A Session
- 8:30 [Assays for CAR-T Cells](#)  
*Ulrike Herbrand, Scientific Director Global in Vitro Bioassay, Charles River Laboratories*
- 9:00 Q & A Session

**9:15 - 9:30 Break**

**Session Topic: Bioassays for COVID-19 Therapeutics**

- 9:30 [Pseudoparticle Expression and Characterization of SARS-CoV-2 Wuhan Strain and Its Variants](#)  
*Martine Boyer, Director, Nexelis*
- 10:00 Q & A Session
- 10:15 [Quantitative Cell-Based Assays for Anti-SARS-CoV-2 Therapeutic and Vaccine Development](#)  
*Jey Cheng, Bioassay Group Leader, Promega Corporation*
- 10:45 Q & A Session
- 11:00 Panel Discussion

**11:30-12:30 Large Panel Discussion (Concurrent Zoom Rooms) Hot Topics**

- **Topic 1: [Software Comparisons: Can we Support Like-for-Like Uses of Different Software Across Laboratories](#)**  
*Moderators: Lauren Little & Natasha Leshinsky*
- **Topic 2: [Statistical Process Control for Bioassays](#)**  
*Moderators: Nancy Niemuth & Perceval Sondag*

**12:30 Conference Adjourns**

### Day 3: Wednesday, March 23, 2022

**Session Topic: Automating Bioassays**

**Session Chair: Siân Estdale, Head of Scientific Affairs, Labcorp Drug Development**

- 7:30 Session Introductions & Audience Survey
- 7:45 [A Modular Approach to Automating Relative Potency Assays \(and Everything Else!\)](#)  
*Sean Johnston, Scientist II, Biogen*
- 8:15 Q & A Session
- 8:30 [Riding the WAVE to the STAR; To Infinity and Beyond](#)  
*Nicole Abello, Research Associate, Seagen*
- 9:00 Q & A Session

**9:15 - 9:30 Break**

**Session Topic: Potency Assay Method Development-Case Studies**

- 9:30 [Development of an iLite® Reporter Cell Platform for the Quantification of Anti-AAV Neutralizing Antibodies](#)  
*Jordi Rodó, Research Scientist, SVAR Life Science AB*
- 10:00 Q & A Session
- 10:15 [Managing Variability from Probabilistic Viral Infection in Bioassays that Detect Viral Replication](#)  
*Alex Rodriguez, Research Scientist, PPD*
- 10:45 Q & A Session
- 11:00 Panel Discussion

**11:30 – 12:30 Roundtable Discussions (Concurrent Zoom Rooms)**

- **Topic 1: [Gene Therapy Products](#)**
- **Topic 2: [Monoclonal Antibodies](#)**
- **Topic 3: [Vaccine Products](#)**
- **Topic 4: [Biosimilars](#)**

**12:30 Conference Adjourns**

*\*Slides not available for distribution are highlighted in RED\**

### Day 4: Thursday, March 24, 2022

**Session Topic: Ins and Outs of Calculating Reportable Values**

**Session Chair: Nancy Niemuth, Principal Data Scientist, Battelle**

- 7:30 Session Introduction & Audience Survey
- 7:45 [Bioassayists, Statisticians, Working Together](#)  
*Tim Schofield, Owner and Consultant, CMC Sciences; David LeBlond, Statistician, Robert Singer Consulting; Stan Deming, President, Statistical Designs*
- 8:15 Q & A Session
- 8:30 [The Interchangeability of Various Software used for the Bioassay Analysis and Potency Result Calculation](#)  
*Natalia Leshinsky, Scientist II, Omeros*
- 9:00 Q & A Session
- 9:15 - 9:30 Break**
- 9:30 [Steps Towards Strategic Control of Potency Bias Caused by Allowed Non-Similarity](#)  
*David Lansky, President, Precision Bioassay Inc*
- 10:00 Q & A Session
- 10:15 [R We Nearly Square Yet?](#)  
*Brooke Franklin, Senior Statistician, Quantics Biostatistics*
- 10:45 Q & A Session
- 11:00 Panel Discussion
- 11:30 Closing Comments

**11:45 – 12:30 Speaker Networking Sessions (Concurrent Zoom Rooms)**  
*Drop in and talk to the Presenters*

Room 1: Day 1 Podium Presenters & Session Chairs  
Room 2: Day 2 Podium Presenters & Session Chairs  
Room 3: Day 3 Podium Presenters & Session Chairs  
Room 4: Day 4 Podium Presenters & Session Chairs

**12:30 Conference Concludes**