**Day 1: Monday, September 20, 2021**

**Developing Potency Biosassays**

Assay Development includes reagent development, establishing and bridging reference material, biological development (usually cells), format selection and calculating the reportable value.

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

14:30 Welcoming Comments by BEBPA’s President

14:45 Audience Survey

15:00 Regulatory’s View on the New Types of Bioassays and Assay Controls

Joana Vesterinen, Head of Section, Finnish Medicines Agency

15:30 Q & A Session

15:45 Early Development of Potency Assays: How do Concentration-Response Curve Parameters Relate to Method Performance Characteristics

Kate Getliffe, Senior Scientist, PsiOxus Therapeutics Ltd

16:15 Q & A Session

16:30 - 16:45 Break

16:45 Statistical Model Selection Using USP <1034>

Steven Wolff, Principal Liaison, U.S. Pharmacopeia

17:15 Q & A Session

17:30 Optimisation of Cell Handling Methods for the Development of Robust Bioassays – Part II: Cell Banking

Sébastien Wieckowski, Research Associate, FHNW

18:00 Q & A Session

18:15 Panel Discussion

**18:45 Conference Adjourns**

**Day 2: Tuesday, September 21, 2021**

**Dealing with “Unorthodox” Dose-Response Curves**

**Session Chair:** Perceval Sondag, Senior Director, Bioassay Development

14:30 Welcoming Comments and Audience Survey

15:00 When You Can Drive My CAR

Stanley Deming, Consultant, Statistical Designs

15:15 Bioassays from the Point of View of an Analytical Chemist

Laureen Little, President, BEBPA

15:30 Resetting Expectations for CAR-T Potency Assessment

Mike Sadick, Senior Director, Precision Biosciences

15:45 A Point Estimate of Relative Potency of a Complex Biologic from a 3-Point Dose-Response Curve

MaryKate Kornmer, Scientist, Organogenesis

16:00 Establishing Cross-Species Parallelism in an Antibody Assay with a Partial Curve

Nancy Nemeth, Principal Data Scientist, Battelle

16:15 When You Can’t Show Similarity, Make Lemonade?

David Lansky, President, Precision Bioassay Inc

16:30 Panel Discussion

17:00 Audience Q&A Session

17:45 - 18:00 Break

**Topic 1: Gene Therapy Products**

- **15-Minute Rapid-Fire Talk:** The New Bioassay Challenge: Gene Therapy Products

  Unrike Herbrand, Scientific Director, Charles River Labs

  - 30-Minute Panel Discussion about Technical Hurdles for Gene Therapy Bioassay Development

**Topic 2: Monoclonal Antibodies**

- **45-Minute Panel Discussion about Technical Hurdles for MA Products**

**Topic 3: Vaccine Products**

- **45-Minute Panel Discussion**

**Topic 4: Biosimilars**

- **45-Minute Panel Discussion**

**18:45 Conference Adjourns**

**Day 3: Wednesday, September 22, 2021**

**Looking Forward: Automation Miniaturized Bioassays and Novel Statistical Approaches**

The bioassay mantra was 96-well plates and cultured cells. The cracks in this approach appeared when we noticed frozen ready-to-use cells yield more homogeneous assay plates. Now, the new technology frontier is taking us into 384-well plates, automated assays, and the use of innovative simulation studies to improve assay throughput.

**Session Chair:** Steven Wolff, Principal Liaison, U.S. Pharmacopeia

14:30 Audience Survey

14:45 384-Well Plate Automation of Bioassays

Denny Dimitrov, Investigator, GlaxoSmithKline

15:15 Q & A Session

15:30 End-to-End Robot System for Cell-Based Potency Assays

Akis Petridou, Research Scientist, Novo Nordisk

16:00 Q & A Session

16:15 - 16:30 Break

16:30 Automation of Cell-Based Potency Assays - Not Only Useful in Times of Pandemic

André Breckner, Scientist II, AbbVie Deutschland GmbH & Co.KG

17:00 Q & A Session

17:15 How Can We Use Simulation to Reduce Lab Work?

Brooke Franklin, Biostatistician, Quantics Biostatistics

17:45 Q & A Session

18:00 Panel Discussion

**18:45-19:30** **Large Panel Discussions**

(in concurrent Zoom breakout rooms)

**Hot Topics**

- **Topic 1:** Statistical Process Control for Bioassays
- **Topic 2:** Bridging Bioassays

19:30 Conference Adjourns

*Slides not available for distribution are highlighted in RED*

**Day 4: Thursday, September 23, 2021**

**Product Specific Case Studies**

**Session Chair:** Stan Eztadale, Head of Scientific Affairs, Labcorp

14:30 Audience Survey

14:45 Developing and Qualifying a SARS-CoV-2 Neutralisation Assay in a Pandemic, Challenges, and Risks

Lorna McNair, Principal Scientist, Public Health England

15:15 Q & A Session

15:30 A Better Understanding of Bioassays – Comparison of Binding Assays, Reporter Gene Assays and Primary Cell-Based Assays of Glycoengineered Monoclonal

Sébastien Wieckowski, Research Associate, FHNW

16:00 Q & A Session

16:15 - 16:30 Break

16:30 Infective Assays for Virus-Based Biologics

Johannes Solzin, Head of Laboratory, Boehringer Ingelheim Pharma GmbH & Co KG

17:00 Q & A Session

17:15 Case Study on the Challenges of Developing a Cell-Based Potency Assay with a Drug Product Containing an Adjuvant

Emma Bowen, Senior Assay Development Scientist, Labcorp Drug Development

17:45 Q & A Session

18:00 Panel Discussion

18:30 Closing Comments

(18:45-19:15) **Speaker Networking Sessions:** Concurrent Zoom breakout 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

Room 5: BEBPA Staff, Scientific Committee & Board of Directors

19:15 **Conference Adjourns**