Day 1 | 27 September

8:00  Check In for In-Person Attendees
9:00  In-Person Workshops
10:30 Morning Break and Rapid-Fire Poster Presentations
11:00 In-Person Workshops
12:00 Lunch

**Session 1 Topic:**
**Current Trends in Bioassays**

**Session Chair:** Siân Estdale, Head of Scientific Affairs, Labcorp
(All Attendees Welcome)

13:30  Welcome and Logistics
13:45  Session Chair Introduction and Audience Survey
14:00  Opening Speaker
Sue Charlton, Head of Clinical Evaluation, Vaccine Development & Evaluation Centre, UKHSA
14:30  USP General Chapter <1033> Biological Assay Validation Update
Ann Yellowlees, Head of Statistics, Quantics Biostatistics
15:00  Q&A
15:20  Afternoon Break and Rapid-Fire Poster Presentations
15:50  Robo meets DoE: Using Fully Automated Design of Experiments Approach (DoE) for Potency Assay Development
Karoline Eppler, Associate Head of Laboratory, Boehringer Ingelheim Pharma GmbH & Co.KG
16:20  Improving Assay Performance through Trending and AI Prediction
Jon Christensen, Senior Scientist, Novo Nordisk
16:50  Q&A
17:10  Stegmann Systems: Diamond Exhibitor Introduction
17:15  Conference Day 1 Adjourns
17:15  Networking Reception

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**Workshop Options**
(For In-Person Attendees Only)

**Workshop 1**
Using Mixed Models to Reduce Relative Potency Bias From Allowed Non-Similarity
This course develops a comprehensive approach to bioassay using statistically efficient designs and nonlinear mixed model analyses. In combination, these support narrow similarity equivalence bounds (reducing bias), improve the precision of potency, and yield quantitative monitoring tools.

**David Lansky, President**
Precision Bioassays

**Workshop 2**
Care and Feeding of a Late-Stage Potency Assay
This two-part workshop covers two critical topics for the debut of late-stage potency assay into a commercial environment:
1) Method transfer and
2) The establishment of potency assay product reference material. Specifically, we will discuss:

**Assay Transfer**
- Assay preparedness for method transfer
- Types of method transfer including co-validation, transfer protocol and other approaches
- Assay monitoring data and the interim system suitability criteria to ease transfer.

**Reference Material**
- Selection of reference material for BLAs and initial years of product approval
- Qualification of reference material
- Requirements for monitoring the reference material

Sian Estdale, Labcorp, Alex Knorre, Eurofins BioPharma Product Testing, Bassam Hallis, UKHSA
### Day 2 | 28 September

<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
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<tbody>
<tr>
<td>9:00</td>
<td>In-Person Interest Groups</td>
</tr>
<tr>
<td>10:30</td>
<td>Morning Break and Rapid-Fire Poster Presentation</td>
</tr>
<tr>
<td>11:00</td>
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</tr>
<tr>
<td>12:00</td>
<td>Lunch</td>
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**Session 2 Topic:**

**Validation of Potency Assays**

*Session Chair: Hans-Joachim Wallny, Executive Director, Novartis Pharma AG  (All Attendees Welcome)*

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**Validation of Potency Assays**

*Session Chair: Hans-Joachim Wallny, Executive Director, Novartis Pharma AG  (All Attendees Welcome)*

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<tr>
<td>13:00</td>
<td>Session Intro and Survey</td>
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<tr>
<td>13:45</td>
<td>Rapid Fire Poster Presentation</td>
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<tr>
<td>14:00</td>
<td>Co-implementation and Co-validation of Potency Methods</td>
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<td>Matthias Hofmann, Head of Bioanalytics, Lonza</td>
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<td>14:30</td>
<td>Validation and Bridging of a Flow Cytometry-Based Potency Assay</td>
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<td>Frances Reichert, Technical Specialist Biologics, Eurofins BioPharma</td>
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<td>Product Testing Munich GmbH</td>
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<tr>
<td>15:00</td>
<td>Q&amp;A</td>
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<tr>
<td>15:20</td>
<td>Afternoon Break and Rapid Fire-Poster Presentation</td>
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<tr>
<td>15:50</td>
<td>Implementation of SARS-CoV-2 Variants of Concern into a Validated</td>
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<td>Microneutralization Assay for Clinical Testing</td>
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<td>Imam Shaik and Alexandra McEntee Project Team Leaders, UKHSA</td>
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<td>16:20</td>
<td>Case Study: Investigation on High Assay Repetition Rate during Otherwise</td>
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<td>Successful Validation</td>
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<td>Marja Kornhuber, Scientist, Richter-Helm Biologics GmbH</td>
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<tr>
<td>16:50</td>
<td>Q&amp;A</td>
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<tr>
<td>17:10</td>
<td>Conference Day 2 Adjourns</td>
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### Interest Group Options

*(In-Person Attendees Only)*

**Interest Group 1: Gene Therapy**

*Leaders: Anton Stetsenko, Director, Orca Bio and Siân Estdale, Head of Scientific Affairs, Labcorp*

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<thead>
<tr>
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<tbody>
<tr>
<td>9:00</td>
<td>Introduction and Survey</td>
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<tr>
<td>9:30</td>
<td>AAV: A Holistic Approach to Development</td>
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<td>Lisa Blackwood, Senior Scientist, Sartorius Stedim BioOutsource</td>
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<tr>
<td>10:00</td>
<td>Statistical Perspectives on Potency Assays for Gene Therapies</td>
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<td>Matthew Stephenson, Director of Statistics, Quantics Biostatistics</td>
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<tr>
<td>10:30</td>
<td>Break</td>
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<tr>
<td>11:00</td>
<td>Q&amp;A</td>
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**Interest Group 2: Monoclonal Ab**

*Leaders: Ulrike Herbrand, Scientific Director, Charles River Labs and Hans-Joachim Wallny, Executive Director, Novartis Pharma AG*

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<thead>
<tr>
<th>Time</th>
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<tbody>
<tr>
<td>9:00</td>
<td>Introduction and Survey</td>
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<tr>
<td>9:30</td>
<td>In-Depth Investigation of SPR-Based Kinetic Binding Assays for the</td>
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<td>Antibody-FcRn Interaction</td>
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<td>Bas Rosier, Scientist, Genmab</td>
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<td>10:00</td>
<td>The Importance of Target Cell Membrane Complement Regulatory Proteins</td>
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<td>(mCRPs) on CDC Assay Development</td>
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<td>Rok Kosir, Senior Expert Science &amp; Technology, Novartis</td>
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<tr>
<td>10:30</td>
<td>Break</td>
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<td>11:00</td>
<td>How Does an Antibody Drug Conjugate (ADC) Work In Vitro? Development &amp;</td>
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<td>Validation of Cell-Based Methods to Measure its Cytotoxic Activity</td>
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<td></td>
<td>and Internalization</td>
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<td></td>
<td>Martina Antonelli, Scientist, Merck KGaA</td>
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<tr>
<td>11:30</td>
<td>Q&amp;A</td>
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Day 3 | 29 September

9:00  In-Person Interest Groups

10:30  Morning Break and 🌞 Rapid Fire Poster Presentation

11:00  In-Person Interest Groups

12:00  Lunch

Session 3 Topic:
From Animals to Molecules:
Simplifying the Potency Assay
Session Chair: Bassam Hallis, Deputy Director, UK Health Security Agency
(All Attendees Welcome)

13:00  Session Intro and Survey

13:45  Rapid Fire Poster Presentation

14:00  Replacing Animal Testing: A Successful Journey to the Approval of an In Vitro Potency Assay for FSH
Chiara Modena, Senior Scientist, Merck KgA

14:30  Is (Cell) Banking Enough to Save Your Investment (in Your Potency Assay)?
Paola Cecchini, Senior Principal Scientist, Lonza

15:00  Afternoon Break and Rapid Fire Poster Presentation

15:30  Turning Cells into Reagents: A Proof-of-Concept Study to Compare Cultured vs Thaw-Use Cells in Cell-Based Potency Assays
Caroline Seiler, Assay Development Scientist, Labcorp

16:00  Potency Assays Using Targeted Mass Spectrometry
Moreno Di Marco, Head of Laboratory, Solvias

16:30  Q&A

17:00  Closing Comments

17:15  Conference Concludes

Interest Group Options
(In-Person Attendees Only)

Interest Group 3: Data Analysis
Leaders: Nancy Niemuth, Statistical Consultant, Act Two Consulting and Anton Stetsenko, Director, Orca Bio

9:00  Introduction and Survey

9:30  Discussion of Repeat Analysis Approaches for Invitro Bioassay Analysis and Reporting
Prema Maheshwari, Head QC Strategic Growth Projects, Lonza

10:00  Incomplete Dose-Response Curves - A contribution to the discussion on “allowed” non-similarity in biological assays
Ralf Stegmann, CEO, Stegmann Systems

10:30  Break

11:00  How much can we reduce the complexity of Bioassays?
Florian Cymer, Principal Scientist, F. Hoffmann-La Roche

11:30  Q&A

Interest Group 4: Stage Appropriate Potency Assays
Leaders: Siân Estdale, Labcorp Drug Development and Alex Knorre, Eurofins BioPharma Product Testing

9:00  Introduction and Survey

9:30  The Matrix Approach for Potency Testing of ATMPs
Sascha Karassek, Scientific Officer R&D, Charles River Laboratories

10:00  Stage-Appropriate Bioassays for Assessing ADCP Activity of Therapeutic Antibodies
Julia Gilden, Senior Scientist, Promega Corporation

10:30  Break

11:00  Potency Assay Strategy from Early to Late Clinical Development: A Bispecifics Case Study
Simone De Haij, Director, Genmab

11:30  Q&A

All times are in Central European Summer Time.
Slides not available for distribution are highlighted in RED.
### Rapid-Fire Schedule

#### Day 1 | 27 September

**10:30**  
Cryopreservation Enables the Omission of Cell Starvation in NFS-60 or TF-1 Cells When They Are Used Instantly After Thawing in Cell-Based Cytokine Potency Assays  
Ute Vespermann  
acCELLerate GmbH

**10:45**  
Development of a New Class of Target Cell Lines to Evaluate Fc-Mediated Cytotoxicity  
Ulrich Mayer  
Svar Life Science

**15:20**  
Development of a MoA-based Bioassay Platform for Safe and Rapid Assessment of Virus Neutralization  
Steven Edenson  
Promega Corporation

**15:35**  
Technical Insight into Product Testing for AAV: A Complex Development Package  
Lorenzo Tudini  
Sartorius AG

#### Day 2 | 28 September

**10:30**  
Semi-Automated Potency Assays with Increased Consistency and Less Hands-On Time  
Frances Reichert  
Eurofins BPT Munich GmbH

**10:45**  
Analytical Instrument Qualification for Bioassays & ELISAs: Challenges of PQ and Implementation  
Agnes Walsh  
MSD Ireland

**13:45**  
QC Potency Assay During Method Life Cycle for Marketed Product  
Antje Wanglin  
Sanofi

**15:20**  
Standardization of the binding assay by ELISA  
Flore Staub  
Sanofi

**15:35**  
ATP Driven Similarity Equivalence Bounds and Assay Size  
David Lansky  
Precision Bioassay Inc

#### Day 3 | 29 September

**10:30**  
Quantify Antibody-Dependent Cell Phagocytosis (ADCP): Application of a Robust, Non-Radioactive KILR Cytotoxicity Platform  
Gaurav Agrawal  
Eurofins DiscoverX

**10:45**  
LNP Vaccine Formulation Screening for Cellular Uptake Using BODIPY-labeled Lipid Nanoparticles  
Caroline Heap  
Labcorp Drug Development

**13:45**  
FCS-free Potency Assays for Future-animal Serum-free Assays: Chances and Challenges  
Silvia Loeblein  
Roche

**15:00**  
NanoBiT Technologies for CAR-T Characterization and Potency Testing  
Gopal Krishnan  
Promega Corporation

### WHOVA Only

Development of a Highly Sensitive ADCC iLite® Reporter Gene Assay with True MoA-Reflecting Properties  
Ulrich Mayer  
Svar Life Science

SPR and BLI - Comparison of Two Label-free Optical Biosensor Technologies and Applications in Affinity, Kinetics and Potency Determination  
Sebastian Lampe  
Eurofins BPT Munich GmbH

Comprehensive & Fit-for-Purpose Solutions to Enable Drug Development for Cytokine Targets  
Alexander Baumann  
Eurofins DiscoverX

Evaluating the Effect of Formulation on the Uptake of a Zika Subunit Vaccine Candidate by Antigen-presenting Cells  
Thomas Caws  
Labcorp Drug Development

Cell-based Luminescent Reporter Bioassays for Immunotherapies Targeting Macrophage Effector Functions  
Julia Gilden  
Promega Corporation

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[Register Online at BEBPA.ORG](https://bebpa.org)  
206-651-4542  
[contactus@bebpa.org](mailto:contactus@bebpa.org)