



# 17th Annual EUR Bioassay Conference

25-27 September, 2024

Hybrid Conference  
In-Person: Hilton Prague Hotel  
Prague, Czech Republic

All times are in Central European Time  
Slides not available for distribution are highlighted in **RED**

## Day 1 | Wednesday, 25 September

**8:00** Check In for In-Person Attendees

**9:00** In-Person Workshops

**10:30** Morning Break ☕

### Morning Keynote: Regulatory Update

(All Attendees Welcome)

**Session Chair:** To Be Announced

**11:00** Welcome and Logistics

**11:15** Session Chair Introduction and Audience Survey

**11:30** Review of Recently Published Guidances Which Impact Potency Assays  
**Speaker To Be Announced**

**12:00** Lunch 🍴

### Session 1: Potency Assay Development: It Can Be Done!

(All Attendees Welcome)

**Session Chair:** To Be Announced

**13:30** [The Road to In Vitro Potency Assay](#)  
**Yvonne Beck, Senior Scientist,**  
**Pfizer Manufacturing Austria GmbH**

**14:00** Talk To Be Announced  
**FDA Speaker To Be Announced**

**14:30** [Case Study: Optimization of an Early Phase Enzyme-Based Potency Assay to Detect NN1 Activity](#)  
**Jon Christensen, Senior Scientist,**  
**Novo Nordisk A/S**

**14:45** Q&A

**15:00** Afternoon Break ☕

**15:30** Talk To Be Announced  
**Speaker To Be Announced**

**16:00** [The Importance of Measuring Protein Interactions under Physiological Conditions by the Example of von Willebrand Factor](#)  
**Gerald Schrenk, Associate Director,**  
**Baxalta Innovations GmbH**

**16:15** Talk To Be Announced  
**FDA Speaker To Be Announced**

**16:30** GLP1 agonist bioassays – A Comprehensive Study of Being Precise and Representative  
**Speaker To Be Announced**

**16:45** Q&A

**17:15** Conference Day 1 Adjourns

**17:30** Networking Reception

### Interest Group Options

(In-Person Attendees Only)

#### Interest Group 1: Developing and Validating Clinical Assays for Vaccine Products

**9:00** Introduction

**9:15** Optimization of A Validated Bioassay Used In SARS-CoV-2 Vaccine Clinical Trials  
**Speaker To Be Announced**

**9:45** [Innovative Bioassays for the Assessment of Therapeutic Anti-SARS-CoV-2 Neutralizing Antibody](#)  
**Justin Jia, Head of Bioassay Center of Excellence, WuXi Biologics**

**10:15** Q&A

#### Interest Group 2: Flow Cytometry Assays

**9:00** Introduction

**9:15** Case Study: Developing a Flow Cytometry Assay  
**Speaker To Be Announced**

**9:45** Case Study: Validating and Comparing Flow Cytometry Potency Assays  
**Speaker To Be Announced**

**10:15** Q&A

Diamond Exhibitor





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## Day 2 | Thursday, 26 September

**9:00** In-Person Interest Groups

**10:30** Morning Break ☕

### Session 2: How To Know If Your Assay Is Good Enough?

(All Attendees Welcome)

**Session Chair:** To Be Announced

**11:00** Session Intro and Survey

**11:15** Total Analytical Error: The Not Any-More Missing Link Between Validation Guidelines Such as ICHQ2(R2), ICHM10, USP 1033, USP 1210, and Many Others  
**Eric Rozet, Director Statistics, Pharmalex Belgium**

**11:45** CombiStats Software - New Web Application  
**David Le Tallec, Statistician, EDQM**

**12:00** Q&A

**12:15** Lunch 🍴

**13:45** Reproducibility is Quintessential - Using R and Quarto for Bioassay Development  
**Paul Hehir, Principal Biostatistician, CSL**

**14:15** Biological Assays Linearity: Making the Link with Assay Intended Use to Derive Fit-for-Purpose Acceptance Criteria  
**Capucine Lepers, Principal Statistician, GSK**

**14:45** Talk To Be Announced  
**Invited FDA Speaker To Be Announced**

**15:00** Q&A

**15:15** Afternoon Break ☕

**15:45** Using Product Specification Limits to Define the Right Number of Cell Plates Used per Sample  
**Lasse Wæhrens, Senior Analytical Scientist, Novo Nordisk A/S**

**16:15** Implementation of suitable SSTs and Outlier Detection Rules: Exemplary Solutions for Different Biossay Formats  
**Sonja Klingelhöfer, Director Biological Assays, Richter-Helm Biologics GmbH**

**16:45** Q&A

**17:00** Conference Day 2 Adjourns

### Interest Group Options

(In-Person Attendees Only)

#### Interest Group 3: Cell and Gene Therapy

**9:00** Introduction and Survey

**9:15** Navigating Phase-Appropriate Potency Testing for Cell and Gene Therapy Products  
**Alicja Fiedorowicz, Senior Consultant, Dark Horse Consulting**

**9:45** The Critical Step of Linking Mechanism of Action to the Potency Assay of a Cell Therapy  
**Lauren Little, President, Quality Services**

**10:00** Development of a Robust Reporter Gene Cell Line for Potency Assessment of AAV-induced Gene Therapy  
**Speaker To Be Announced**

**10:15** Q&A

#### Interest Group 4: Determining Non-Similarity in Your Bioassay

**9:00** Introduction and Survey

**9:15** Limiting Potency Bias from Allowed Non-Similarity While Protecting the Similarity Pass Rate  
**David Lansky, President, Precision Bioassay Inc**

**9:45** Apples and Oranges: Case Studies on Similarity, Comparability and Equivalence Regarding Potency Determination  
**Hermann Beck, Project Lead Bioassay Development, F. Hoffmann-La Roche Ltd.**

**10:15** Q&A



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## Day 3 | Friday, 27 September

**9:00** In-Person Interest Groups

**10:30** Morning Break ☕

### Session 3: Automation

(All Attendees Welcome)

**Session Chair:** To Be Announced

**11:00** Session Intro and Audience Survey

**11:15** Functional Design of Experiment (DoE) for Potency Assay Optimization and In-Silico Simulation  
**Karoline Eppler, Associate Head of Laboratory, Boehringer Ingelheim Pharma GmbH & Co.KG**

**11:45** To Run or Not to Run 384-Well Cell-Based Assays  
**Speaker To Be Announced**

**12:00** Lunch 🍴

**13:30** Advancing Potency Assay Automation: Strategies for Conquering Challenge  
**Speaker To Be Announced**

**14:00** A New Assay Principle Allowing High Throughput Determination of Infectious Virus Titers via Kinetic Microscopy  
**Johannes Solzin, Senior Principal Scientist / Lab Head, Boehringer Ingelheim Pharma GmbH & Co KG**

**14:30** Development of Automated Cell Culture Methods for Use in a Validated Microneutralisation Assay for Clinical Testing  
**Speaker To Be Announced**

**14:45** Introduction Of An Automated Assay Trending Platform For Assay Monitoring  
**Sara Carney, Senior Analytical Development Scientist 2, Immunocore**

**15:00** Q&A

**15:30** Afternoon Break ☕

**16:00** Talk To Be Determined

**16:30** From Manual to Automated: Case Studies for Increasing Bioassay Precision and Throughput by Adding Modular Components in Bioassay Workflow  
**Frances Reichert, Technical Specialist Biologics, Eurofins BioPharma Product Testing Germany GmbH**

**17:00** Q&A

**17:30** Closing Comments

**18:00** Conference Concludes

### Interest Group Options

(In-Person Attendees Only)

#### Interest Group 5: Characterizing Monoclonal Antibody Products

**9:00** Introduction and Survey

**9:10** Why Agonistic Antibodies Remain Challenging to Identify & Characterize? Development & Qualification of a Tailored Bioassay Approach for Assessing Agonistic Activity of Immune-checkpoint Antibodies  
**Gaurav Agrawal, Global Head of Scientific Development, Eurofins DiscoverX**

**9:30** Case Study: Using SPR to Characterize Antibody/Receptor Interactions  
**Speaker To Be Announced**

**9:50** Dual-Targeting Antibody-Based Drugs: Development of Robust, Orthogonal Techniques for Binding Assessment with AqBD Approach  
**Natalia Urbanska, Junior Specialist for Biological Analytical Methods, Mabion S.A.**

**10:10** Q&A

#### Interest Group 6: Developing and Validating Serum Bactericidal Bioassays

**9:00** Introduction and Survey

**9:15** Development, Qualification and Validation of a Serum Bactericidal Assay (SBA) for Clinical Testing  
**Speaker To Be Announced**

**9:45** Using a Design of Experiments (DOE) to Optimize the Operating Conditions of a Serum Bactericidal Assay  
**An Tran Ly Binh, Principal Statistician, GSK**

**10:00** Talk To Be Determined

**10:15** Q&A