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

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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 Determined

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
Laureen 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 Talk To Be Determined

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
Capucine Lepers, Principal Statistician, GSK

10:00 Talk To Be Determined

10:15 Q&A