16th Annual

EUR Bioassay Conference

27-29 September, 2023

Hybrid Conference
In-Person: Rikli Balance Hotel
Bled, Slovenia

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

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

Workshop Options

(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

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Day 2 | 28 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 2 Topic:
Validation of Potency Assays

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

13:30 Session Intro and Survey

13:45 Rapid Fire Poster Presentation

14:00 Co-implementation and Co-validation of Potency Methods

Matthias Hofmann, Head of Bioanalytics, Lonza

14:30 Validation and Bridging of a Flow Cytometry-Based Potency Assay

Frances Reichert, Technical Specialist Biologics, Eurofins BioPharma Product Testing Munich GmbH

15:00 Q&A

15:20 Afternoon Break and
Rapid Fire-Poster Presentation

15:50 Implementation of SARS-CoV-2 Variants of Concern into a Validated Microneutralization Assay for Clinical Testing

Imam Shaik and Alexandra McEntee Project Team Leaders, UKHSA

16:20 Case Study: Investigation on High Assay Repetition Rate during Otherwise Successful Validation

Marja Kornhuber, Scientist, Richter-Helm Biologics GmbH

16:50 Q&A

17:10 Conference Day 2 Adjourns

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

9:00 Introduction and Survey

9:30 AAV: A Holistic Approach to Development

Lisa Blackwood, Senior Scientist, Sartorius Stedim BioOutsource

10:00 Statistical Perspectives on Potency Assays for Gene Therapies

Matthew Stephenson, Director of Statistics, Quantics Biostatistics

10:30 Break

11:00 Q&A

Interest Group 2: Monoclonal Ab

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

9:00 Introduction and Survey

9:30 In-Depth Investigation of SPR-Based Kinetic Binding Assays for the Antibody-FcRn Interaction

Bas Rosier, Scientist, Genmab

10:00 The Importance of Target Cell Membrane Complement Regulatory Proteins (mCRPs) on CDC Assay Development

Rok Kosir, Senior Expert Science & Technology, Novartis

10:30 Break

11:00 How Does an Antibody Drug Conjugate (ADC) Work In Vitro? Development & Validation of Cell-Based Methods to Measure its Cytotoxic Activity and Internalization

Martina Antonelli, Scientist, Merck KGaA

11:30 Q&A

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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)

13:30 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 Afternon 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

Prerna 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

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Rapid-Fire Schedule

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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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Diamond Exhibitor

STEGMANN SYSTEMS

Gold Exhibitors

eurofins | BioPharma Product Testing

eurofins | DiscoverX

labcorp

Promega

QUALITY ASSISTANCE
Contract Research Organisation

QUANTICS
Biostatistics

SVAR
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