



Inaugural Asia Bioassay Conference

November 4-6, 2026

Hybrid Conference
In-Person: Incheon, South Korea

Day 1 | Wednesday, November 4

8:00 Check-In for in-Person Attendees

Keynote Session

(All Attendees Welcome)

Session Chair: Laureen Little, President, BEBPA

9:00 Welcome and Logistics

9:15 Session Chair Introduction and Audience Survey

9:30 **The Bioassay from a Regulatory Perspective**
Gerry Feldman, Ex-FDA, USA

Session 1: Regulatory Aspects

(All Attendees Welcome)

Session Chair: Laureen Little, President, BEBPA

10:15 **Bioassay Submission Mistake from a Consultant Perspective**
Laureen Little, Quality Services, USA

10:45 Connection Break ☕

11:15 **Presentation To Be Determined**
Invited Speaker from US USP

11:45 **Not Just a MoA-Reflective Potency Assay: Addressing Regulatory Inquiry by Sensitivity Comparison of Cell-Based vs SPR**
Speaker To Be Announced, Japan

12:15 Q&A Panel Discussion

12:45 Scientific Poster Session

1:15 Hosted Lunch 🍴

Session 2: Development

(All Attendees Welcome)

Session Chair: To Be Announced

14:30 **Engineering and Selecting Cell Lines to Enhance AAV Transduction and Improve Potency Assay Sensitivity**
Speaker To Be Announced, USA

15:00 **Applying Design of Experiments (DoE) within the ICH Q14 Enhanced Approach during the development of a Cell Based Potency Bioassay**
Paul Hehir, CSL, Australia

15:30 Connection Break ☕

16:00 **Potency Assay Development and Use of DoE for a Tetravalent Vaccine Candidate**
Melody Janssen, GreyRigge Associates, United Kingdom

16:30 **Advancing Potency Assay Development using Automated Robotic System and Cell Line Development Strategies**
Sayaka Ogawa, Astellas Pharma Inc., Japan

17:00 Q&A Panel Discussion

17:30 Platinum Exhibitor Introduction:
Stegmann Systems

17:45 Conference Day Adjourns

17:45 Hosted Welcome Networking Reception



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Day 2 | Thursday, November 5

8:00 Check-In for in-Person Attendees

9:00 Concurrent In-Person Workshops

10:30 Connection Break ☕

12:00 Hosted Lunch & Learn 🍴

Session 2: Product Specific Potency Assays

(All Attendees Welcome)

Session Chair: To Be Announced

13:30 Welcome and Logistics

13:45 Session Chair Introduction and Audience Survey

2:00 A Reporter-Based Fcγ Receptor Activation Assay for Functional Characterization of Therapeutic Monoclonal Antibodies
Minoru Tada, National Institute of Health Sciences, Japan

14:30 Genetically Encoded Homogeneous Binding Assays for Lot-Release-Ready Evaluation of ADC Biotherapeutics
Speaker To Be Announced, USA

15:00 Q&A Panel Discussion

15:15 Connection Break ☕

15:45 Development of a Gene-of-Interest-Specific Expression-Based Relative Potency Assay for AAV9 CNS Programs
Speaker To Be Announced, USA

16:15 Presentation To Be Announced
Speaker To Be Announced, China

16:45 Q&A Panel Discussion

17:00 Conference Day Adjourns

In-Person Concurrent Workshops

(In-Person Attendees Only)

Workshop 1: Bioassay Basics

Leader: Lauren Little, BEBPA

14:00 Introduction and Audience Survey

15:30 Connection Break ☕

17:00 Workshop Adjourns

Workshop 2: Introduction to DoE

Leader: To Be Announced

14:00 Introduction and Audience Survey

15:30 Connection Break ☕

17:00 Workshop Adjourns



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Day 3 | Friday, November 6

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| 8:00 | Check-In for in-Person Attendees | 14:15 | Lessons for Potency Method Derived from Specific Assay Condition: Learns Toward Robust Cell-Free Assay
<i>Risa Kobayashi, Chugai Pharma Manufacturing Co., Ltd., Japan</i> |
| 9:00 | Concurrent In-Person Workshops | 14:45 | Connection Break ☕ |
| 10:30 | Connection Break ☕ | 15:15 | Faster. Leaner. Brighter: Transforming cAMP Assays for Improved Speed, Efficiency, and Sensitivity
<i>Gaurav Agrawal, Eurofins DiscoverX, USA</i> |
| 12:00 | Hosted Lunch 🍴 | 15:45 | Presentation To Be Determined
<i>Speaker To Be Determined</i> |
| Session 4: Late Stage Development Activities
(All Attendees Welcome)
Session Chair: To Be Announced | | | |
| 13:15 | Welcome and Logistics | 16:15 | Q&A Panel Discussion |
| 13:30 | Session Chair Introduction and Audience Survey | 16:45 | Closing Comments |
| 13:45 | Demonstrating Equivalence in Potency Assays: Case Studies of Bridging Strategies
<i>Daishi Tanaka, Kyowa Kirin Co., Ltd., Japan</i> | 17:15 | Conference Day Adjourns |

In-Person Concurrent Workshops

(In-Person Attendees Only)

Workshop 3:

Are You Confident? Or Is It An Outlier?

Leader: To Be Announced

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|--------------|--|
| 14:00 | Basic Review of Confidence Intervals
<i>Speaker To Be Announced</i> |
| 14:30 | Confidence Intervals for Relative Potency: A Monte Carlo Simulation Study
<i>Ralf Stegmann, Stegmann Systems, Germany</i> |
| 15:00 | Q&A Panel Discussion |
| 15:30 | Connection Break ☕ |
| 16:00 | Outliers in Bioassays: A User's Perspective
<i>Marja Kornhuber, Richter BioLogics, Germany</i> |
| 16:30 | Q&A Panel Discussion |
| 17:00 | Workshop Adjourns |

Workshop 4:

Potency Assays for Advanced Therapeutic Medicinal Proteins (ATMP's)

Leader: Gaurav Agrawal, Eurofins DiscoverX

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| 14:00 | Introduction and Audience Survey |
| 14:15 | Potency Assay for Novel Products – Challenges and Considerations
<i>Ravish Patel, Kodo Life Science, India</i> |
| 14:45 | Development of a Robust Reporter Gene Cell Line for Potency Assessment of AAV-Induced Gene Therapy
<i>Ulrich Mayer, SVAR Life Science, Sweden</i> |
| 15:00 | Q&A Panel Discussion |
| 15:30 | Connection Break ☕ |
| 16:00 | Implementing a Cross-Modality Framework for Phase-Appropriate, Mechanism-Aligned Potency Assay Development
<i>Sung Ryeol Park, Charles River Laboratories, USA</i> |
| 16:30 | Q&A Panel Discussion |
| 17:00 | Workshop Adjourns |