8th Annual

US Bioassay Conference

March 11-13, 2024

Hybrid Conference
In-Person: The Westin Long Beach
Long Beach, California

Day 1 | Monday, March 11

All times are in Pacific Daylight Time
Slides not available for distribution are highlighted in RED

8:00 Check In for In-Person Attendees

Session 1: Lifecycle Assay Development

(All Attendees Welcome)
Location: *Centennial Ballroom*
Session Chair: *Laureen Little, FasTrain & BEBPA*

9:00 Welcome Comments and Logistics

9:15 Session Introduction and Audience Survey

9:30 Phase-Appropriate Potency Assay Development Strategies for Gene Therapy Products
Arkadi Manukyan, Senior Scientist, Sanofi

10:00 Establishing Strategies to Develop Potency Assays to Ensure Transferability during Clinical Development
Dorota Bulik, Senior Director, Ultragenyx

10:30 Q&A

10:45 Morning Break

11:15 Development of a New High Throughput Quantitative Potency Assay for a CD19 Chimeric Antigen Receptor T Cell Therapy
Louise Webb, Senior Scientist II, Autolus Therapeutics

11:45 Re-Development and Qualification of a Cell-Based Potency Assay from Cultured Cells to Ready-to-Use Cells for Greatly Improved Assay Performance
Teresa Youngberg, Manager, Tanvex CDMO

12:15 Q&A

12:30 Panel Discussion

1:00 Lunch

2:30 In-Person Workshops (Part 1)

3:30 Afternoon Break

4:00 In-Person Workshops (Part 2)

5:00 Conference Day 1 Adjourns

5:15 Networking Welcome Reception
Location: *Centennial Ballroom Foyer*

In-Person Workshop

(In-Person Attendees Only)

Workshop 1
Location: *Centennial Ballroom C*

Comparability - Challenges and Lessons Learned
Kevin Brooks, Principal Consultant, K.R. Brooks & Associates

2:30 Workshop Part 1

3:30 Afternoon Break

4:00 Workshop Part 2

Workshop 2
Location: *Centennial Ballroom D*

Basics of How We Calculate Relative Potency
Laureen Little, President, Quality Services & FasTrain

The relative potency calculation is often based upon a ratio of the ED50 of the test article to the reference material. However, there is a step-wise approach which goes into preparing the data set for this calculation. This workshop covers the basic calculation, the data requirements for similarity and provides a discussion of confidence intervals and how they are used in today's potency world. This is a great workshop to attend if you are not a statistician, but want to sit in on the statistical interest group later in the conference. It will provide you basic understanding so you can be part of the discussion!

2:30 Workshop Part 1

3:30 Afternoon Break

4:00 Workshop Part 2

Day 2 | Tuesday, March 12

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Session 2A: Biosimilar Potency Assay Development

(All Attendees Welcome)
Location: *Centennial Ballroom*
Session Chair: *Dorota Bulik, Ultragenyx*

8:30 Session Introduction and Audience Survey

8:45 Define Critical Parameters of Bioassays to Gain a Better Understanding of Biochemical Basis of Different Bioassay Platforms to Inform Biosimilar Development
Wen Jin Wu, Senior Investigator, U.S. FDA

9:15 Impact of Product Variants on Product Functional Activity and Stability in the Content of Biosimilars
Ravish Patel

9:30 Rapid and Precise Potency Assays with Label-Free Laser Force Cytology
Sean Hart, CSO & CEO, LumaCyte

10:00 Q&A

10:15 Morning Break

Session 2B: Managing your Potency Assays in the Real World

(All Attendees Welcome)
Location: *Centennial Ballroom*

10:45 Challenges of Defining Potency for Gene Editing Therapeutics
Matt Evans, Global Director-Genomics, Labcorp

11:15 Cell-Based Bioassay Development With Operational Efficiency In Mind
Katherine Bonnington, Scientist, Bristol-Myers Squibb

11:45 Session 2A/2B Q&A/Panel Discussion

12:15 Lunch

1:45 In-Person Interest Groups (Track 1 - next page)

3:30 Afternoon Break

4:00 In-Person Interest Groups (Track 2 - next page)

5:30 Conference Day 2 Adjourns

Gold Exhibitors

accellerate
Catalent
LumaCyte
SVAR Answers in Life Science

Silver Exhibitors

labcorp
Promega
QUBAS BIOASSAY SOFTWARE quantics in an app
STEGMANN SYSTEMS

Day 2 | Tuesday, March 12

Track 1 Interest Group Options

(In-Person Attendees Only)

Interest Group 1: Data Analysis
Location: *Centennial Ballroom C*
Leaders: *Nancy Niemuth, Act Two Consulting*

1:45 Introduction and Audience Survey

2:00 Using Equivalence Testing to Define Lot Release Limits for Product Potency
Nancy Sajjadi, Founder and Principal Consultant, Sajjadi Consulting

2:20 All You Ever Wanted to Know About Target Measurement Uncertainty and Total Analytical Error for Analytical Validation
Pierre Lebrun, Director Statistics, Pharmalex Belgium SA

2:40 Limiting Potency Bias From Allowed Non-Similarity While Protecting The Similarity Pass Rate
David Lansky, President, Precision Bioassay Inc

3:00 Q&A

Interest Group 2: Assuring Potency for Cell and Gene Therapy Products
Location: *Centennial Ballroom D*
Leaders: *Mike Sadick, Imugene and Laureen Little, BEBPA*

The FDA now has two guidances about the potency of Cell and Gene Therapies (CGT). The most recent was released December 2023 entitled "Potency Assurance for Cellular and Gene Therapy Products Draft Guidance for Industry". The older guidance entitled "Guidance for Industry Potency Tests for Cellular and Gene Therapy Products" has been around since 2011. These two guidances will be discussed in this interest group

1:45 Introduction and Audience Survey

2:00 Mixture of Talks & Discussions

3:00 Q&A

Track 2 Interest Group Options

(In-Person Attendees Only)

Interest Group 3:
Handling Dose-Response Curves
Location: *Centennial Ballroom C*
Leaders: *Anton Stetsenko*

4:00 Introduction and Audience Survey

4:05 Partial Dose-Response Curves - Contributions To The Discussion On "Allowed" Non-Similarity In Biological Assays
Ralf Stegmann, CEO, Stegmann Systems

4:25 Replicates: Should They Be Averaged Before Modelling?
Matthew Stephenson, Director of Statistics, Quantics Biostatistics

4:45 Poster Presentation: Outlier Analysis for Relative Potency Assays Using SoftMax Pro Function for Rosner Extreme Studentized Deviate Test
Alena Nikolskaya, Associate Director, Abzena

5:00 Q&A

Interest Group 4: Cell Culture Special Interest Group
Location: *Centennial Ballroom D*
Leaders: *Oliver Wehmeier, aCELLerate and Vinh Nguyen, QC Scientist, Genentech/Roche*

You will certainly agree that cell culture is essential to invitro potency assays. Sure, but everyone knows how to cultivate cells. That's not a big deal and not a hot topic anymore. Is that really true? Do I exactly know how culture conditions impact cell response? What's the best cell banking strategy, how do I qualify and where do I store them. If you have an opinion or even the only valid answer to any of the questions, please join the discussion, to get cell culture to the next level of standardization.

4:00 Introduction and Audience Survey

4:05 Mixture of Talks & Discussions
- Where To Get Your Cells From
- Commercial Cell Banking Strategy
- Cell Culture Guideance - quo vadis?
- Why To Remove FBS From Your Bioassay

5:00 Q&A

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Day 3 | Wednesday, March 13

Session 3A: Reference Material

(All Attendees Welcome)
Location: *Centennial Ballroom*
Session Chair: *Kristin Clement, Bio-Val Consulting*

9:00 Session Introduction and Audience Survey

9:15 Development and Characterization of Anti-CD19 CAR-T Lentiviral Vector Integration Copy Number Candidate Reference Material
Zhiyong He, Biologist, NIST

9:45 Connecting the Dots: Primary and Working Reference Standards for Allogeneic CAR T Cells
Michael Sadick, Senior Director, Imugene

10:15 Q&A

10:30 Morning Break

11:00 Navigating mAb Reference Standard and Bridging Strategy for Orthogonal Potency Assays
Céline Vongsouvanh, Senior Scientist, Allakos

11:30 Considerations for Potency Evaluation in Connection with Biotherapeutic Product Enhancements
Kelli Matthies, Principal Scientist, Amgen, Inc.

12:00 Q&A

12:15 Lunch

Session 3B: Rapid-Fire Talks

(All Attendees Welcome)
Location: *Centennial Ballroom*

1:45 Introduction & Audience Survey

2:00 Development of a MoA-based Bioassay Platform for Safe and Rapid Assessment of Viral Entry Inhibitors
Jonathan Mitchell, Senior Research Scientist, Promega Corporation

2:15 Co-Validation and Technology Transfer of Cell-Based Potency Assay with Automation
Sai Akshaya Balabhadrapatruni, Associate Scientist, GSK

2:30 Engineering a Novel ILT3 Chimera Cell Line Enables the Development of a Functional Cell-Based Potency Assay
Julie McIntosh, Associate Principal Scientist, Merck & Co., Inc.

2:45 Panel Discussion

3:15 Closing Comments & Summary

3:30 Conference Concludes

Virtual Exhibitors