



March 14-16, 2023

7th Annual US Bioassay Conference

Best Practices for the Best Potency Assays

Hybrid Conference
In-Person: MOTIF Seattle
Seattle, WA

All Times are in US PACIFIC DAYLIGHT TIME

Day 1 Tuesday, March 14, 2023

Day 1

Day 2

Day 3

Morning Presentations: For Virtual and In-Person Attendees

Session 1: Assay Lifecycle

Session Chair: Laureen Little, President, BEBPA

7:30-8:30

Check-in For On-Site Attendees

8:30-9:00

Welcome Comments, Session Introduction
& Audience Survey

9:00-9:30

Bioassay Critical Reagent vs Reference Standards
- How are they the same, how are they different?

Seth Foltz, Senior Principal Scientist,
Eli Lilly and Company

9:30-10:00

Defining a Lot Release Bioassay During
Late-Stage Product Development

Victoria Swiss, Senior Principal Scientist,
Bristol Myers Squibb



10:00 - 10:30
Poster Viewing & Break



10:30-11:00

Lessons Learned for Potency Assays for Bispecific
mAbs for Accelerated Programs

Marianne Hayes, Director, Janssen R&D

11:00-11:30

Warp-Speed Animal Testing Removal and
Replacement in Human Vaccines' Final Testing.
Industry and Regulatory Work and
Remaining Challenges

Laura Viviani, consultant to
Humane Society International

11:30-11:35

Book Giveaway: The 4PL by Stan Deming

11:35-12:15

Panel Discussion



12:15 - 1:30 Lunch



12:15 Virtual Conference Adjourns

Afternoon Workshops: For In-Person Attendees Only

Workshop Options

Workshop 1: Statistical Process Control for
Bioassays

Moderators: Perceval Sondag, Novo Nordisk
& Tara Scherder, SynoloStats

Workshop 2: Mixed Models and Similarity

Moderator: David Lansky, Precision Bioassay Inc

Workshop 3: Vaccine Interest Group

Moderators: Bassam Hallis, Public Health England
& Anton Stetsenko, 4D Molecular Therapeutics

Workshop 4: Automation Interest Group

Moderators: Nicole Abello, Seagen
& Alayna Forler, Seagen

1:30-3:00

Workshops 1-4 in Adjacent Rooms



3:00 - 3:30 Afternoon Break



3:30-5:00

All Workshops Repeated

5:00

On-Site Conference Adjourns



5:30 Networking Happy Hour

Hosted by BEBPA at the Yard House!



BEBPA.org

PO Box 4458
Bremerton WA, 98312

Register HERE

206-651-4542

contactus@bebpa.org



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Day 2 Wednesday, March 15, 2023

[Day 1](#)

Day 2

[Day 3](#)

Morning Presentations: For Virtual and In-Person Attendees

Session 2: Potency Assay Development for Complex Products

Session Chairs: Hans-Joachim Wallny, Executive Director, Novartis Pharma AG Switzerland & Kristin Clement, Principal Consultant, Bio-Val Consulting

8:15-8:30

Session Introduction & Audience Survey

8:30-9:00

State of the Cell and Gene Therapy Industry

Michael Lehmiche, Vice President,
Alliance for Regenerative Medicine

9:00-9:30

Potency Matrix for AAV Gene Therapies

Cullen Mason, Head of Gene Therapy,
Bioassay Development and Analytics, Biogen

9:30-10:00

In Vitro Potency Analytical Development for Gene Therapies

Shewit Tekeste, Principal Scientist, Janssen



10:00 - 10:30

Poster Viewing & Break



10:30-11:00

A Novel, Relative Potency Based IFN γ Measurement Approach for CAR-T Potency Assessment

Agatha Feltus, Director, CMC-AD, Precision BioSciences

11:00-11:15

Rapid Fire: Bioluminescence Reporters for In-process Potency Testing of T Cell Redirecting Viral Vectors

Julia Gilden, Senior Scientist, Promega Corp.

11:15-11:30

Rapid Fire Talk: How to Deal with Assays with Partial Dose-Response Curves

John Dunn, CEO, Brendan Bioanalytics

11:30-11:35

Book Giveaway: Statistical Method in Biological Assay by David John Finney

11:35-12:15

Panel Discussion



12:15 - 1:30 Lunch



12:15 Virtual Conference Adjourns

Workshop Options Afternoon Workshops: For In-Person Attendees Only

Workshop 5: mAb Interest Group

Moderators: Hans-Joachim Wallny, Novartis & Ulrike Herbrand, Charles River

Workshop 6: Cell & Gene Therapy Interest Group

Moderators: Mike Sadick, Precision BioSciences & Kristin Clement, Bio-Val Consulting

Workshop 7: Statistics Interest Group

Moderator: Nancy Niemuth, Battelle

Workshop 8a: Utilizing Commercially Available Kits and Reagents for Potency Assays

Moderator: Therese Segerstein, Svar Life Sciences & Laureen Little, Quality Services, LLC

Workshop 8b: Animal Assays: Switching from in-vivo to in-vitro Methods

Moderators: Laureen Little, Quality Services, LLC & Laura Viviani, consultant to Humane Society International

Workshop 9: Rare Reagents Interest Group

Moderators: Luc Gagnon, Nexelis, a Q2 solutions company & Bassam Hallis, UK Health Security Agency

1:30-3:00

Workshops 5, 6, 7 & 8a in Adjacent Rooms



3:00 - 3:30

Afternoon Break



3:30-4:15

Workshops 5, 6, 7, & 8b in Adjacent Rooms



4:15 - 4:30 Cookie Break!



4:30-5:15

Workshops 9 in Main Conference Hall

5:15

On-Site Conference Adjourns



5:15 Networking Happy Hour

Hosted by Nexelis,
a Q2 solutions company



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Day 3 Thursday, March 16, 2023

[Day 1](#)

[Day 2](#)

[Day 3](#)

All Sessions Today for Virtual and In-Person Attendees

Session 3: Statistical Tools

Session Chair: Nancy Niemuth, Consultant,
Act Two Consulting

8:15-8:30

Session Introduction & Audience Survey

8:30-9:00

USP General Chapter <1033> Biological Assay Validation Update

Ann Yellowlees, Director, Quantics Biostatistics

9:00-9:30

Speed Root Cause Analysis with Data Exploration Tools

Tara Scherder, Principal, SynoloStats

9:30-10:00

Overview of Statistical Software for Bioassay Scientists

Perceval Sondag, Senior Director-Data Science,
Novo Nordisk



10:00 - 10:30

Poster Viewing & Break



Session 4: Antibody Product Potency Assay Development

Session Chair: Ulrike Herbrand, Scientific Director,
Charles River Labs

10:30-10:45

Session Introduction & Audience Survey

10:45-11:15

A Fab-ulous Live Cell Assay that Addresses a Dual Control System Potency Strategy

Jeanette Villarreal Kinney, Tech Dev Scientist III,
Genentech

11:15-11:45

Combination of SPR-Based Binding Kinetic and SEC-Based Conformational Assay to Evaluate mAb-Target Antigen Physicochemical Properties Important for ADCs Therapeutic Function

Alessandra Mariani, Analytical Development
Bioassays Specialist, Menarini Biotech

11:45-12:30

Panel Discussion



12:30 - 1:30 Lunch



Session 5: Workshop Summary

Session Chair: To Be Announced

1:30-1:45

Session Introduction & Audience Survey

1:45-2:00

Workshop 1: Statistical Process Control for Bioassays

Moderators: Perceval Sondag, Novo Nordisk
& Tara Scherder, SynoloStats

2:00-2:15

Workshop 2: Mixed Models and Similarity

Moderator: David Lansky, Precision Bioassay Inc

2:15-2:30

Workshop 3: Vaccine Interest Group

Moderators: Bassam Hallis, UK Health Security Agency
& Anton Stetsenko, 4D Molecular Therapeutics

2:30-2:45

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Moderator: Nicole Abello, Seagen &
Alayna Forler, Seagen

2:45-3:00

Workshop 5: mAb Interest Group

Moderators: Hans-Joachim Wallny, Novartis
& Ulrike Herbrand, Charles River



3:00 - 3:30 Afternoon Break



3:30 - 3:45

Workshop 6: Cell & Gene Therapy Interest Group

Moderators: Mike Sadick, Precision BioSciences
& Kristin Clement, Bio-Val Consulting

3:45 - 4:00

Workshop 7: Statistics Interest Group

Moderator: Nancy Niemuth, Battelle &
Perceval Sondag, Novo Nordisk

4:00 - 4:15

Workshop 8a: Utilizing Commercially Available Kits and Reagents for Potency Assays

Moderators: Therese Segerstein, Svar Live Sciences AB &
Laureen Little, Quality Services LLC

4:15 - 4:30

Workshop 8b: Animal Assays: Switching from in-vivo to in-vitro Methods

Moderators: Laureen Little, Quality Service, LLC
& Laura Viviani, consultant to Humane Society International

4:30 - 4:45

Workshop 9: Rare Reagents Interest Group

Moderators: Luc Gagnon, Nexelis &
Bassam Hallis, UK Health Security Agency

4:45 - 5:00

Closing Comments and Gift Basket Giveaway

5:00: Conference Concludes

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