

Bioassays 2024: Scientific Approaches and Regulatory Strategies

Schedule

Monday, 15 April, 2024

08:00-09:00 Washingtonian Ballroom Foyer
[Registration \(For Workshop Attendees Only\)](#)

Registration for Full Symposium opens on Tuesday, April 16, 2024 at 7:30 AM Eastern.

09:00-10:00 Lakeside Ballroom 1
[Workshop Part I: Introduction to Bioassay Development: CMC Strategy and Practical Application](#)

Patrick Hussmann, Scott Umlauf

Workshop Instructors: Scott Umlauf, Ph.D. and Patrick Hussmann Ph.D. both of AstraZeneca Dept of Bioassay, Biosafety and Impurities

The workshop will provide practical knowledge on Bioassay method development, with a particular emphasis on Potency Assays. Method development and lifecycle management will be covered in the context of the unique role of Bioassays in CMC control strategy of Biopharmaceuticals, including monoclonal antibodies, antibody-drug conjugates, fusion proteins, such as T cell engagers, vaccines and cell and gene therapy.

10:00-10:30 Lakeside Ballroom 1
[Networking and Coffee Break](#)

10:30-12:30 Lakeside Ballroom 1
[Workshop Part I: Introduction to Bioassay Development: CMC Strategy and Practical Application](#)

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12:30-13:30 Lakeside Ballroom Foyer
[Lunch \(For Full Day Workshop Attendees Only\)](#)

13:30-15:00 Lakeside Ballroom 1

Workshop Part II: Practical Applications for Method Design and Performance

Tara Stauffer

Workshop Instructors:

Tara Stauffer, *Bristol-Myers Squibb Company*

Colleen Santoro, *Bristol-Myers Squibb Company*

In this interactive session, participants will work collaboratively on case studies relevant to current challenges in bioassay development, deployment, and lifecycle. This session will expand on the morning session and is recommended for both novice and experienced attendees.

15:00-15:30 Lakeside Ballroom 1

Networking and Coffee Break

15:30-17:00 Lakeside Ballroom 1

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Tuesday, 16 April, 2024

06:30-07:30

WATCH NOW: Utilizing HiBiT Targeted Cell Killing Bioassays To Validate Cell Therapy and mAb-Mediated Immunotherapy Potency

This technical Seminar will be available to watch on demand 24/7 during the Symposium. Click on this session to access the presentation video.

Presented by: Promega Corporation

[View Presentation](#)

06:30-07:30

WATCH NOW: Assay Development Within the Field of AAV Therapies; Engineering iLite® Cell Lines for Specific and Analytical Applications

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Presented by: Svar Life Science

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06:30-07:30

WATCH NOW: Best Practices, Strategies & Utilization of Novel Biological Responses for Robust Cell-Based Potency Assays

This technical Seminar will be available to watch on demand 24/7 during the Symposium. Click on this session to access the presentation video.

Presented by: Catalent, Inc

[View Presentation](#)

07:30-08:30 Washingtonian Ballroom Foyer

Registration

In-Person registration is open until 17:00 PM Eastern.

07:30-08:30 Washingtonian Ballroom A-C

Continental Breakfast

Networking/Break

Breakfast will be available until 09:00 AM Eastern.

08:30-08:45 Washingtonian Ballroom D-G

CASSS Welcome and Introductory Comments

Bhavin Parekh

IP - In Person

Welcome to Bioassays 2024, thank you for joining us!

08:45-09:30 Washingtonian Ballroom D-G

Keynote Presentation - Gains and Losses Regarding the Harmonization of Specifications during the COVID-19 Pandemic: Science Versus the Fear Factor

IP - In Person

Dean Smith, *Health Canada*

While a globally harmonized product specification is often noted as an industry objective, judging by how industry approaches regulatory agency engagements, and especially interagency engagements, it's not clear that all the tools at their disposal are being utilized. Additionally, from an agency prospective, until recently, interagency harmonization has often not been an important consideration. The urgency of the COVID-19 pandemic provided some manufactures with an opportunity to be more effective in achieving a globally harmonized specification. However, in the absence of that urgency, other approaches may be needed. In this presentation, I will focus on the benefits of a well-articulated pre-clinical and clinical product development program that is demonstrated to support a patient-centric specification (PCS), and industry's role in driving multi-agency interactions to enhance global harmonization of that specification. Pre-pandemic and pandemic case studies will highlight elegant patient-centric product development programs that experienced varying degrees of success in achieving a harmonized specification, at least initially. However, because the PCS product development was not clearly articulated during registration, the ability to maintain the specification was subsequently jeopardized when longstanding regulatory practices such as specification tightening came into play. This is in spite of a PCS and the preclinical, clinical and platform data supporting it. As the ICH Q6B revision is underway, this an important time to discuss rational, data-driven approaches to PCS that can support harmonization, as well as interagency collaboration to the benefit of industry, regulators, and most importantly, patients.

09:30-10:00 Washingtonian Ballroom A-C

Networking Break

Networking/Break

Join us for a networking break! Connect with industry professionals, members of the CASSS community, and share insights.

10:00-11:45 Washingtonian Ballroom D-G

Session I: Nuts and Bolts of Bioassays

Stephen Hartman, Martin Nemec, Adelheid Rohde

IP - In Person

Workshop

Session Speakers:

Lessons Learned for Potency Assays for Bispecific mAbs for Accelerated Programs

Marianne Hayes, *Johnson & Johnson*

Potency Assay Automation and How We Have Enhanced Cell Use and Production

Sheri Mahan-Hunter, *Pfizer, Inc.*

Potency Assurance for Cellular and Gene Therapy Products

Andrew P. Byrnes, *CBER, FDA*

In Vitro Functional Potency Assay Development and Qualification for a Late Stage AAV Based Gene Therapy Product

Debashree Basu, *Ultragenyx Pharmaceutical Inc.*

11:45-12:00 Washingtonian Ballroom A-C

Networking Break

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12:00-13:00 Washingtonian Ballroom D-G

Session I: Panel Discussion

Stephen Hartman, Martin Nemec, Adelheid Rohde

IP - In Person

Workshop

Panelists:

Marianne Hayes, *Johnson & Johnson*

Sheri Mahan-Hunter, *Pfizer, Inc.*

Andrew P. Byrnes, *CBER, FDA*

Debashree Basu, *Ultragenyx Pharmaceutical Inc.*

13:00-14:30 Washingtonian Ballroom D-G

Lunch and Learn: Vendor Showcase

Stephen Hartman

Lunch will be available in Ballroom A-C. Grab lunch and head back to Ballroom D-G for the Vendor Showcase.

Join us during lunch to hear from the following vendor partners to learn what they are working on and how it can better serve your needs.

Participating Vendor Partners:

acCELLerate GmbH

Labcorp

Promega Corporation

Stegmann Systems

Svar Life Science AB

14:30-16:15 Washingtonian Ballroom D-G

Session II: Lifecycle Management for Bioassays

Katrin Buss, Denise Gavin, Thomas Millward
Workshop

Session Speakers:

Adapting CMC Bioassay Strategies in Response to an Evolving ADC Pipeline

Patrick Hussman, *AstraZeneca*

Co-validation and Technology Transfer of an Automated Cell-Based Potency Method

Shelley Fang, *GlaxoSmithKline*

Apples and Oranges - Case Studies on Similarity, Comparability and Equivalence Regarding Potency Determination

Hermann Beck, *F. Hoffmann-La Roche Ltd.*

Regulatory Considerations for Bioassay Lifecycle Management

Leyun Boone, *CDER, FDA*

16:15-16:30 Washingtonian Ballroom A-C

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16:30-17:30 Washingtonian Ballroom D-G

Session II - Panel Discussion

Katrin Buss, Denise Gavin, Thomas Millward

Panelists:

Patrick Hussman, *AstraZeneca*

Shelley Fang, *GlaxoSmithKline*

Hermann Beck, *F. Hoffmann-La Roche Ltd.*

Leiyun Boone, *CDER, FDA*

17:30-18:30 Washingtonian Ballroom A-C / Foyer

Exhibitor Reception

Reception

Come interact and with our exhibitors and mingle with others in attendance while viewing the latest information pertaining to bioassays at this great way to end the day reception.

Wednesday, 17 April, 2024

06:30-07:30

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[Registration](#)

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[Continental Breakfast](#)

IP - In Person

Breakfast will be available until 09:00 AM Eastern.

08:30-10:15 Washingtonian Ballroom D-G

[Session III: Structure Function](#)

David Cirelli, Scott Umlauf, Jyoti Velayudhan

IP - In Person

Workshop

Session Speakers:

Meaningful Bioassays to Elucidate Structure-Function and Demonstrate Control

Colleen Santoro, *Bristol-Myers Squibb Company*

Assay Development and Concept Verification of a Tri-Specific Antibody

Yuri Mizuno, *Chugai Pharmaceutical Co., Ltd*

Variant Characterization in Bioassay - An Underestimated Step

Daniel Markx, *Ingelheim Pharma GmbH & Co. KG*

10:15-10:30 Washingtonian Ballroom A-C

[Networking Break](#)

Poster Session

Join us for a networking break! Connect with industry professionals, members of the CASSS community, and share insights.

10:30-11:30 Washingtonian Ballroom D-G

Session III: Panel Discussion

David Cirelli, Scott Umlauf, Jyoti Velayudhan

IP - In Person

Workshop

Panelists:

Colleen Santoro, *Bristol-Myers Squibb Company*

Yuri Mizuno, *Chugai Pharmaceutical Co., Ltd*

Daniel Markx, *Ingelheim Pharma GmbH & Co. KG*

Additional Panelist:

Leiyun Boone, *CDER, FDA*

11:30-12:15 Washingtonian Ballroom A-C / Foyer

Poster Session

Poster Session

12:15-13:15 Washingtonian Ballroom A-C

CASSS Hosted Lunch

Please join us for a nutritious and delicious lunch hosted by CASSS.

13:15-15:00 Washingtonian Ballroom D-G

Session IV: Process Improvements/Innovation in Bioassays

Jill Crouse-Zeineddini, Bhavin Parekh, Tara Stauffer

IP - In Person

Workshop

Session Speakers:

Quantifying Endogenous Protein Content to Measure and Control Potency of Antibody-PROTAC Conjugates

Clare So, *Genentech, a Member of the Roche Group*

Potency Testing Approaches: Challenges and Opportunities for mRNA Therapeutics

Jan Falcke, *BioNTech SE*

Modular Application of Automated Liquid Handling

Alissa Sheils, *Amgen Inc.*

Automation for the Win: Improving Bioassay Method Performance and Efficiency

Ahmed Hendawi and Sophia Arackal, *Pfizer, Inc.*

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Networking Break

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15:15-16:15 Washingtonian Ballroom D-G

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Bhavin Parekh, Tara Stauffer

Panelists:

Clare So, *Genentech, a Member of the Roche Group*

Jan Falcke, *BioNTech SE*

Alissa Sheils, *Amgen Inc.*

Ahmed Hendawi, *Pfizer, Inc.*

Sophia Arackal, *Pfizer, Inc.*

Additional Panelist:

Martin Nemeč, *Health Canada*

16:15-16:30 Washingtonian Ballroom D-G

Closing Remarks and Invitation to Bioassays 2025

David Cirelli