

## Bioassays 2025: Scientific Approaches and Regulatory Strategies

### Schedule

Monday, 7 April, 2025

07:00-08:00

[WATCH NOW: Development of a New Class of Target Cell Lines to Evaluate Fc-Mediated Cytotoxicity |](#)  
[Presented by Svar Life Science](#)

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

NOTE: If prompted to login to view the video, enter your CASSS member credentials.

Presented by: Svar Life Science

[Click to Watch Video](#)

08:00-09:00 Washingtonian Foyer

[Registration \(For Workshop Attendees Only\)](#)

Registration will be open until 17:00

09:00-10:30 Lakeside Ballroom I

[Workshop Part I - Introduction to Bioassay Development: CMC Strategy and Practical Application](#)

Workshop Instructors: Patrick Hussman, *AstraZeneca* and Scott Umlauf, *AstraZeneca*

10:30-11:00 Lakeside Foyer

[Networking and Coffee Break](#)

11:00-12:30 Lakeside Ballroom I

[Workshop Part I Continued](#)

Workshop Instructors: Patrick Hussman, *AstraZeneca* and Scott Umlauf, *AstraZeneca*

12:30-13:30 Lakeside Foyer / Ballroom I

[Lunch \(For Full Day Workshop Attendees Only\)](#)

13:30-15:00 Lakeside Ballroom I

[Workshop Part II - Practical Applications for Method Design and Performance](#)

Workshop Instructors: Tara Stauffer, *Bristol-Myers Squibb Company* and Colleen Santoro, *Bristol-Myers Squibb Company*

15:00-15:30 Lakeside Foyer

[Networking and Coffee Break](#)

15:30-17:00 Lakeside Ballroom I

Workshop Part II Continued

Workshop Instructors: Tara Stauffer, *Bristol-Myers Squibb Company* and Colleen Santoro, *Bristol-Myers Squibb Company*

Tuesday, 8 April, 2025

07:00-07:30

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07:30-08:30 Washingtonian Foyer

Registration

Registration will be open until 17:00.

07:30-08:30 Salons A-C

Breakfast

Networking/Break

Join us for breakfast to start the day! Breakfast will be available until 8:30.

08:30-08:45 Salons D-G

CASSS Welcome and Introductory Comments

IP - In Person

Welcome to Bioassays 2025, thank you for joining us!

08:45-09:30 Salons D-G

Keynote Presentation - The Special World of Bioassay: Key Learnings, Special Situations and Keys to Success

IP - In Person

Keynote Speaker:

Ned Mozier, Ph.D. (*Pfizer, Inc. Retired*)

09:30-10:00 Salons A-C

Networking Break

Networking/Break

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

09:30-10:00 Lakeside Ballroom

New Member Networking Event

Networking/Break

This is open to New Members of CASSS only. If you are a new member, please join us for a networking break where you can meet and mingle with other new members as well as CASSS committee members.

10:00-11:20 Salons D-G

Session I: Bioassays Foundations / Nuts and Bolts of Bioassays

Birgit Schmauser, Tara Stauffer

IP - In Person

Workshop

Session Chair: Tara Stauffer, *Bristol-Myers Squibb Company* and Birgit Schmauser, *BfArM, Federal Institute for Drugs and Medical Devices*

Session Speaker:

A Novel Cell-Based Potency Assay to Measure Cell/Cell Phagocytosis Induced by Antibody-Dependent Cellular Phagocytosis

Lena Knauber, *AbbVie Inc.*

Afucosylation: Potency Evaluation Strategies

Victoria Swiss, *Bristol Myers Squibb*

Of Mice and (Wo)Men

Simone Tomaschek, *Roche Diagnostics GmbH (Germany)*

11:20-11:45 Salons A-C

Networking Break

Networking/Break

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

11:45-12:30 Salons D-G

Session I: Panel Discussion

Birgit Schmauser, Tara Stauffer

IP - In Person

Workshop

Session Chairs: Tara Stauffer, *Bristol-Myers Squibb Company* and Birgit Schmauser, *BfArM, Federal Institute for Drugs and Medical Devices*

Additional Panelist:

Rajesh K. Gupta, *Biologics Quality & Regulatory Consultants, LLC*

12:30-13:45 Salons A-C

Lunch

12:45-13:45 Salons D-G

### Lunch and Learn: Vendor Showcase

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:

BioAgilytix  
acCELLerate  
Catalent  
Labcorp  
Svar Life Science  
Promega Corporation  
Smithers  
LumaCyte, Inc.,  
Stegmann Systems GmbH  
DPX Technologies

13:45-15:05 Salons D-G

### Session II: Bioassay Strategies for Multi-Specific Antibodies

Jill Crouse-Zeineddini, Stephen Hartman  
Workshop

Session Chairs: Jill Crouse-Zeineddini, *Amgen Inc.* and Stephen Hartman, *AbbVie, Inc.*

#### *Session Speakers:*

Navigating the Complexities of Bi-Specifics: Leveraging Bioassays for Product Variant Characterization and Process Development

Yishi Liu, *Genentech, a Member of the Roche Group*

Elranatamab: Bispecific mAb Bioassay Strategy from R&D to Commercialization

Peter Richard, *Pfizer, Inc.*

Bridges Over Montgomery County: Revamping the Potency Specification Strategy for a Complex Modality

Dylan Weil, *AstraZeneca*

15:05-15:50 Salons D-G

### Session II - Panel Discussion

Jill Crouse-Zeineddini, Stephen Hartman

Session Chairs: Jill Crouse-Zeineddini, *Amgen Inc.* and Stephen Hartman, *AbbVie, Inc.*

15:50-16:15 Salons A-C

### Networking Break

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

16:15-17:15 Washingtonian Foyer

Poster Session

Poster Session

16:15-17:15 Lakeside Ballroom

Roundtable Session 1

Poster Session

Table 1 - Let's Brainstorm on Applications of AI for Bioassays

Table 2 - Method Comparability and Method Bridging: Are They the Same Thing?

Table 3 - Life Cycle Management of Reagents and Equipment

Table 4 - Managing the Potency of Your Reference Standards

Table 5 - How Are You Monitoring the Health of Your Bioassay Methods?

17:15-17:25

Transition Time

Head to Salons D-G for the Emerging Professionals Session.

17:25-18:00 Salons D-G

Emerging Professionals Session

Jill Crouse-Zeineddini, Bhavin Parekh

Session Chairs: Jill Crouse-Zeineddini, *Amgen Inc.* and Bhavin Parekh, *Eli Lilly and Company*

Session Panelists:

Development of an in Vitro Bystander Killing Bioassay for ADCs

Andrea Parsons, *Pfizer, Inc.*

Potency Control Strategy for Biotherapeutic Fusion Proteins

Long Zheng, *Bristol-Myers Squibb*

18:00-19:00 Salons 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, 9 April, 2025

07:00-07:30

WATCH NOW: Development of a New Class of Target Cell Lines to Evaluate Fc-Mediated Cytotoxicity | Presented by Svar Life Science

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Presented by: Svar Life Science

[Click to Watch Video](#)

07:30-08:30 Salons A-C

Breakfast

IP - In Person

Join us for breakfast to start the day! Breakfast will be available until 8:30.

07:30-08:30 Washingtonian Foyer

Registration

IP - In Person

*In-Person Registration is open until 16:00 Eastern.*

08:30-09:50 Salons D-G

Session III: Antibody Drug Conjugates

Bhavin Parekh, Scott Umlauf

IP - In Person

Workshop

Session Chairs: Scott Umlauf, *AstraZeneca* and Bhavin Parekh, *Eli Lilly and Company*

*Session Speakers:*

Navigating Complexity: A Strategic Framework for Streamlining and Simplifying Antibody Drug Conjugates Development and Potency Assay Lifecycle Management

Larisa Touloukhonova, *Merck & Co., Inc.*

Inducible Promoter Systems: Pioneering the Future of Bioassay Development for Enhanced Precision Control

Nicole Shi, *Eli Lilly and Company*

Use of High Content Imaging to Enable Cell-Based Potency Assay Development for ADCs

Madhumati Mukherjee, *AstraZeneca*

09:50-10:35 Salons D-G

Session III: Panel Discussion

Bhavin Parekh, Scott Umlauf

IP - In Person

Workshop

Session Chairs: Scott Umlauf, *AstraZeneca* and Bhavin Parekh, *Eli Lilly and Company*

10:35-10:45

Transition Time

Head to the Roundtable and Poster Sessions.

10:45-11:45 Lakeside Ballroom

Roundtable Session 2

Poster Session

Table 1 - Let's Brainstorm on Applications of AI for Bioassays

Table 2 - Method Comparability and Method Bridging: Are They the Same Thing?

Table 3 - Life Cycle Management of Reagents and Equipment

Table 4 - Managing the Potency of Your Reference Standards

Table 5 - How Are You Monitoring the Health of Your Bioassay Methods?

10:45-11:45 Washingtonian Foyer

Poster Session

Poster Session

11:45-12:50 Salons A-C

CASSS Hosted Lunch

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

12:50-14:05 Salons D-G

Session IV: Emerging Technologies / Innovations in Bioassays

David Cirelli, Adelheid Rohde

IP - In Person

Workshop

Session Chairs: David Cirelli, *Pfizer, Inc.* and Adelheid Rohde, *F. Hoffmann-La Roche Ltd.*

Session Speakers:

MoA-Reflective Bioassays for Next-Gen QC Testing

Ayumi Takayanagi, *Chugai Pharmaceutical Co., Ltd.*

Development of Cell-based Potency Assays For a Novel Immunostimulatory Drug Conjugate

Marshall Davis, *Pfizer, Inc.*

Development of Fc-Receptor Bioassays to Unravel the Impact of Glycosylation

Caterina Giorno and Daniel Marx, *Boehringer Ingelheim Pharma GmbH & Co. KG*

14:05-14:50 Salons D-G

Session IV: Panel Discussion

David Cirelli, Adelheid Rohde

Session Chairs: David Cirelli, *Pfizer, Inc.* and Adelheid Rohde, *F. Hoffmann-La Roche Ltd.*

14:50-15:20 Salons A-C

Networking Break

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

15:20-16:35 Salons D-G

Session V: Cell and Gene Therapy and More!

Martin Nemec, Tara Stauffer

IP - In Person

Workshop

Session Chairs: Martin Nemec, *Health Canada* and Tara Stauffer, *Bristol-Myers Squibb Company*

Session Speaker:

Overcoming Challenges in Potency Bioassay Development: A Case Study on an Immunostimulatory Virus-Like Particle Investigational Drug

Cristinel Sandu, *Regeneron Pharmaceuticals*

Uniting for Success: Collaboration between Analytics, Research and Process Development for a CAR Potency Assurance Strategy

Sonia Connaughton, *Sanofi*

Bridging Potency: Implementation of AAV Infectivity by Viral Entry Assay

Ting He, *Ultragenyx Pharmaceutical Inc.*

16:35-17:20 Salons D-G

Session V: Panel Discussion

Martin Nemec, Tara Stauffer

Session Chairs: Martin Nemec, *Health Canada* and Tara Stauffer, *Bristol-Myers Squibb Company*

17:20-17:30 Salons D-G

Closing Remarks and Invitation to Bioassays 2026