

# Bioassays 2026: Scientific Approaches and Regulatory Strategies

Schedule

Monday, 27 April, 2026

08:30-09:00 Washingtonian Foyer

## Registration For Short Course Attendees Only.

Presentation type: IP - In Person

Registration will be open until 17:00

08:30-09:00 Lakeside Ballroom

## Short Course Information

Presentation type: IP - In Person

You do not need to be registered for the Symposium to participate in the Short Course. We highly encourage attendees to participate in both the Symposium and Short Course to maximize their bioassay learning experience. Registration for the short course is not included in the Symposium registration fee. The Short Course requires an additional registration, which can be added to your Symposium registration at the time of purchase.

The morning session on "Introduction to Bioassay Development: CMC Strategy and Practical Application" provides practical knowledge on bioassay method development, with a particular emphasis on potency assays. The afternoon session on "Practical Applications for Method Design and Performance" allows participants to work collaboratively on case studies relevant to current challenges in bioassay development, deployment, and lifecycle.

09:00-10:30 Lakeside Ballroom

## Short Course Part I - Introduction to Bioassay Development: CMC Strategy and Practical Application

Presentation type: IP - In Person

The morning session 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.

Short Course Instructors:

Patrick Hussman, *AstraZeneca*

Scott Umlauf, *AstraZeneca*

10:30-11:00 Lakeside Foyer

## Networking and Coffee Break

Presentation type: IP - In Person

11:00-12:30 Lakeside Ballroom

## Short Course Part I Continued

Presentation type: IP - In Person

The morning session 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.

Short Course Instructors:

Patrick Hussman, *AstraZeneca*

Scott Umlauf, *AstraZeneca*

12:30-13:30 Lakeside Foyer

## Lunch For Full Day Short Course Attendees Only.

Presentation type: IP - In Person

13:30-15:00 Lakeside Ballroom

Short Course Part II - Practical Applications for Method Design and Performance

Presentation type: IP - In Person

In this interactive afternoon 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.

Short Course Instructors:

Isam Qahwash, *Bristol-Myers Squibb Company*

Victoria Swiss, *Bristol-Myers Squibb Company*

15:00-15:30 Lakeside Foyer

Networking and Coffee Break

Presentation type: IP - In Person

15:30-17:00 Lakeside Ballroom

Short Course Part II Continued

Presentation type: IP - In Person

In this interactive afternoon 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.

Short Course Instructors:

Isam Qahwash, *Bristol-Myers Squibb Company*

Victoria Swiss, *Bristol-Myers Squibb Company*

Tuesday, 28 April, 2026

07:00-08:00 Washingtonian Foyer

Registration

Presentation type: IP - In Person

Registration will be open until 17:00.

07:00-08:00 Salons A-C

Breakfast

Presentation type: IP - In Person

Join us for breakfast to start the day! Breakfast will be available until 8:00.

08:00-08:15 Salons D-G

CASSS Welcome and Introductory Comments

Presentation type: LS - Livestreamed

Welcome to Bioassays 2026, thank you for joining us!

08:15-09:15 Salons D-G

Joint Keynote Presentation - Hindsight is 20/20: 50 Years of Combined Bioassay Experiences

Presentation type: LS - Livestreamed

Keynote Speaker:

Nadine Ritter, *Global Biotech Experts, LLC*

and

Chana Fuchs, *Retired from the FDA*

09:15-09:45 Salons A-C

Networking Break

Presentation type: IP - In Person

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

09:15-09:45 Lakeside Ballroom

### First Time Attendee Networking Event

Presentation type: IP - In Person

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 meet and mingle with other new members as well as CASSS committee members.

09:45-11:25 Salons D-G

### Session I - Nuts and Bolts of Bioassays

Sonia Connaughton, Jyoti Velayudhan

Presentation type: LS - Livestreamed

Session Speakers:

Nutty About Potency: Bolting Down a Robust Late-Stage Relative Potency Assay

Erika Farmer, *AstraZeneca*

Better Lifecycle Quality—Powered by Reagent Management

Yukina Umemoto, *Chugai Pharmaceutical Co., Ltd.*

Plug and Play Potency: Platform Binding Assay Strategies for Rapid Method Development

Sarah Owen, *Pfizer, Inc.*

Advancing Cell-Based Potency Assays: Strategies and Challenges in Developing a Robust Functional Assay for Monoclonal Antibody

Arkadi Manukyan, *Sanofi*

11:25-11:35 Salons A-C

### Networking Break

Presentation type: IP - In Person

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

11:35-12:20 Salons D-G

### Session I: Panel Discussion

Sonia Connaughton, Jyoti Velayudhan

Presentation type: LS - Livestreamed

12:20-13:35 Salons A-C

### Lunch

Presentation type: IP - In Person

12:35-13:35 Salons D-G

### Lunch and Learn: Designing Robust Cell-Based Potency Assays: Strategic Frameworks and Emerging Biological Readouts | Presented by Catalent Pharma Solutions

Presentation type: LS - Livestreamed

Session Speaker:

Pedro Morales, *Catalent Pharma Solutions*

13:35-14:05 Lakeside Foyer

### Poster Session

Presentation type: IP - In Person

14:05-14:10

### Transition Time

Presentation type: IP - In Person

14:10-15:10 Lakeside Ballroom

### Roundtable Session 1

Presentation type: IP - In Person

Table 1 - Method Comparability Considerations

Table 2 - Platform Methods: Practical Considerations for the Implementation of Updated ICH Q14, ICH Q2, and USP <1220>

Table 3 - Learnings From Bioassay Transfers

Table 4 - Product Characterization and Role of Your Potency Assays

Table 5 - Brainstorming on Applications of AI

15:10-15:15

### Transition Time

Presentation type: IP - In Person

15:15-16:30 Salons D-G

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

Jill Crouse-Zeineddini, Thomas Millward, Adelheid Rohde

Presentation type: LS - Livestreamed

Session Speakers:

Challenges and Strategies for Potency Assay Development in High-Valency Vaccines

Milica Grozdanovic, *Merck & Co., Inc.*

Advancing Drug Development: Utilizing T-cell Activation Reporter Gene Assays for Potency Monitoring from the Pre-Clinical to the Commercial Stages

Felix Feng, *AstraZeneca*

Managing Variability in Cell-Based Potency Assays: Science, Statistics, and Lifecycle Control

Ravish Patel, *Nirma University*

16:30-16:40 Salons A-C

### Networking Break

Presentation type: IP - In Person

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

16:40-17:25 Salons D-G

### Session II - Panel Discussion

Thomas Millward, Adelheid Rohde

Presentation type: LS - Livestreamed

17:25-18:30

### Exhibitor Reception

Presentation type: IP - In Person

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, 29 April, 2026

07:30-08:30 Washingtonian Foyer

### Registration

Presentation type: IP - In Person

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

07:30-08:30 Salons A-C

### Breakfast

Presentation type: IP - In Person

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

08:30-09:45 Salons D-G

### Session III - Antibody Drug Conjugates

Stephen Hartman, Birgit Schmauser, Nailing Zhang

Presentation type: LS - Livestreamed

Session Speakers:

ADC Potency Strategy and Structure-Function Studies

Ganesh Shankarling, *Bristol-Myers Squibb Company*

Developing a Potency Strategy for a Novel Antibody-drug Conjugate

Swayam Prabha, *Genentech, a Member of the Roche Group*

CMC Regulatory Considerations for Antibody-Drug Conjugates (ADCs) – From the Biologics Perspective

Lei Zhang, CDER, FDA

09:45-09:55 Salons A-C

### Networking Break

Presentation type: IP - In Person

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

09:55-10:40 Salons D-G

### Session III - Panel Discussion

Birgit Schmauser, Nailing Zhang

Presentation type: LS - Livestreamed

10:40-10:45

### Transition Time

Presentation type: IP - In Person

10:45-11:45 Lakeside Ballroom

### Roundtable Session 2

Presentation type: IP - In Person

Table 1 - Method Comparability Considerations

Table 2 - Platform Methods: Practical Considerations for the Implementation of Updated ICH Q14, ICH Q2, and USP <1220>

Table 3 - Learnings From Bioassay Transfers

Table 4 - Product Characterization and Role of Your Potency Assays

Table 5 - Brainstorming on Applications of AI

Table 6 - How Can We Enable Career Development for Young Scientists?

11:45-13:00 Salons A-C

### CASSS Hosted Lunch

Presentation type: IP - In Person

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

12:00-13:00 Salons D-G

### Lunch and Learn: Vendor Showcase

Presentation type: LS - Livestreamed

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  
Catalent  
Promega Corporation  
acCELLerate  
Custom Biologics  
Charles River  
Stegmann Systems GmbH  
Labcorp  
Svar Life Science

13:00-14:15 Salons D-G

### Session IV - Innovations in Bioassays

Stephen Hartman, Bhavin Parekh, Victoria Swiss

Presentation type: LS - Livestreamed

Session Speakers:

In Vitro Alternative Assays to Cell-Based Potency Assays: Regulatory Considerations for Biologics

Nailing Zhang, *FDA, CDER*

Navigating Critical Reagent Challenges in Cell-Based Potency Assays: Case Studies on Variability and Solutions

Bhoomi Patel, *BioAgilytix Labs, LLC*

Considerations and Analytical Control Strategies for Half-life Extension of Biotherapeutics

Zhijie (Jey) Cheng, *Merck & Co., Inc.*

14:15-14:25 Salons A-C

### Networking Break

Presentation type: IP - In Person

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

14:25-15:10 Salons D-G

### Session IV - Panel Discussion

Stephen Hartman, Victoria Swiss

Presentation type: LS - Livestreamed

15:10-15:40 Washingtonian Foyer

### Poster Session

Presentation type: IP - In Person

15:40-16:55 Salons D-G

### Session V - Data Science in Bioassays

Bhavin Parekh, Scott Umlauf

Presentation type: LS - Livestreamed

Session Speakers:

Potency Assay Generated Data - Is It a Minefield or a Knowledge Bank and Are They Useable

Jan Amstrup, *Novo Nordisk*

Potency Assay Data Engineering

Ryan Spooner, *Amgen Inc.*

Investigating the Source of Non-Parallelism in Forced Degraded Antibody-RNA Conjugates

Alexa Mealy, *Eli Lilly and Company*

16:55-17:05 Salons A-C

Networking Break

Presentation type: IP - In Person

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

17:05-17:50 Salons D-G

Session V - Panel Discussion

Bhavin Parekh, Scott Umlauf

Presentation type: LS - Livestreamed

17:50-18:00 Salons D-G

Closing Remarks and Invitation to Bioassays 2027

Presentation type: LS - Livestreamed