Bioassays 2023

April 17-19, 2023

Workshop: Potency Assay Strategies for Biopharmaceuticals and for CGT Therapeutics

13:00 - 17:00
Monday, April 17, 2023
Location Lakeside Ballroom 1
Co-Chairs Michael Sadick, Jyoti Velayudhan

CASSS Welcome and Introductory Comments

08:30 - 08:45
Tuesday, April 18, 2023
Location Washingtonian Ballroom D-G

Keynote: "Bioassays: The Superstar of Drug Development"

08:45 - 09:30
Tuesday, April 18, 2023
Location Washingtonian Ballroom D-G

Speaker: Helena Madden, *bluebird bio, inc.*

Networking Break

09:30 - 10:00
Tuesday, April 18, 2023
Location Washingtonian Ballroom A-C

New Member Networking Break

09:30 - 10:00
Tuesday, April 18, 2023
Location Lakeside Ballroom 1

First time attendees and New Members should take this fun opportunity to mingle and meet others within the CASSS Community.

Workshop Session I: Nuts and Bolts of Bioassays

10:00 - 11:45
Tuesday, April 18, 2023
Location Washingtonian Ballroom D-G

Co-Chairs Jill Crouse-Zeineddini, Stephen Hartman, Katrin Buss

Bioassays are one of the more complex assays used to support therapeutic product development. As such, the practical elements of bioassays (the “nuts and bolts”) can also be complex. These elements can range from the critical reagents selected for use in the bioassay (e.g.-cell line(s), recombinant proteins, serum) to assay formats (e.g.-dual cell-based cytotoxicity assays, single cell-based reporter gene assays, non cell-based binding assays), to the data analysis model selected (e.g.-4 -parameter logistic curve fit, 5-parameter curve fit). The sustainability of these “nuts and bolts” is vital to establishing and maintaining bioassays over the lifecycle of a therapeutic product. This session will focus on different practical elements of bioassays and their impact on establishing desired method performance.

Speakers:

From Research to Market: The Evolving Assay Strategy of a Bi-Specific Antibody
Alexandre Briguet, *F. Hoffmann-La Roche AG*

A Tale of Two Readouts
Nancy Sajjadi, *Sajjadi Consulting*

Calculating Non-constant Relative Potency
Paul Faya and Wendy Walton, *Eli Lilly and Company*

Surface Plasmon Resonance: Reagent Screening for Product Quality Assessments and Assay Development
Kevin Whang, *Genentech, a Member of the Roche Group*

Networking Break

11:45 - 12:00
Tuesday, April 18, 2023
Location Washingtonian Ballroom A-C

Workshop Session I: Panel Discussion

12:00 - 13:00
Tuesday, April 18, 2023
Location Washingtonian Ballroom D-G
Co-Chairs Katrin Buss, Stephen Hartman, Jill Crouse-Zeineddini

Additional Panel Member:

Helena Madden, bluebird bio, Inc.

Lunch and Learn: Vendor Showcase

13:00 - 14:00
Tuesday, April 18, 2023
Location Washingtonian Ballroom D-G

Networking Break

14:00 - 14:30
Tuesday, April 18, 2023
Location Washingtonian Ballroom A-C

Workshop Session II: Bioassays for Vaccines and Anti-Infective Therapies

14:30 - 15:50
Tuesday, April 18, 2023
Location Washingtonian Ballroom D-G
Co-Chairs David Cirelli, Scott Umlauf

Development of Potency Assays for vaccines and anti-infective biologics can present a unique set of challenges. As the human immune system is complex, frequently the full mechanism of protection is not known, so best judgment must be used to select a mechanism for a representative potency assay. This is particularly true for novel vaccine technology (e.g., mRNA, nanoparticles) and pandemic response, both of which have occurred in the last few years. The talks in this session will provide insight into the approaches of multiple teams to address these challenges, including use of modern potency techniques where feasible.

Key questions to address:

1. How to select the assay format: e.g. in vitro vs. in vivo?

2. What is the minimum requirement for correlation of in vitro and in vivo data?

3. For genetic vaccines, can in vitro expression be assumed to reflect immunogenicity?

4. For new vaccine technology, applied in an established space, such as influenza, how best to introduce modern potency assay techniques?

5. Given the challenge of strain updates and multivalent strategies, what approaches can be taken to “platform” release methods so that assays for new strains can be quickly validated?

6. What lessons from efforts undertaken to rapidly respond to the pandemic may be applied to other programs?

Speakers:

In-vitro Expression Assay (IVE) for Potency Expression of mRNA Vaccine Product
Yana Miteva, *Pfizer Inc.*

Development of a Reporter Cell Line and Assay for Merck’s Ebola Vaccine (rVSV-ΔG-ZEBOV-GP)
Brian Meyer, *Merck & Co. Inc.*

EVUSHELD: Delivering Bioassay Methods and Critical Regents Under Highly Accelerated Timelines from Clinical to Commercial Phases
LeeAnn Machiesky, *AstraZeneca*

Networking Break

15:50 - 16:20
Tuesday, April 18, 2023
Location Washingtonian Ballroom A-C

Workshop Session II - Panel Discussion

16:20 - 17:20
Tuesday, April 18, 2023
Location Washingtonian Ballroom D-G
Co-Chairs David Cirelli, Scott Umlauf

Additional Panel Members:

Arno Kromminga, *BioNTech*

Xiao Wang, *CBER, FDA*

Exhibitor and Poster Reception

17:20 - 18:30
Tuesday, April 18, 2023
Location Washingtonian Ballroom A-C
.

Workshop Session III: Bioassays for Cell and Gene Therapeutics

08:30 - 10:15
Wednesday, April 19, 2023
Location Washingtonian Ballroom D-G
Co-Chairs Bhavin Parekh, Michael Sadick, Xu-Rong Jiang

Cell and Gene Therapies (CGT) are transforming not just how humans treat genetic and intractable diseases but are altering the entire pharmaceutical ecosystem. CGT are rapidly becoming established as the new wave of biological therapeutics with autologous or allogeneic engineered cells as the active therapeutic (Cell Therapy), or the gene delivery system (Gene Therapy; e.g., LNP's, AAV's, etc.). More than 18 CTx or GTx products were approved by US FDA in 2020. Around 990 companies are engaged in R&D and commercialization of next-generation CGT. In short, CGT is in the process of becoming a mainstream.

Compared to other biological such as mAbs, BsAbs and proteins, CGT therapeutics are much more complex both physically and biologically, and present specific challenges for developing in vitro potency assays due to their complex mechanisms of action, complicated manufacturing processes and variable critical quality attributes (CQAs). This session will explore considerations and case studies demonstrating strategies of dealing with these biological complexities throughout the product life cycle.

Speakers:

Potency Bioassays for Cell and Gene Therapy Products
Matthew Klinker, *CBER, FDA*

Development of Flow Cytometry-Based Methods for Release and Characterization of CAR-T Products
Jen Fox, *AstraZeneca*

Development of a Cytotoxicity Method for the Measurement of CAR-T Drug Product Killing Activity
Serena Hamada, Bristol-Myers Squibb Company

Versatile Potency Assay for AAV Gene Therapy Drug Product
Dan Lee, *Novartis*

Networking Break

10:15 - 10:30
Wednesday, April 19, 2023
Location Washingtonian Ballroom A-C

Workshop Session III: Panel Discussion

10:30 - 11:30
Wednesday, April 19, 2023
Location Washingtonian Ballroom D-G
Co-Chairs Xu-Rong Jiang, Bhavin Parekh, Michael Sadick

Poster Session

11:30 - 12:15
Wednesday, April 19, 2023
Location Washingtonian Ballroom A-C

Hosted Lunch

12:15 - 13:15
Wednesday, April 19, 2023
Location Washingtonian Ballroom Foyer

Workshop Session IV: Process Improvements/Innovation in Bioassays

13:15 - 15:00
Wednesday, April 19, 2023
Location Washingtonian Ballroom D-G
Co-Chairs Adelheid Rohde, Thomas Millward, Tara Stauffer

There are several drivers behind the need for process improvements and innovation in the CMC bioassay space. Most organizations experience a constant pressure to reduce cost, increase throughput, and be more efficient. Sometimes, there is a need or a strong desire to improve a bioassay by making it more accurate, precise, or robust. And in some cases, bioassay innovation is driven by the drug itself: for example, by the need to adequately capture increasingly complex modes of action in simple model systems, characterize specific attributes, or the requirement to distinguish the effects of different drug molecules. At the same time, improvements and innovations need to be designed and executed so as to ensure data integrity, using instrumentation and procedures that are transferrable to a QC testing lab. Navigating these different needs and constraints can be challenging. In this session, we will focus on how different organizations have approached and balanced these challenges.

Speakers:

Expectations on Potency Assays for Antibody-based Novel Modalities - A Regulatory Perspective
Nailing Zhang, *CDER, FDA*

Simulation Tool to Optimize and Validate Bioassay Control Strategy
Tillman Polonio-Vallon, *Abbvie, Inc.*

Novel Fluorescence-Linked Immunosorbent Assay to Evaluate Bispecific Antibody Potency
Patrick Wong, *Bristol-Myers Squibb Company*

Real-time Bioassay Analysis for Potency Determination using xCelligence
Daniel Markx, *Boehringer Ingelheim Pharma GmbH & Co. KG*

Networking Break

15:00 - 15:15
Wednesday, April 19, 2023
Location Washingtonian Ballroom Foyer

Workshop Session IV: Panel Discussion

15:15 - 16:15
Wednesday, April 19, 2023
Location Washingtonian Ballroom D-G
Co-Chairs Tara Stauffer, Adelheid Rohde, Thomas Millward

Additional Panel Member:

Marianne Hayes, *Janssen Research & Development*

Closing Remarks and Invitation to Bioassays 2024

16:15 - 16:30
Wednesday, April 19, 2023
Location Washingtonian Ballroom D-G