11th Annual

US Bioassay Conference

March 8-10, 2027

All times are in Eastern Time
Hybrid Conference | College Park, Maryland

Day 1 | Monday, March 8

8:00 Check-In for in-Person Attendees

Session 1: US Regulatory Insights

(All Attendees Welcome)
Session Chair: *Laureen Little, BEBPA*

9:00 Welcome and Logistics

9:15 Session Chair Introduction and Audience Survey

9:30 CBER Perspective on Bioassays
Invited US FDA Speaker

10:00 Recognizing a Mistake the Second Time You See It! - 60 Combined Years of Bioassay "Prior Knowledge"
Chana Fuchs, Retired, US FDA & Nadine Ritter, President, Global Biotech Experts, LLC

10:30 Connection Break

11:00 Update on USP Bioassay Chapters
Walter Hauck, US Pharmacopeia

11:30 Q&A Panel Discussion

12:00 Scientific Poster Session

12:45 Hosted Lunch

Session 2: Devloping, Validating and Transferring Biological Assays

(All Attendees Welcome)
Session Chair: *To Be Announced*

2:00 Session Introduction

2:15 Development, Qualification, and Validation of Filovirus (EBOV, SUDV, MARV, and BDBV) ELISAs
Tom Rudge, Senior Research Scientist, Battelle

2:45 A Novel Multiplexed Target Binding Method for Potency Evaluation of Multi-Specific Biologics
Long Zheng, Senior Scientist, Bristol Myers Squibb

3:15 Connection Break

3:45 The Ins and Outs of Ratios in Bioassays: Statistical Problems vs Biological Problems
Invited US FDA Speaker

4:15 Q&A Panel Discussion

4:45 Platinim Exhibitor Introduction

5:00 Conference Day Adjourns

5:00 Welcome Mix & Mingle Reception

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Day 2 | Tuesday, March 9

8:00 Check-In for in-Person Attendees

9:00 Concurrent In-Person Education Sessions

Education Session 1:
Bioassay Technical Transfer to a Quality Control or Contract Laboratory
Leaders: *To Be Announced*

9:00 Introduction and Audience Survey

10:30 Connection Break

12:00 Education Session Adjourns

Education Session 2:
Statistical Process Control
Leaders: *To Be Announced*

9:00 Introduction and Audience Survey

10:30 Connection Break

12:00 Education Session Adjourns

10:30 Connection Break

12:00 Hosted Lunch

Session 3: Establishing Product Potency Specification

(All Attendees Welcome)
Session Chair: *To Be Announced*

1:30 Welcome, Logistics and Audience Survey

1:45 Potency Assay Considerations for Biotechnology Products
Invited US FDA Speaker

2:15 Challenges and Considerations in Establishing DP Potency Specifications for ATMPs
Gregory Wood, Director, Autolus Therapeutics plc

2:45 Life Cycle of Your Reference Material and Other Critical Rare Reagents
Invited US FDA Speaker

3:15 Q&A Panel Discussion

3:30 Connection Break

Session 4: Control Strategies for Various Therapeutic Modalities

(All Attendees Welcome)
Session Chair: *To Be Announced*

4:00 Structure–Function Studies Enable a Phase-Appropriate Potency Control Strategy for Therapeutic Antibodies
Speaker To Be Announced

4:30 Potency Assurance Strategy for iPSC-Derived Therapies
Speaker To Be Announced

5:00 Q&A Panel Discussion

5:30 Conference Day Adjourns

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Day 3 | Wednesday, March 10

8:00 Check-In for in-Person Attendees

9:00 In-Person Education Sessions

Education Session 3:
FDA Reviewer Hot Topics
Leaders: *To Be Announced*

9:00 Introduction and Audience Survey

10:30 Connection Break

12:00 Education Session Adjourns

10:30 Connection Break

12:00 Hosted Lunch

Session 5: Commercial Readiness

(All Attendees Welcome)
Session Chair: *To Be Announced*

1:30 Welcome, Logistics and Audience Survey

1:45 Late-Stage Bioassay Development - Avoiding Post Registration Changes
Lasse Waehrens, Senior Research Scientist, Novo Nordisk

2:15 From ELISA to FRET: A Case Study in Transitioning a Potency Assay for Late-Stage Development and Commercial Readiness
Emma Walen, Scientist I, Biogen

2:45 Connection Break

3:15 Navigating Analytical Method Transfer for Biologics: Scientific and Regulatory Alignment with USP <1224>
Invited US FDA Speaker

3:45 Q&A Panel Discussion

4:15 Closing Comments

4:45 Conference Day Adjourns