



# 9th Annual US Bioassay Conference

March 24-26, 2025

Hybrid Conference  
Marriott Tucson University Park Hotel  
Tucson, Arizona

## Day 1 | Monday, March 24

All times are in Pacific Daylight Time  
Slides not available for distribution are highlighted in **RED**

**8:00** Check In for In-Person Attendees

### Session 1A: Regulatory Update

(All Attendees Welcome)

**Session Chair:** To Be Announced

**9:00** Welcome Comments and Logistics

**9:15** Session Introduction and Audience Survey

#### Podium Talks Now Being Recruited:

- FDA Potency Product Guidances Update
- Impact of New ICH Guidance Documents

**10:30** Q&A

**10:45** Morning Break

### Session 1B: Phase Appropriate Assay Validation and Optimization

(All Attendees Welcome)

**Session Chair:** To Be Announced

#### Case Study Podium Talks Now Being Recruited

**12:15** Q&A

**12:30** Panel Discussion

**1:00** Lunch

**2:30** In-Person Interest Groups

**3:30** Afternoon Break

**4:00** In-Person Interest Groups

**5:00** Conference Day 1 Adjourns

**5:15** Networking Welcome Reception

### In-Person Interest Group

(In-Person Attendees Only)

#### Interest Group 1: Transitioning From Early Stage Proof of Concept Assays to Releasing Clinical Material

**Location:** To Be Announced

Combination of discussions and presentations. Please submit case studies on these topics for inclusion.

**2:30** Interest Group (Part 1)

**3:30** Afternoon Break

**4:00** Interest Group (Part 2)

#### Interest Group 2: Regulatory Audit Trends for Potency Assays

**Location:** To Be Announced

Combination of discussions and presentations. Please submit case studies on these topics for inclusion.

**2:30** Interest Group (Part 1)

**3:30** Afternoon Break

**4:00** Interest Group (Part 2)



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## Day 2 | Tuesday, March 25

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### Session 2A: Automation of Cell Based Potency Assays

(All Attendees Welcome)

**Session Chair:** To Be Announced

**8:30** Session Introduction and Audience Survey

**Case Study Podium Talks Now Being Recruited:**

- Automation in Cell Cultures
- Data Analysis Automation

**10:00** Q&A

**10:15** Morning Break

### Session 2B: Managing your Potency Assays in the Real World

(All Attendees Welcome)

**Podium Talks Now Being Recruited:**

- Bridging of Continuous Culture to FRTU Cells
- Critical Reagent Management

**12:15** Lunch

**1:45** In-Person Interest Groups

**3:30** Afternoon Break

**4:00** In-Person Interest Groups

**5:30** Conference Day 2 Adjourns

### In-Person Interest Group

(In-Person Attendees Only)

#### Interest Group 3: Cell and Gene Therapy

**Location:** To Be Announced

Combination of discussions and presentations. Please submit case studies on these topics for inclusion.

**2:30** Interest Group (Part 1)

**3:30** Afternoon Break

**4:00** Interest Group (Part 2)

#### Interest Group 4: Recombinant Protein Products

**Location:** To Be Announced

Combination of discussions and presentations. Please submit case studies on these topics for inclusion.

**2:30** Interest Group (Part 1)

**3:30** Afternoon Break

**4:00** Interest Group (Part 2)



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## Day 3 | Wednesday, March 26

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### Session 3A: New Technology

(All Attendees Welcome)

**Session Chair:** To Be Announced

**8:30** Session Introduction and Audience Survey

**Case Study Podium Talks Now Being Recruited:**

- Artificial Intelligence
- Organ-On-A-Chip

**10:00** Q&A

**10:15** Morning Break

### Session 3B: Reference Material

(All Attendees Welcome)

**Podium Talks Now Being Recruited:**

- Bridging References in Early and Late Stage Clinical Development
- Implementing a Two-Tier Reference System

**12:15** Lunch

**1:45** In-Person Interest Groups

**3:30** Afternoon Break

**4:00** In-Person Interest Groups

**5:30** Conference Day 2 Adjourns

### In-Person Interest Group

(In-Person Attendees Only)

#### Interest Group 5: Meeting of Statistical Interest Group (Discussion of Free Webinar)

**Location:** To Be Announced

Combination of discussions and presentations. Please submit case studies on these topics for inclusion.

**2:30** Interest Group (Part 1)

**3:30** Afternoon Break

**4:00** Interest Group (Part 2)

#### Interest Group 6: Stability Indicating Properties of Potency Assays

**Location:** To Be Announced

Combination of discussions and presentations. Please submit case studies on these topics for inclusion.

**2:30** Interest Group (Part 1)

**3:30** Afternoon Break

**4:00** Interest Group (Part 2)