

APA 2022 CONFERENCE AGENDA

DAY 1: Monday, Sept. 19

Regulated Bioanalysis Workshop

7:00 - 8:00 AM **Registration**
8:00 - 8:10 AM **Workshop Introduction**
Ang Liu, Daiichi Sankyo

11:20 - 11:40 AM **Capacity and Supply Chain Capabilities**
Christine Callahan, ThermoFisher
11:40 - 11:45 AM **Q & A**

SESSION I: The State of the FDA: Guidance, Approval, and Beyond

8:10 - 8:15 AM **Session Introduction**
Ang Liu, Daiichi Sankyo & Joe Tweed, Bicycle Therapeutics

8:15 - 8:40 AM **State of the FDA - Overview of Recent Guidances**
Brian Booth, FDA
8:40 - 8:45 AM **Q & A**

8:45 - 9:20 AM **PLENARY: Clinical Pharmacology of ADCs: Critical Bioanalytical Role**
Malaz Abutarif, Daiichi Sankyo
9:20 - 9:25 AM **Q & A**

9:25 - 10:00 AM **State of the FDA - Antibody Drug Conjugates**
Salaheldin Hamed, FDA
10:00 - 10:05 AM **Q & A**

10:05 - 10:30 AM **Panel Discussion: ICH M10**
Brian Booth, Malaz Abutarif, Jennifer Zimmer & Jenifer Vija, Salahedin Hamed

10:30 - 10:50 AM **VENDOR PRESENTATION: Bioanalytical, Biotherapeutic and Biomarker Analysis in Drug Development: Challenges and Solutions**
Kenneth Swart, Inotiv
10:50 - 10:55 AM **Q & A**

10:55 - 11:15 AM **Break**

SESSION II: Roadmap To the Approval of COVID 19 Treatments & Testing

11:15 - 11:20 AM **Session Introduction**
James Schiller, Merck

SPONSOR SHOWCASE

12:05 - 12:25 PM **Application of Micro-Sampling Device, Tasso M20 in Pfizer's COVID-19 Therapeutic Drug Paxlovid Development**
Haihong Shi, Pfizer
12:25 - 12:30 PM **Q & A**

12:30 - 12:50 PM **Preclinical Bioanalytical Challenges in Supporting the Covid-19 Oral Antiviral, Molnupiravir, during a Pandemic**
Sheila Breidinger, Merck
12:50 - 12:55 PM **Q & A**

12:55 - 1:55 PM **LUNCH**

Session III: Immunogenicity and Bioanalytical Considerations

1:55 - 2:00 PM **Session Introduction**
Darshana Jani, Moderna & Jenifer Vija, CRL

2:00 - 2:20 PM **Practical Considerations for Neutralizing Antibody Assay Development**
Jason DelCarpini, Moderna
2:20 - 2:25 PM **Q & A**

2:25 - 2:45 PM **Recommendations for Harmonization of Anti-Drug Antibody Sample Testing and Reporting**
Michele Gunsior, Astria
2:45 - 2:50 PM **Q & A**

2:50 - 3:10 PM **Recommendations for Development and Validation of qPCR Assays for Regulated Bioanalysis**
Amanda Hays, BioAgilityx
3:10 - 3:15 PM **Q & A**

3:15 - 3:35 PM **Break**

Session IV: Emerging Technologies for New Modalities & Biomarkers

- 3:35 - 3:40 PM **Session Introduction**
Lori Payne, Alturas Analytics & Yongjun Xue, BMS
- 3:40 - 4:00 PM **The Promise of Peptide-oligonucleotide Conjugates for Neuromuscular Diseases**
Pallavi Lonkar, PepGen
- 4:00 - 4:05 PM **Q & A**
- 4:05 - 4:25 PM **Use of 1 β -Hydroxydeoxycholic Acid as a Potential Biomarker for Assessment of CYP3A DDI Activity**
Yongjun Xue, BMS
- 4:25 - 4:30 PM **Q & A**
- 4:30 - 5:45 PM **Reception & Posters**