



**OCTOBER 1-3, 2018**  
SHORT COURSES - SEPTEMBER 30

**SHERATON BOSTON HOTEL**  
39 DALTON STREET • BOSTON, MA 02199

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# WELCOME TO APA 2018!

## MONDAY, OCTOBER 1

**REGISTRATION & Breakfast**  
Workshop Introduction

### REGULATED BIOANALYSIS

#### SESSION I: Regulatory Guidance

Common BA/BE Inspection Observations and their Mitigation Strategies  
Arindam Dasgupta, FDA

Recent Inspectorial Observations on Immunogenicity  
Michael F. Skelly, FDA

Unique Aspects and Case Studies of Bioanalysis in Support of Veterinary Products  
Valerie Kvaternick, Merial

#### Panel Discussion

#### SESSION II: Bioanalytical Support for Novel Therapies

CART-ography: Lessons Learned from the Analytical Characterization of the First Two FDA Approved Chimeric Antigen Receptor Therapies  
Sadik Kassim, MustangBio

When the Cell is the Drug, Challenges for Bioanalysis  
Keith Sutton, Charles River Laboratories UK

Bioanalytical Support for Gene Therapy Program Using AAV Delivery Vectors  
Lilia Macovei, Pfizer

Development of a Robust Neutralizing Antibody (NAb) Assay with High Drug and Target Tolerance to Support Clinical Development of an anti-TFPI Therapeutic Monoclonal Antibody (mAb)  
Yuhong Xiang, Pfizer

#### SESSION III: Challenges of Immunogenicity in a Regulated Environment

Monitoring the Function of Single Immune Cells – How to Tackle Daunting Task and Apply Cutting-Edge Developments for Obtaining Meaningful Data  
Sylvia Janetz, Zellnet Consulting

Cell Line Characterization to Support Immunogenicity Testing  
Cynthia Inzano, BMS

Navigating the Development and Validation of Neutralizing Antibody Assays in Support of Biosimilar Assessment  
Dominique Gouty, BioAgilytix Labs

#### Poster Session & Evening Reception

### MECHANISTIC ADME WORKSHOP

**REGISTRATION & Breakfast**  
Workshop Introduction

**SESSION I: Toxicology, Clinical Safety Prediction, and SM Biomarkers**

#### Plenary Lecture:

Safety Lead Optimization: What We have Learned from Kinase Inhibitors  
Donna Dambach, Genentech

Systems Approaches to Translation of Preclinical Safety Signals to Inform Compound Discovery and Early Development  
Jay Mettetal, AstraZeneca

An ADME Perspective on DILI Hazard Identification  
Debra Luffer-Atlas, Eli Lilly

Discovery Toxicology: Input and Impact in Early Drug Development  
Yvonne Dragan, Takeda

#### SESSION II: Unusual Metabolic Pathways: Time to Expect the Unexpected?

Systematic Characterization of Uncommon Metabolites: Case Studies with Paritaprevir and Ombitasvir  
Jianwei Shen, AbbVie

Late-Occurring and Long-Circulating Major Metabolites Formed by Metabolic Cyclization and Aromatization from a CNS Candidate Drug of AstraZeneca  
Chuck Gu, Biogen

N-methylation of BI 187004 by thiol S-methyltransferase  
Holly Maw, Boehringer Ingelheim

#### SESSION III: Speciality Molecules; Going Beyond Rule of 5

Title TBA  
John Link, Gilead



# WELCOME TO APA 2018!

Working Beyond the Rule of 5: Designing Cyclic Peptide C5a Antagonist with Oral Bioavailability  
Kevin Beaumont, Pfizer

ADME Screening Paradigm for Covalent Inhibitor Drugs – Role of Traditional vs Non-Traditional Assays  
Ashutosh Kulkarni, Allergan

## BEYOND ADME AND BIOANALYSIS WORKSHOP “GLOBAL HEALTH”

Antiparasitic Drug Discovery from Marine Cyanobacteria  
William Gerwick, Scripps Institution of Oceanography and Skaggs School of Pharmacy and Pharmaceutical Sciences, UC San Diego

Attention to Neglected Tropical Diseases: The Impact of the Pharmaceutical Industry and the mission of Celgene Global Health  
Vikram Khetani or Joseph Camardo, Celgene

Title TBA  
Arnab Chatterjee, California Institute for Biomedical Research

Poster Session & Evening Reception

## TUESDAY, OCTOBER 2

Mentoring Breakfast

### REGULATED BIOANALYSIS WORKSHOP

**Plenary Lecture:**  
The Impact of a Reagent Center of Excellence on Bioanalysis, and a Company’s Strategy around Variabilization  
Binodh DeSilva, Bristol-Myers Squibb

**SESSION IV: Utility of Clinical Biomarkers to Support Drug Development**  
“Total” or “Free” PD Biomarker Assay in Biotherapeutic Drug Development: From Platform Selection to Methodology Evaluation  
Jenny Zhang, Pfizer

Target Engagement and Receptor Occupancy Based Translational Strategy for Therapeutic Biologics  
Weirong Wang, J&J

Sensitive and Robust Trapping-Micro-LC-MS for the Quantification of Biomarkers and Antibody Biotherapeutics  
Jun Qu, SUNY-Buffalo

**SESSION V: New Technologies and Applications**  
Enhanced Immuno-affinity for Hybrid LBA–LC-MS: Considerations and Challenges  
Ang Liu, BMS

LC/MS Intact Quantitation of Biologics in Development  
Beth Groeber, Charles River Laboratories

New Developments in Patient Centric Sampling and Their Application in Clinical Trials  
Melanie Anderson, Merck

**MECHANISTIC ADME WORKSHOP**  
**SESSION IV: Software for Met ID**  
Automated Metabolite Identification for Design Ideation  
Christopher Kochansky, Merck

Accelerating the Delivery of Small Molecule High Resolution Accurate Mass Structure Elucidation Results Through the Use of Thermo Scientific™ Compound Discoverer Software™  
Jonathan Bauman, Pfizer

Fast and Comprehensive Detection and Characterization of Cyclic Peptide Metabolites using Software-Aided Data Processing Tools  
Ming Yao, BMS

Evening Reception & Posters

### DISCOVERY WORKSHOP REGISTRATION & Mentoring Breakfast

**SESSION I: New Technologies**  
Biomarkers of Neurodegeneration – a Single Molecule Approach via Quanterix Platform  
Krishna Midde, PPD

Immunocapture-LC/MS Based Target Engagement Measurement in Tumor Plasma Membrane  
Hiroshi Sugimoto, Takeda

Title TBA  
Giovanna Scapin, Merck

**SESSION II: Predictive Tools and Novel Approaches to Evaluate Immunogenicity Response of Biotherapeutics**  
Title TBA  
Jochem Gokemeijer, BMS

Current Perspectives on Preclinical Predictive Tools for Immunogenicity Risk Assessment and their Clinical Translation  
Vibha Jawa, Merck

Human Leukocyte Antigen class II-associated Immunopeptidomics for Immunogenicity Studies of Biologics  
Andrea Casasola-LaMacchia, Pfizer

**Plenary Lecture:**  
New Developments in Ion Mobility-Mass Spectrometry Enabling Higher Throughput and More Sensitive Proteomics and Pan-Omics Measurements for Clinical Diagnostics and Personalized Medicine  
Richard Smith, Pacific Northwest National Laboratory

**SESSION III: Omics**  
Chemoproteomics  
An Chi, Merck

Application of Targeted Mass Spectrometry to the Quantitative Assessment of Internalization Kinetics for Cell-surface Membrane Protein Targets  
Dhiman Ghosh, Takeda

Title TBA  
David Pirman, Agios

Evening Reception & Posters

## WEDNESDAY, OCTOBER 3

Registration & Breakfast

### BEYOND ADME AND BIOANALYSIS WORKSHOP “NASH”

Research Models for NASH  
Joe Cornicelli, Charles River Laboratories

NASH Biomarkers  
Name, Company

NASH Pathology  
Name, Company

### DISCOVERY BIOANALYSIS AND NEW TECHNOLOGIES WORKSHOP

**SESSION IV: IT/Information/Knowledge**  
Progress in Proteogenomics  
Daniel Liebler, Prototypia

Topic in Modeling and Simulation of Exposure/Response to Model Disease and Translation  
Fei Hua, Applied BioMath

Computational and Statistical Approaches to Multi-Dimensional Data  
Bing Zhang, Baylor College of Medicine

Vendor Presentation 

### DISCOVERY AND MECHANISTIC ADME COMBINED WORKSHOP

**SESSION V: Role of DMPK in New Modalities**  
Gene Therapy/Biodistribution  
Nag Chemuturi, Novartis

Mechanistic ADME of siRNA-GalNAc Conjugates  
Jing Tao Wu, Alnylam

Role of DMPK in the Development of Cell Therapies  
Sarah Voytek, Bluebirdbio

**SESSION VI: Biomarkers: Discovery and Implementation**

Use of In Vitro Tools and Genetic Data to Identify Transporter Endogenous Biomarkers  
Xiaomin Liang, Gilead

Evaluation of Endogenous Biomarkers for Transporter Inhibition: Current State and Future Considerations  
Xiaoyan Chu, Merck

Absolute Quantitation of 2-HG, an Oncometabolite, in Human Brain Tumors to Support Clinical Development  
Guowen Liu, Agios

Raffle Drawing

Closing Remarks for the 14th Annual Applied Pharmaceutical Analysis Conference

**SHORT COURSE:**

**Challenges and Solutions to Biomarker Bioanalysis: Exploratory, Decision Making, Companion Diagnostics to C-Path Initiative**

**What are Biomarkers? What is the Role of Biomarkers in Drug Development?**  
Darshna Jani, Pfizer

**Challenges to Transition from Clinical Biomarkers to Companion Diagnostics**  
Flora Berisha, Daiichi Sankyo Pharma Inc.

**Title**  
Paul Rhyne, Biologics Development Services

**Biomarker Analysis using Flow Cytometry Focused on Preclinical Study**  
Martin Schwickart, Celgene

**Vendor Presentation**

**Biomarker Quantitation by LC-MS : Solutions to Challenges**  
Name, Company

**Q & A Session**



**REGISTRATION**

Online registration will close at 5:00 pm on Wednesday, September 26th.

	SOCIETY RATE	AFFILIATE RATE *	SPONSOR RATE	STUDENT RATE FULL ACCESS	FREE STUDENT PASS (LIMITED)	SHORT COURSE
Before 7/1/18	\$700	\$1000	\$700	\$250	\$0	\$400
7/1/18 - 9/26/18	\$800	\$1500	\$800	\$300	\$0	\$400
On-site Registration	\$900	\$1600	\$900	\$350	\$0	\$400

\*This rate is for software vendors, consultants, CRO's, and instrumentation companies who have a commercial interest in the meeting. It does not apply to FDA, pharmaceutical, or academic scientists, who are invited to apply at the Attendee rate.

**ORGANIZING COMMITTEES**

**PRESIDING CHAIRS**

**Chair:** Johanna Mora, Bristol-Myers Squibb  
**Chair-Elect:** Mehran Moghadam, Orox Bioscience

**Regulated Bioanalysis**

**Chair:** C.T.Viswanathan, C.T.Viswanathan and Associates, Inc  
**Chair-Elect:** Fumin Li, PPD  
**Committee:** Jakal Amin, Charles River Laboratories; Stephanie Padas Farmer, BioData Solutions; Andre Iffland, Vertex; Darshana Jani, Pfizer; Ang Liu, BMS; Johanna Mora, BMS; Diana Najarian, Shire; Lori Payne, Intertek; Farhad Sayyarpour, Concord Biosciences; Joseph Tweed, Pfizer; Jenifer Vija, Charles River Laboratories; Eric Woolf, Merck; Yongjun Xue, Celgene

**Discovery Bioanalysis & New Technologies**

**Chair:** Hongying Gao, Innovo Bioanalysis LLC  
**Chair-Elect:** Dieter Drexler, BMS  
**Committee:** Mark Cancilla, Merck; Montserrat Carrasco-Triguero, Genentech; Scott Fountain, Charles River Laboratories; Elizabeth Groeber, Charles River Laboratories; Hanlan Liu, Catabasis Pharmaceuticals; Mark Qian, Takeda; Jing Tu, PPD; Liyu Yang, Vertex

**Mechanistic ADME**

**Chair:** Mehran Moghaddam, OROX Biosciences  
**Chair-Elect:** Eric Ballard, Pfizer  
**Committee:** Silvi Chacko, BMS; Lisa Christopher, BMS; James Driscoll, MyoKardia; Kirk Henne, Denali Therapeutics; Cyrus Khojasteh, Genentech; Mark Milton, Novartis; Chandra Prakash, Agios Pharmaceuticals; David Stresser, AbbVie; Richard Voorman, RMLV Partners; Greg Walker, Pfizer; Cindy Xia, Takeda; Hongbin Yu, Boehringer-Ingelheim