

22ND ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis



Where Technology and Solutions Meet

**Clinical and Pharmaceutical Analysts United:
Human Wellbeing is Our Responsibility**

MEETING PROGRAM

October 28 - 31, 2019
Sheraton Bucks County
Langhorne, PA

UPDATED FROM PRINT

Expert Brief: Solutions for Oligonucleotide Analysis

SCIEX offers high performance end-to-end solutions for LC-MS oligonucleotide quantitation and characterization. Our solutions utilize our market leading negative ion mode performance instruments, delivering robust microflow capability. Plus, a complete software solution along with an easy to use sample preparation kits.

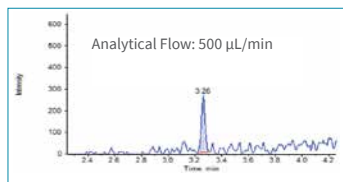
What Makes Oligonucleotide Analysis So Challenging?

- It is frequently difficult to get adequate sensitivity for oligonucleotides
- Common ion-pairing reverse phase chromatography modifiers make it challenging to keep instruments up and running
- Data analysis is slow, fragmented and usually requires multiple pieces of software

Achieve the unexpected with the SCIEX complete end-to-end solutions for fast, easy, and confident LC-MS oligonucleotide analysis.

Unrivaled Sensitivity

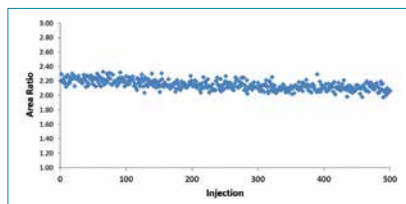
pg/ml sensitivity in ESI negative mode enabled by HED detector and OptiFlow® Source.



Uninterrupted Operation

Run hundreds of samples between cleanings enabled by OptiFlow® Source.

- Very few parameters to optimize
- No manual adjustment required
- Microflow dramatically reduces ion pairing use



Unquestionable Results

Get fully compliant results using SCIEX OS-Q or MultiQuant™ Software.

- Flexible quantitation the way you want it – MS or MS/MS
- Easily sum multiple ions
- Fully 21 CFR Part 11 compliant ready

20 out of the top **20**

Pharma and BioPharma companies use SCIEX compliant LC-MS software solutions



Bottom Line

SCIEX Oligonucleotide Analysis Solutions will dramatically shorten your time to a confident answer by speeding up your data analysis, increasing your sensitivity, simplifying and improving your sample preparation and system set-up, while saving costs on expensive reagents.

For more information visit sciex.com/oligoanalysis



The Power of Precision

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WELCOME

Inspiration. Collaboration.

October 28, 2019

Dear Colleagues:

On behalf of the organizing committee and our sponsors, it is our pleasure to welcome you to the 22nd annual Symposium on Clinical and Pharmaceutical Solutions through Analysis (CPSA USA 2019). The meeting and related events feature lively discussions, memorable interactions, and the sharing of real-world experiences that focus on the unique challenges facing the modern analytical laboratory and the risks – and reality – of personalized healthcare.

The goal of CPSA is to provide timely, in-depth reviews of innovative technology and emerging practices through open discussion of industry related issues and needs. Our program co-chairs, Timothy Olah and Neil Spooner, have followed Alla Kloss' vision from last year's annual meeting and developed the theme for CPSA USA 2019: Clinical and Pharmaceutical Analysts United: Human Wellbeing is Our Responsibility.

Our intent is to feature scientific leaders within diversified symposia, colloquia, and sponsored events that are specially designed to be highly interactive where professionals can openly share their experiences and visions in a collegial setting – where technology and solutions meet!

We are extremely delighted to feature a provocative line up of courses, symposia, colloquia, sponsored events, and distinguished guests. On Monday, we will kick the meeting off with the Distinguished Lecture Series, once again generously sponsored by SCIEX, and featuring Athena Zuppa from The Children's Hospital of Philadelphia speaking on "Integration of VAMS into Pediatric Research and Clinical Programs: What Have We Learned So Far?" Our Plenary Lecture on Tuesday will feature Lorin Bachmann of VCU Health System with "The Impact of Bioanalytical Decision Making on Patient Care." Carla Cuthbert from the Centers for Disease Control and Prevention will deliver the Keynote Lecture on Wednesday, "Strategic Plan for Implementing Change," followed by the Distinguished Analytical Scientist Award, this year presented to Rick Yost of the University of Florida.

The short courses at CPSA continue to focus on specialized training with a unique workshop-style format that promotes open discussion on current industry practices, emerging applications and first-hand experiences with innovative analytical technologies. Symposia sessions provide a unique forum for opinion leaders to openly share and benchmark industry issues and needs as well as early experiences with new technology and methods. Colloquia sessions provide focus on industrial activities related to regulatory issues and emerging laboratory workflows. These sessions further enhance the specialized training from our CPSA Short Courses.

Communications and media have grown with CPSA and the dynamic use of video and interactive surveys are now ready to be fully integrated into CPSA events – worldwide – Brazil, China, Europe, and USA! Also, our Graduate Student Session, formally recognized as the Steven A. Hofstadler Graduate Student Session, brings us new and fresh perspectives. Finally, we are excited to share our significant progress with our CPSA Charitable Giving and CPSA Institute initiatives during the Sponsors Dinner event.

We encourage you to actively participate, interact, and share ideas during the event. Creativity and imagination have been key ingredients to making CPSA meetings a memorable experience all over the world. In this way, a genuine passion for the analytical sciences can lead to personal growth as well as opportunities to significantly impact the field through participation and leadership.

Special thanks go to the sponsors of this unique event. In particular, we wish to thank SCIEX, New Objective, Shimadzu, and Thermo Fisher Scientific for giving this meeting life. Thank you! All CPSA sponsors share the passion and commitment for both innovative technologies and the acceleration of product development. CPSA sponsors and participants are dedicated to the spirit of cooperation. Imagination needed!

Sincerely,

Handwritten signature of Mike S. Lee in black ink.

Mike S. Lee
CPSA Founder

Handwritten signature of Timothy V. Olah in black ink.

Timothy Olah
2019 Program Co-Chair

Handwritten signature of Neil Spooner in black ink.

Neil Spooner
2019 Program Co-Chair

2019 ORGANIZING COMMITTEE

PROGRAM CO-CHAIRS

Timothy Olah
Bristol-Myers Squibb

Neil Spooner
Spooner Bioanalytical Solutions

SYMPOSIA & SESSIONS

Susan Abbatiello
Thermo Scientific

Dave Abramowitz
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Mark Arnold
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Lorin Bachmann
Virginia Commonwealth University

Kevin Bateman
Merck

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Jim Shen
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Petia Shipkova
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Joe Siple
New Objective

James Small
Merck

Daniel Spellman
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Neil Spooner
Spooner Bioanalytical Solutions

Matthew Szapacs
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Stephen Tomisich
Trajan Scientific & Medical

Gary Valaskovic
New Objective

Roy Vaz
Sanofi

Sihe Wang
Akron Clinic

Helen Weng
Frontage Laboratories

Naidong Weng
Janssen Research & Development

Clark Willard
inVentiv Health

Enaksha Wickremsinhe
Eli Lilly & Co.

Eric Woolf
Merck

Sophia Xu
Bristol-Myers Squibb

Weifeng Xu
Bristol-Myers Squibb

Eric Yang
GlaxoSmithKline

Nathan Yates
University of Pittsburgh

Anthony Yeung
Fox Chase Cancer Center

Ismael Zamora
Molecular Discovery

Yi Zhang
SCIEX

Athena Zuppa
The Children's Hospital of Philadelphia

LOGISTICS & MANAGEMENT

Logistics & Communications

Carla Marshall-Waggett
New Objective

Management & Correspondence

Mike Lee
Milestone Development Services

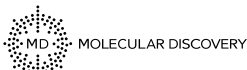
SPONSORS

Thank You!

The CPSA annual symposium is made possible by the broad-based support of industry sponsors. The passion for the analytical sciences and the accelerated discovery and development of pharmaceuticals is shared by each sponsor. As a result, the event is dedicated to promoting awareness and understanding of the issues and needs associated with research and development in the hopes of inspiring significant advances in the field.



NEW OBJECTIVE



EXHIBITION

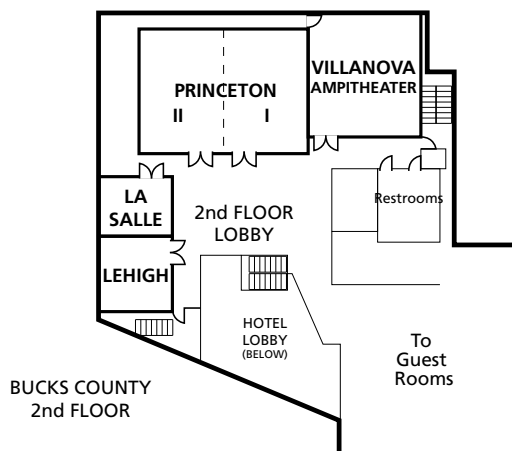
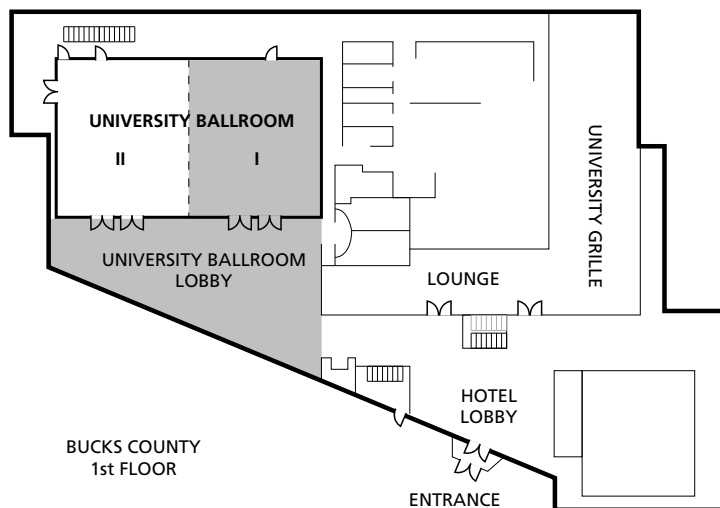
Wednesday October 30

EXHIBITORS	BOOTH
Adaptas Solutions	14
Agilent Technologies	4
Altasciences	23
Alturas Analytics	12
Cambridge Isotope Labs	3
Chinese American Chromatography Association	20
Covance	10
Elucidata	8
IMCS	15
IonSense	19
MAC-MOD Analytical	9
Molecular Discovery	7
Myriad RBM	18
New Objective	24
PerkinElmer	11
Prolab Instruments GmbH	16
SCIEX	13
Shimadzu Scientific Instruments	25
Tasso, Inc.	17
Tecan	6
Thermo Fisher Scientific	22
VICI / Valco Instruments	5

EXHIBIT LOCATIONS & HOTEL LOCATIONS

Exhibit booths are located in University I Ballroom, University Ballroom Lobby, and in the 2nd Floor Lobby

Booths 1 - 13 University Ballroom I
 Booths 14 - 25 University Ballroom Lobby



SHORT COURSES & EVENTS

Monday October 28

7:30 AM - 8:30 AM

REGISTRATION & CONTINENTAL BREAKFAST

2nd Floor Lobby

SHORT COURSES

8:30 AM - 4:00 PM

Princeton I

Protein Identification, Quantification, and Biomarker Analysis

Instructors: Weixun Wang, Merck; Harris Bell-Temin, Bristol-Myers Squibb; Nalini Sadagopan, Agilent Technologies, Nathan Yates, University of Pittsburgh

8:30 AM - 4:00 PM

Princeton II

Bioanalysis of Mix Modalities via Hybrid and Orthogonal Approaches

Instructors: Suzanne Cordovado, CDC; Barry Jones, Q2 Solutions; Linlin Luo, Merck; Jim Shen, Bristol-Myers Squibb

12:00 PM - 4:00 PM

University Grille

Microsampling and Patient Centric Sampling:

A Journey through What It Is and How You Can Incorporate It into Your Workflows

Instructors: Neil Spooner, Spooner Bioanalytical Solutions; Joe Siple, New Objective; Kevin Bateman, Merck; Tim Olah, Bristol-Myers Squibb; Enaksha Wickremsinhe, Eli Lilly & Co.; Melanie Anderson, Merck

12:00 PM - 4:00 PM

LaSalle

Business of Science: Biomarker CRO Selection, Qualification and Oversight

Instructors: Olga Kavetskaia, Pfizer; Arkady Gusev, Novartis

8:30 AM - 4:00 PM

Lehigh

Building a Better Clinical Diagnostics / Bioanalytical Mass Spectrometry Lab

Instructors: Mark Hayward, Active Ingredient Technologies; Ganesh Moorthy, The Children's Hospital of Philadelphia with Guest Discussion Leader: Shane Needham

7:30 AM - 9:30 AM

*Makefield Highlands Golf Club
Yardley, PA*

CPSA 5K WALK *CPSA Charitable Foundation*

Organizers: Nicole Matz, PRA Health Sciences; Guowen Liu, Agios; Naidong Weng, Janssen Research & Development; Helen Weng, Frontage Laboratories

10:00 AM - 3:00 PM

*Makefield Highlands Golf Club
Yardley, PA*

CPSA OPEN EVENT *CPSA Charitable Foundation*

Organizers: John Butler, Agilent Technologies; Clark Willard, Syneos Health Clinical Lab

12:30 PM - 4:00 PM

Villanova Amphitheater

MOLECULAR DISCOVERY USERS MEETING:

Discussion Leader: Ismael Zamora, Molecular Discovery

MONDAY, OCTOBER 28

MEETINGS & EVENTS

Monday October 28

4:30 PM - 5:30 PM

University I & II

EXECUTIVE ROUNDTABLE: WHERE TECHNOLOGY AND SOLUTIONS MEET BUSINESS

Leveraging Diversity and Inclusion for Better Business Outcomes

Discussion Leaders: Lucinda Hittle, Merck; Emily Ehrenfeld, New Objective

Panelists:

Brad Ackermann, Eli Lilly & Co.

Mark Arnold, Covance

Lorin Bachmann, VCU Health System

Amanda Berg, New Objective

Stephanie Cape, Covance

Suzanne Cordovado, Centers for Disease Control & Prevention

Carla Cuthbert, Centers for Disease Control & Prevention

Binodh DeSilva, Bristol-Myers Squibb

Anahita Keyhani, Altasciences

Alla Kloss, Sanofi

Tim Olah, Bristol-Myers Squibb

Kayte Parlevliet, Trajan Scientific & Medical

Joanna Pols, Regeneron

Robyn Rourick, Genetech

Nalini Sadagopan, Agilent Technologies

Neil Spooner, Spooner Bioanalytical Solutions

And More...

6:00 PM - 9:00 PM

University I & II

RECEPTION, SPONSOR'S DINNER & DISTINGUISHED LECTURE

Hosted by SCIEX

Opening Remarks

Timothy Olah, Bristol-Myers Squibb, Neil Spooner, Spooner Bioanalytical Solutions, and Mike Lee, Milestone Development Services

CPSA Charitable Foundation

Distinguished Lecture Series

Integration of VAMS into Pediatric Research and Clinical Programs: What Have We Learned So Far?

Athena Zuppa, The Children's Hospital of Philadelphia



3rd ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis

February 4-7, 2020 • Cambridge, U.K.

Program Co-Chair

Neil Spooner

Spooner Bioanalytical Solutions

Program Co-Chair

Ismael Zamora

Molecular Discovery

Plenary Speaker

Fleur Chandler

Duchenne UK

Imagine Speaker

Christophe Stove

University of Ghent

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Symposia • Roundtables • Analysis Trends • New Technology • Vendor Session
Performance Benchmarks • Mainstream Appliances • Social Events

www.cpsa-europe.com

Where Technology and Solutions Meet

MONDAY, OCTOBER 28

PROGRAM AGENDA

Tuesday October 29

7:30 AM - 8:30 AM

REGISTRATION & CONTINENTAL BREAKFAST

University Ballroom Lobby

7:30 AM - 8:30 AM

GRADUATE STUDENT / MENTOR BREAKFAST

University I & II

Leaders: Petia Shipkova, Bristol-Myers Squibb; Mike Lee, Milestone Development Services

CPSA offers a unique opportunity for a selected group of graduate students to directly interact with Industry leaders at the Graduate Student Breakfast event. Personal accounts and stories of individual journeys and professional development in a friendly and informal setting allow students to talk, share, learn, establish connections and plan their future careers.

8:30 AM - 9:00 AM

WELCOME & OPENING REMARKS - DISEASE IS THE ENEMY!

University I & II

Welcome

Mike Lee, Milestone Development Services

Objectives, Format, and Opening Remarks

*Timothy Olah, Bristol-Myers Squibb
Neil Spooner, Spooner Bioanalytical Solutions*

9:00 AM - 9:45 AM

PLENARY LECTURE

University I & II

The Impact of Bioanalytical Decision Making on Patient Care

Lorin Bachmann, VCU Health System

TUESDAY, OCTOBER 29



CPSA
ANALYTICS

4th ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis

May 4-5, 2020 • Boston, MA

Program Co-Chair
Amanda Berg
New Objective

Program Co-Chair
Alla Kloss
Sanofi

Plenary Speaker
Enaksha Wickremsinhe
Eli Lilly & Co.

CPSA ANALYTICS FOCUS: SOLUTIONS FOR THE PATIENT

Symposia • Roundtables • Analysis Trends • Imagine Summit • Social Events
Workshops • Performance Benchmarks • New Technology • Expo

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Where Technology and Personalized Healthcare Meet!

PROGRAM AGENDA

Tuesday October 29

10:00 AM - 11:45 AM

PARALLEL SESSIONS

<p>Track 1 Symposium Session <i>Princeton I</i></p>	<p>Track 2 Colloquium Session <i>Princeton II</i></p>
<p>From Nomination to Implementation – How New Conditions are added to the National Newborn Screening Panel. The Story of Spinal Muscular Atrophy <i>Discussion Leaders: Suzanne Cordovado and Carla Cuthbert, Centers for Disease Control and Prevention</i></p> <ul style="list-style-type: none"> ▶ Charting the Path for Spinal Muscular Atrophy Newborn Screening <i>Carla Cuthbert, Centers for Disease Control and Prevention</i> ▶ Navigating the Challenges of State Implementation of Newborn Screening for Spinal Muscular Atrophy <i>Suzanne Cordovado, Centers for Disease Control and Prevention</i> 	<p>Powering Future Clinical Testing with Longitudinal and Predictive Markers <i>Discussion Leaders: Erwin Berthier, Tasso Inc.; James Rudge, Neoteryx</i></p> <p>Longitudinal personalised clinical testing offers huge benefits in catching perturbations in biochemistry before abnormal pathology is observed allowing early intervention. In recent years, there has been a huge interest in developing highly specific tests in the omics / novel biomarkers fields to allow the dream of personalised testing to supplant standard clinical tests. This session showcases 4 leaders in the field of personalised testing and how their research and potential assay deployments will help to revolutionise future healthcare.</p> <ul style="list-style-type: none"> ▶ Delivering Mass Spectrometry-Based Multiplexed Protein Biomarkers for Improved Patient Outcomes <i>Steve Pennington, University College Dublin</i> ▶ Predictive Inflammation Biomarkers <i>Ben Herbert, Sangui Bio</i>
<p>Track 3 Colloquium Session <i>Villanova Amphitheater</i></p>	<p>Track 4 Colloquium Session <i>Lehigh</i></p>
<p>Updates on the Road to Regulation for Biomarkers <i>Discussion Leaders: Brad Ackermann, Eli Lilly & Co.; Robyn Rourick, Genentech</i></p> <p>Biomarker Qualification as a regulatory process and utilization of all biomarkers in the drug development process. What is required to qualify a biomarker? How it can be used? What are current regulatory guidelines and standards for submission of biomarker data?</p> <ul style="list-style-type: none"> ▶ The Biomarker Qualification Process at the FDA <i>Chris Leptak, FDA</i> ▶ Biomarker Assay Validation for Every Conceivable Situation: One Size Fits All! <i>Steven Piccoli, GlaxoSmithKline</i> 	<p>CACA and CPSA, The Winning Partners <i>Joint Session with Chinese American Chromatography Association (CACA)</i> <i>Discussion Leaders: Naidong Weng, Janssen Research & Development; Chuping Luo, Advanced Materials Technology</i></p> <ul style="list-style-type: none"> ▶ Using Superficially Porous Particle Technology for HPLC Method Modernization & Development <i>Stephanie Schuster, Advanced Materials Technology</i> ▶ Novel Strategy for Sensitive Analytical Method Development Based on HPLC-MS <i>Hongyue Guo, GlaxoSmithKline</i> ▶ Determining Cyclooxygenase Selectivity in Human Whole Blood Assay and Optimizing Assay Conditions Utilizing LC-MS/MS <i>Yifan Shi, Janssen Research & Development</i>

TUESDAY, OCTOBER 29

PROGRAM AGENDA

Tuesday October 29

12:00 PM – 1:00 PM

University I & II

SPONSORED LUNCH & ROUNDTABLE DISCUSSION

The Future of LC-MS

Sponsored by New Objective

Discussion Leaders: Jeremiah Tipton, BioTech & OMICSx Solutions, LLC; Bernhard Nemec, ProLab Instruments; Neil Spooner, Spooner Bioanalytical Solutions; and Emily Ehrenfeld, New Objective

1:00 PM

University Lobby

LET THEM EAT CAKE!

"Happy Birthday!"

1:00 PM – 3:00 PM

University Lobby

POSTER SESSION & ROUNDTABLE DISCUSSION

Leaders: Mark Cancilla, Merck; Helene Cardasis, Thermo Fisher Scientific; Scott Hottenstein, GlaxoSmithKline; Wenkui Li, Novartis; Enaksha Wickremsinhe, Eli Lilly & Co.; Matthew Szapacs, GlaxoSmithKline; Thomas Mencken, GlaxoSmithKline

Featured Students: Taylor Domenick, University of Florida and Allison Levy, University of Florida

3:15 PM – 4:45 PM

PARALLEL SESSIONS

Track 5 Symposium Session

University I

Partnering with CROs for Positive and Effective Project Progression

Discussion Leader: Anahita Keyhani, Altasciences

Bioanalysis is integral to the drug development pathway. As bioanalytical outsourcing to CROs continues to increase in both volume and scope, bioanalytical support is evolving significantly beyond routine, small-molecule LC-MS. Biologics, biomarkers and new molecular modalities are a growing segment of drug-development pipelines, and bioanalytical CROs are keeping pace, transforming into centers of technological/scientific innovation and regulatory expertise. This session discusses strategies and best practices using case studies for partnering with CROs for positive and effective project progression.

- ▶ **Managing Bioanalytical Support Externally and Internally – Best Practices in Building Relationships through Communication**

Lisa Borbridge, Allergan

- ▶ **How to Utilize the Expertise of your CRO**

Joanna Gore, Appili Therapeutics

Track 6 Colloquium Session

University II

Biomarker Discovery and Quantitation

Discussion Leaders: Naidong Weng, Janssen Research & Development; Wenying Jian, Janssen Research & Development

- ▶ **Metabolic Profiling of the Cellular and Mitochondrial Dynamics by LC-MS**

Yanping Lin, Janssen Research & Development

- ▶ **A Deconvoluted Proteomics for in Situ, Unambiguous Quantification of Cancer Markers in Patient-Derived Xenograft Models**

Jun Qu, SUNY Buffalo

- ▶ **Anti-peptide Antibody Immunocapture-LC-MS/MS Strategy to Quantify PD-1 and PD-L1 as Clinical Biomarkers in FFPE Tissues for Immuno-Therapy Development**

Naiyu Zheng, Bristol-Myers Squibb

TUESDAY, OCTOBER 29

PROGRAM AGENDA

Tuesday October 29

3:15 PM – 4:45 PM

PARALLEL SESSIONS (cont'd)

<p>Track 7 Colloquium Session <i>Villanova Amphitheater</i></p>	<p>Track 8 Colloquium Session <i>Lehigh</i></p>
<p>To Be Announced <i>Discussion Leaders: Sara Naseri, Qurasense; Søren Therkelsen, Qurasense</i></p>	<p>Engaging Examples of Pharmaceutical Analytical Sciences Research <i>Discussion Leader: James Small, Merck</i></p> <ul style="list-style-type: none"> ▶ Enrichment of Relevant Oxidative Degradation Products in Pharmaceuticals with Targeted Chemoselective Oxidation <i>Kausik Nanda, Merck</i> ▶ Structure Elucidation and Mechanistic Interpretation of a Novel Rearranged Degradant and Subsequent Use as an Ultra Violet (UV) Relative Response Factor (RRF) Standard <i>James Small, Merck</i>

5:00 PM – 6:00 PM

SOCIAL HOUR & SPONSORED WORKSHOPS

Princeton I & II

Microsampling and Patient Centric Blood Sampling and Analysis: Practical Aspects of Implementation

Sponsored by Spooner Bioanalytical Solutions

Workshop Leaders: Neil Spooner, Spooner Bioanalytical Solutions; Enaksha Wickremsinhe, Eli Lilly and Company; Joe Siple, New Objective; Athena Zuppa, The Children's Hospital of Philadelphia

This Workshop will be of benefit for medical professionals, those involved in running pediatric clinical trials, bioanalysts, blood sampling and analysis technology developers and anyone who has an interest in collecting high quality blood samples from children whilst minimising the impact of this process on them.

Villanova Amphitheater

A Story of Innovation and Translation: Advances in Plasma A β Biomarkers for Alzheimer's Disease

Sponsored by Shimadzu Scientific

Accurate biomarker information is necessary to facilitate clinical trials of disease-modifying therapies for Alzheimer's disease, which are expected to be most efficacious at the earliest and mildest stages of the disease. Currently, only positron-emission tomography (PET) imaging and the measurement of amyloid- β in cerebrospinal fluid are validated methods for identifying amyloid- β deposition in the brain. Minimally invasive, cost-effective blood-based biomarkers are needed. Recently, Koichi Tanaka et al. (*Nature*. 2018 Feb 8;554(7691):249-254. doi: 10.1038/nature25456. Epub 2018 Jan 31) demonstrated the ability of amyloid- β precursor protein (APP)669-711/amyloid- β (A β)1-42 and A β 1-40/A β 1-42 ratios to predict individual brain amyloid- β -positive or -negative status. These biomarkers showed high performance when predicting brain amyloid- β burden. The composite biomarker showed very high areas under the receiver operating characteristic curves (AUCs) in both data sets (discovery, 96.7%, n=121 and validation, 94.1%, n=111) with an accuracy approximately equal to 90% when using PIB-PET as a standard of truth. These test biomarkers were correlated with amyloid- β -PET burden and levels of A β 1-42 in cerebrospinal fluid. These results demonstrate great potential utility of these research use only plasma biomarkers for predicting brain amyloid- β burden at an individual level. This talk will review these innovative biomarkers as well as describe efforts to bring reliable and accurate testing services online in North America.

TUESDAY, OCTOBER 29



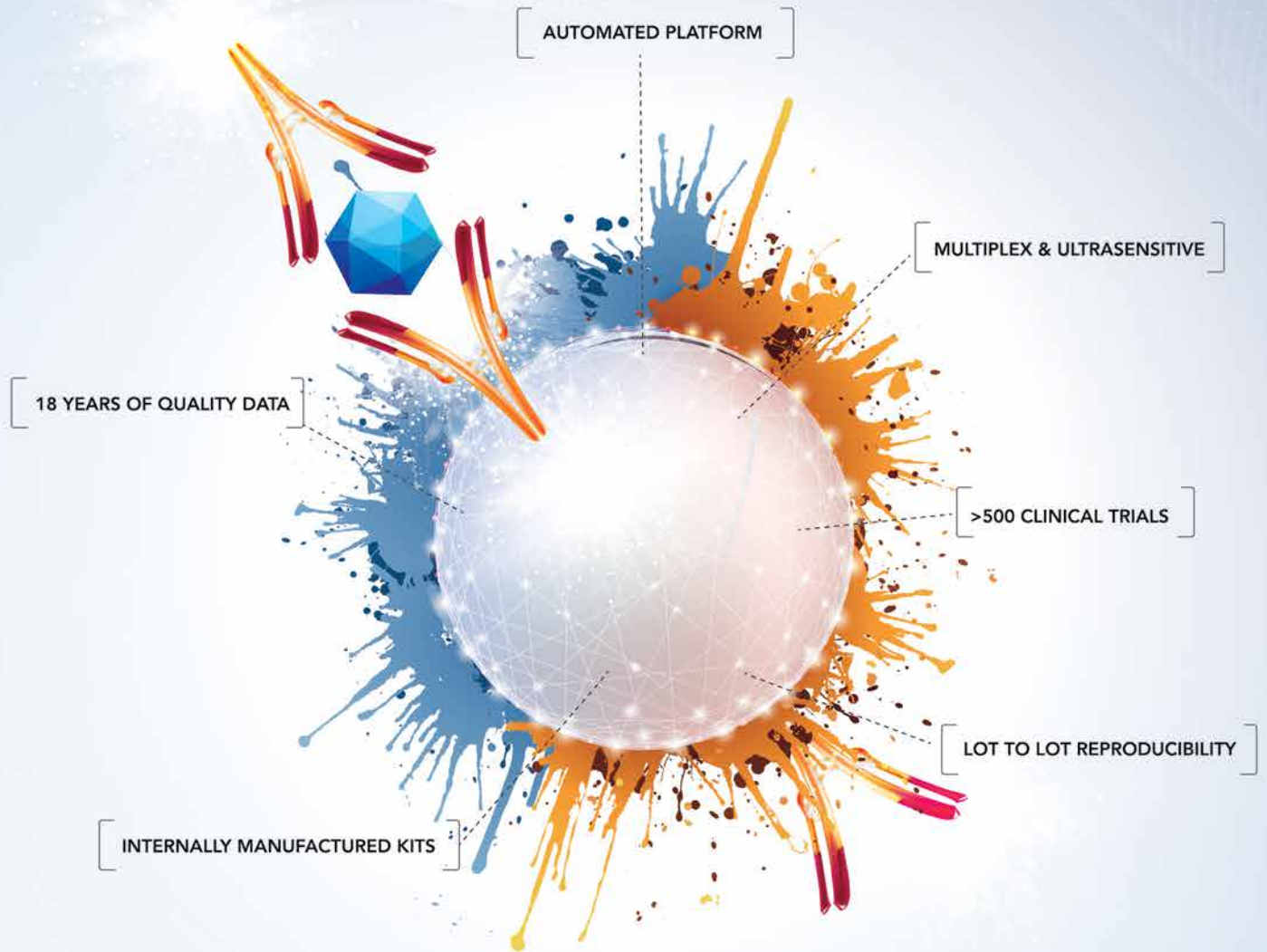
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INNOVATIVE BIOMARKER SOLUTIONS

MyriadRBM.com



SOFTWARE AND SERVICES

CHEMISTRY
ADMET/DMPK



AUTOMATIC STRUCTURE ELUCIDATION



Small Molecule/Peptides

DMPK: **MassMetaSite**
Chemistry: **MassChemSite**
Met.ID service

IN SILICO TOOLS



ADMET:

SoM prediction: **MetaSite**
Physico-chemistry:
pKa, logD (**Moka**), **Volsurf+**

Modeling:

Molecular Interaction Field: **GRID**
Ligand/Receptor virtual screening: **Flap**
System biology: **BioGPS**
Modeling services

DATABASE AND ANALYSIS TOOLS



Small Molecule/Peptides

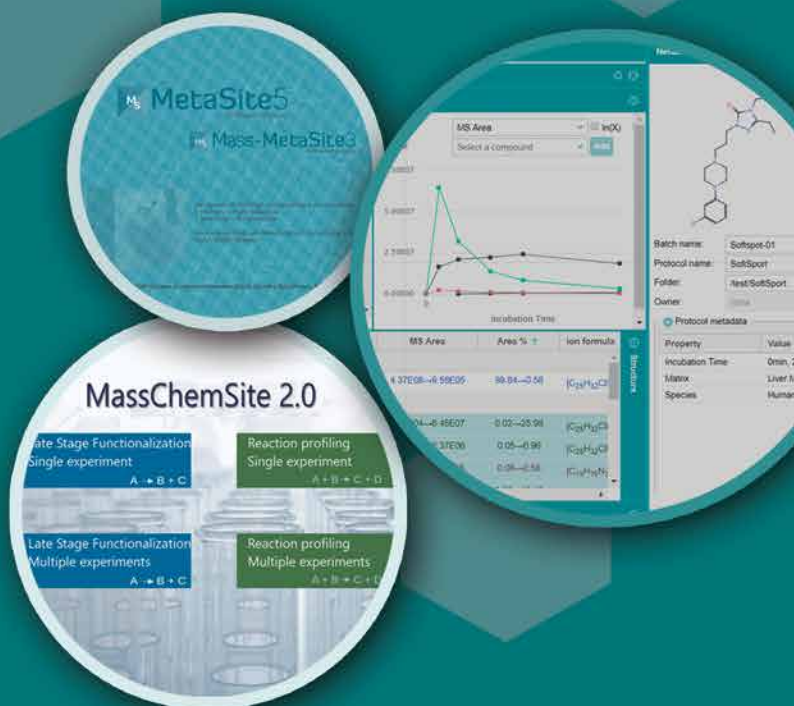
WebMetabase

LCMS database and tools
Automatic reporting/SAR

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Lipidomics: **Lipostar**
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PROGRAM AGENDA

Tuesday October 29

5:00 PM – 6:00 PM

SOCIAL HOUR & SPONSORED WORKSHOPS *(cont'd)*

Lehigh

WORKSHOP

To Be Announced

Sponsored by Tasso, Inc.

6:30 PM - 9:30 PM

SPONSOR HOSPITALITY & EVENING WORKSHOPS

University I

Imagine Summit

Sponsored by New Objective and Spooner Bioanalytical Solutions

Workshop Leaders: Kevin Bateman, Merck; Timothy Olah, Bristol-Myers Squibb; Neil Spooner, Spooner Bioanalytical Solutions; Enaksha Wickremsinhe, Eli Lilly & Co.

Welcome

Neil Spooner, Spooner Bioanalytical Solutions and Emily Ehrenfeld, New Objective

Imagine Building Tomorrow Today

Melanie Anderson, Merck

University II

WORKSHOP

To Be Announced

Sponsored by Thermo Fisher Scientific

TUESDAY, OCTOBER 29



6th ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis

March 16-18, 2020 • Columbia, S.C.

Program Co-Chair

Andrew Lee

IMCS

Program Co-Chair

Abiheshek Jha

Elucidata

CPSA METABOLOMICS FOCUS: STANDARDIZATION

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PROGRAM AGENDA

Wednesday October 30

7:30 AM – 8:30 AM

REGISTRATION & CONTINENTAL BREAKFAST

University Ballroom Lobby

7:30 AM - 8:30 AM

FOUR CORNERS INITIATIVE BREAKFAST

University I & II

Discussion Leaders: Mark Arnold, Covance; Lorin Bachmann, Virginia Commonwealth University

Ongoing discussions since last year’s annual CPSA USA meeting as well as the CPSA Metabolomics event held this year in Atlanta have generated a clearer understanding of the next steps required to guide the development of cutting-edge technology into the clinic or home to improve personal health and overall wellbeing. This year, our evolving discussion will focus on a convergence point: data/data aggregation and standardization within the framework of key stakeholders in healthcare.

8:30 AM – 10:00 AM

SYMPOSIUM SESSION & ROUNDTABLE DISCUSSION

University I & II

Clinical Protein Analysis by Mass Spectrometry: Current Capabilities and Future State

Discussion Leader: Brad Ackermann, Eli Lilly & Co.

The use of mass spectrometry to quantify proteins in clinical specimens continues to gain traction by offering capabilities not available by other methods. At the same time, widespread adoption remains limited by cost and other factors. This session will examine current capabilities and the path to greater clinical utilization in two clinical areas: pharmaceutical development and CLIA. This session will frame the current state in each of these areas and generate an open dialogue on the best opportunities for future engagement.

- ▶ **Protein Biomarker Mass Spectrometry in BioPharma: New Frontiers**
Joseph Palandra, Pfizer
- ▶ **Clinical Proteomics in the Reference Lab: Where Did All the Putative Biomarkers Go?**
Chris Shuford, LabCorp
- ▶ **Clinical Proteomics in the Hospital Lab: Meeting the Needs of Patients**
Andy Hoofnagle, University of Washington

WEDNESDAY, OCTOBER 30

PROGRAM AGENDA

Wednesday October 30

10:15 AM – 11:45 AM

PARALLEL SESSIONS

<p>Track 1 Symposium Session <i>Villanova Amphitheater</i></p>	<p>Track 2 Colloquium Session <i>Princeton I & II</i></p>
<p>Enabling Mass Spectrometry-based Assays via Innovations in Sample Processing <i>Discussion Leader: Brian Musselman, IonSense, Inc.</i></p> <ul style="list-style-type: none"> ▶ Bead-Assisted Mass Spectrometry (BAMSTM): Higher Order Immunoassay Multiplexing for Targeted Quantification and Biomarker Discovery <i>Vladislav Bergo, Jeffrey Silva, Sergey Mamaev, Camilla Worsfold, and W. Adam Hill of Adeptrix</i> ▶ Molecular Imaging in Preclinical Drug Discovery <i>B. Healey, Revolution Biosciences</i> ▶ Submicroliter Sampling for Ambient MS - Reducing Sample size for Improved Analyte Detection <i>B. Musselman, F. Li, and P. Liang of IonSense, Inc.</i> 	<p>Patient Centric Sampling Interest Group– Achievements and Next Steps <i>Discussion Leaders: Erwin Berthier, Tasso; Søren Therkelsen, Qurasense; Joe Siple, New Objective, Neil Spooner, Spooner Bioanalytical Solutions</i></p> <p>This session will give attendees an introduction to the PCSIG, an update on current activities and will discuss potential future collaborative efforts for the group, including an independent clinical trial into the use of these novel technologies.</p> <hr/> <p>Track 3 Colloquium Session <i>Lehigh</i></p> <hr/> <p>Self-Innovation Strategies <i>Discussion Leaders: Lucinda Hittle, Merck; Liz Pierson, Merck</i></p>

12:00 PM -1:00 PM

University I & II

SPONSORED LUNCH & ROUNDTABLE

Sponsored by Shimadzu Scientific

- ▶ **High Throughput Plasma Proteomics Pipeline: More Proteins from Less Plasma**
Benoit Fatou, Boston Children’s Hospital/Harvard Medical School
- ▶ **Introduction to the Shimadzu MALDImini-1: The First Commercially Available Compact Digital Ion Trap Mass Spectrometer**
Mohamed Boutaghou, Shimadzu Scientific

1:15 PM – 2:15 PM

Princeton I & II

SOCIAL HOUR & SPONSORED WORKSHOPS

The Future of LC-MS: High Performance Redefined

Sponsored by New Objective

- ▶ **High Performance: Simple, Easy, Scalable**
Emily Ehrenfeld, New Objective
- ▶ **High Performance: Integrated Solutions**
Neil Spooner, Spooner Bioanalytical Solutions
- ▶ **High Performance: Education and Specialized Training**
Jeremiah Tipton, BioTech & OMICSx Solutions, LLC
- ▶ **High Performance Redefined**
Dan Spellman, Merck

WEDNESDAY, OCTOBER 30

PROGRAM AGENDA

Wednesday October 30

1:15 PM – 2:15 PM

SOCIAL HOUR & SPONSORED WORKSHOPS *(cont'd)*

Villanova Amphitheater

Mitra® VAMS: From Sample Collection to Bioanalysis, What are the Remaining Challenges?

Sponsored by Altasciences

Workshop Leaders: Jeff Plomley and Anahita Keyhani, Altasciences

The increased adoption of Mitra® VAMS technology for supporting low-volume blood collection in clinical studies may be attributed to the elimination of the HCT effect biasing sampling volume, coupled with the ease of device implementation. However, additional downstream bioanalytical challenges remain, such as age-related extractability and recovery bias linked to blood HCT. Solutions to these bioanalytical challenges shall be addressed by Jeff Plomley in his presentation detailing the application of Impact-Assisted Extraction to Mitra® microsamples as a novel, and potentially universal, sample preparation approach. In addition, Altasciences will share their recent results evaluating the Tasso On-Demand “anywhere, anytime” pain-free blood sampling device, supporting the industry drive towards patient centricity.

Following the presentation, an open discussion shall follow where participants can share their experiences and challenges incorporating Mitra® technology into their microsampling programs, from sample collection to bioanalysis. By leveraging the combined expertise of all workshop members, the remaining “pain-points” associated with Mitra® technology can be identified and potential solutions derived to facilitate continued implementation of the technique.

The Workshop is expected to benefit key stakeholders involved with Mitra® VAMS technology, including technology developers.

Lehigh

WORKSHOP

To Be Announced

Sponsored by Thermo Fisher Scientific

LaSalle

WORKSHOP

To Be Announced

Sponsored by Elucidata

WEDNESDAY, OCTOBER 30



11th ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis

April 20-24, 2020 • Shanghai, China

Program Co-Chair

Guo Fang
Easymass

Program Co-Chair

Baomin Xin
Shanghai Medicilon

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Poster Session • Social Events • Student Session

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PROGRAM AGENDA

Wednesday October 30

2:30 PM – 3:30 PM

PARALLEL SESSIONS

<p>Track 5 Symposium Session <i>Princeton I & II</i></p> <p>Biomarkers and Business of Science: Fueling the Disruptive Innovation <i>Discussion Leaders: Arkady Gusev, Novartis and Olga Kavetskaia, Pfizer</i></p> <p>Biomarkers and Business of Science: Fuelling the Disruptive Innovation” This session continues to build on 2018’s CPSA session theme on “The Business of Science”. This year we focus on leveraging CRO experiences for biomarker analysis in clinical studies including using cutting edge technologies, operationalizing of complex clinical biomarker strategies and CRO-Pharma partnership models.</p> <ul style="list-style-type: none"> ▶ Efficiently Quantifying Peripheral Blood-Based Proteins for Clinical Trials: Recent Case Studies of Pharmacodynamics, Prognostic, and Predictive Biomarkers of Drug Response <i>Dominic Eisinger, Myriad RBM</i> ▶ The Nuts and Bolts of Making Complex Biomarker Strategies Work in Clinical Trials <i>Chad J Briscoe, PRA Health Sciences</i> ▶ Can a CRO Select its Pharma Clients? <i>Roger Hayes, ICON</i> 	<p>Track 6 Colloquium Session <i>Lehigh</i></p> <p>Women in Science and Technology <i>Discussion Leaders: Kayte Parlevliet, Trajan Scientific & Medical and Robyn Rourick, Genentech; Suzanne Cordovado, Centers for Disease Control and Prevention; Amanda Berg, New Objective; Alla Kloss, Sanofi; Lucinda Hittle, Merck; Emily Ehrenfeld, New Objective</i></p> <p>This facilitator led workshop will focus on discussing the role of women in science and technology and how we all as individuals can contribute to promoting and progressing this important cause in our own careers and lives.</p>
<p>Track 7 Colloquium Session <i>University II</i></p> <p>Frontiers of Innovation, Technology and Solutions <i>Session Leaders: Alla Kloss, Sanofi and Ganesh Moorthy, Children’s Hospital of Philadelphia</i></p> <ul style="list-style-type: none"> ▶ Challenges to Personalized Antimicrobial Dosing in Pediatrics: How Microsampling Can Help Us Move from Therapeutic Drug Monitoring to Management <i>Kevin J. Downes, The Children’s Hospital of Philadelphia</i> ▶ Real Time Therapeutic Drug Monitoring: Is This a Reality or Just a Dream? <i>Ganesh S. Moorthy, The Children’s Hospital of Philadelphia</i> ▶ The Surprising Value of Real World Data <i>Arthur H. Combs, MC 10, Inc.</i> 	<p>Track 8 Steven A. Hofstadler Graduate Student Session <i>Villanova Amphitheater</i></p> <p>Sponsored by New Objective <i>Session Leaders: Petia Shipkova, Bristol-Myers Squibb and Emily Ehrenfeld, New Objective</i></p> <ul style="list-style-type: none"> ▶ A Photocleavable Surfactant for Top-Down Proteomics <i>Kyle Brown, University of Wisconsin</i> ▶ Trends from >15,000 Assigned Fragment Ions in Top-Down Mass Spectrometry <i>Ashley Ives, Northwestern University</i> ▶ Rapid Analysis of Tryptophan Metabolites in Serum Using Wide-Isolation Strategies for UHPLC-HRMS/MS <i>Vanessa Rubio, University of Florida</i> ▶ Use of Ultrahigh Pressure and Multidimensional LC-MS for Lipidomics <i>Matt Sorensen, University of Michigan</i>

WEDNESDAY, OCTOBER 30

PROGRAM AGENDA

Wednesday October 30

3:45 PM – 5:30 PM

Princeton I & II

VENDOR SESSION - "5 MINUTES OF FAME" - 5MOF

Session Leaders: Mark Hayward, Active Ingredient Technologies; Jeremiah Tipton, BioTech & OMICSx Solutions

This is the unique, totally one of a kind exhibitor session at CPSA. There are no rules other than the 5 minute time limit and presenters are actively encouraged to make it fun. As a result, presenters tend to bring their A-game in entertainment and try to make it memorable.

5:30 PM – 6:30 PM

EXHIBITION & SOCIAL HOUR - WHERE TECHNOLOGY AND SOLUTIONS MEET!

University I, University Ballroom Lobby

6:30 PM – 7:30 PM

University II

CPSA AWARD PRESENTATIONS & ANNOUNCEMENTS

Local ACS Discussion Groups

CPSA Announcements

- ▶ CPSA Announcements and Upcoming Events
- ▶ Steven A. Hofstadler Graduate Student Award/Recognition
Petia Shipkova, Merck and Emily Ehrenfeld, New Objective
- ▶ Innovator Award Presentation
Mark Cancilla, Merck; Dan Spellman, Merck
- ▶ Program Chair Recognition
Mike Lee, Milestone Development Services
- ▶ CPSA USA 2020 Program Chair Announcement
Timothy Olah, Bristol-Myers Squibb
Neil Spooner, Spooner Bioanalytical Solutions

7:30 PM - 9:00 PM

University II

**KEYNOTE LECTURE
PRESENTATION OF THE DISTINGUISHED ANALYTICAL SCIENTIST AWARD**

Sponsored by New Objective

Keynote Lecture

Strategic Plan for Implementing Change

Carla Cuthbert, Centers for Disease Control and Prevention

Distinguished Analytical Scientist Award Presentation

Introduction and presentation of award by Todd Gillespie, Eli Lilly & Company and Jim Stephenson, Thermo Fisher Scientific

Tools and Technologies to Push the Bioanalytical Envelope

Rick Yost, University of Florida

PROGRAM AGENDA

Thursday October 31

7:30 AM – 8:30 AM

REGISTRATION & CONTINENTAL BREAKFAST

2nd Floor Lobby

7:30 AM - 8:30 AM

WOMEN IN SCIENCE AND TECHNOLOGY BREAKFAST

Princeton I & II

Discussion Leaders: Amanda Berg, New Objective and Suzanne Cordovado, Centers for Disease Control and Prevention

Please join us for an invigorating breakfast discussion centered around mentoring and how it can be used to encourage and promote Women in Science and Technology. Through the sharing of personal experiences – storytelling – we will explore the role and power of mentoring, the evolution of mentoring needs over one’s career and identify different approaches used by successful women.

8:30 AM – 10:00 AM

COLLOQUIA & ROUNDTABLES

Princeton I & II

PK LCMS BMV in a FFP World

Discussion Leader: Steve Lowes, Q2 Solutions

The term ‘regulated bioanalysis’ is typically ascribed to quantitative determination of drugs and their metabolites in support of pharmacokinetic (PK) studies. In this sense, liquid chromatography-mass spectrometry (LCMS) has been the favored tool of bioanalysts contributing the development of small molecule drugs for over 20 years. Amazingly it is still the technique of choice for such analytes however the modern practitioner of bioanalysis is well advised to be looking at what is coming soon if not already upon us. Drug modalities, analytical technique/technologies and fundamental approaches to disease treatment are presenting new needs and opportunities that must be addressed. Establishing assays that are ‘suitable for intended use’ has historically abided by bioanalytical method validation (BMV) guidance but such a priori guideline themselves are debatably insufficient or inappropriate for the challenges presented to today’s bioanalysts. Some regulatory guidance have anticipated the current and future needs with reference to fit-for-purpose (FFP) approaches while others continue to evolve around a narrower scope of application. In any case, the modern bioanalyst needs to be able to adapt and defend the science that supports the accuracy, precision, sensitivity, selectivity, stability and reproducibility of bioanalytical measurements. This session will explore some practical and rationale approaches to bioanalysis in the context of today’s needs that are not necessarily best served by traditional BMV approaches.

- ▶ **Using Real World Data to Inform Appropriate Acceptance Criteria for Hybrid Immuno-Affinity LC-MS/MS Assays**
Rachel Basile, Genentech
- ▶ **Navigating the Unknown: Between Discovery BioA and Regulated (GLP) BioA Adopting and Executing FFP Bioanalysis**
Enaksha Wickremsinhe, Eli Lilly & Co.

THURSDAY, OCTOBER 31

PROGRAM AGENDA

Wednesday October 30

10:15 AM - 11:45 AM

PARALLEL SESSIONS

Track 1 Symposium Session <i>Villanova Amphitheater</i>	Track 2 Colloquium Session <i>Lehigh</i>
<p>The DAVINCI Project: Development of Next Generation Analytical Technologies <i>Discussion Leader: Eugene Ciccimaro, Agilent Technologies</i></p> <p>This workshop style session guided by an expert panel will walk through the stages of vendor-industry collaborations. Our goal is to begin to answer the question: how can our community work together better to more quickly and successfully nurture collaborations leading to new analytical solutions to address today's challenges?</p> <p><i>Panelists and Presenters:</i> <i>Carl Myerholtz, Agilent Technologies</i> <i>Harsha Gunawardena, Janssen Research & Development</i> <i>Jay Johnson, Pfizer</i> <i>Jonathan Josephs, Sanofi</i> <i>Jim Murphy, Waters Corporation</i> <i>Tim Olah, Bristol-Myers Squibb</i> <i>Scott Peterman, Thermo Fisher Scientific</i> <i>Kayte Parlevliet, Trajan Scientific & Medical</i> <i>Dan Spellman, Merck</i> <i>Patty Sun, SCIEX</i></p>	<p>Bioanalytical Considerations in Biological Therapeutics <i>Discussion Leaders: Xiaohui Xu, Bristol-Myers Squibb and Weifeng Xu, Merck</i></p> <p>Biological drugs include monoclonal antibodies, antibody fragments (e.g., minibodies), antibody–drug conjugates, nonantibody protein drugs (e.g., growth hormones), peptide and nucleic acid-based drugs. With a sharp increase of biological drug candidates entering the drug development programs over the past decade, the demand for robust and sensitive bioanalytical assays as well as critical reagents to support bioanalysis in both nonregulated (exploratory) and regulated laboratory environment has been increasing. The critical role of bioanalytical support is highlighted by the fact that bioanalysis is required throughout an entire drug-development: from in vitro screening, pharmacokinetics, safety and efficacy biomarkers development, immunogenicity assessment to product release pharmacovigilance. In this session, challenges and considerations for bioanalytical support will be discussed, covering cell Therapy, Mass Spectrometry for Ummuno Assay, the importance of quality control of reagents as well as experiences in expanding reagent group.</p> <ul style="list-style-type: none"> ▶ Expanding Reagent Capability from BA Perspective in Supporting Growing Biologics Portfolio <i>Yang Xu, Merck</i> ▶ Bioanalytical Testing for Cell and Gene Therapy Pharmacokinetic Parameter Assessment Using PCR <i>Robert Dodge, Novartis</i> ▶ MSIA (Mass Spec Immuno Assay) and MFLC-MS/MS for the Bioanalysis of Humira from Human Plasma <i>Chad Christianson, Alturas Analytics</i> ▶ Reagent Consideration in Biologics Development <i>Jonathan Haulenbeek, Bristol-Myers Squibb</i>

WEDNESDAY, OCTOBER 30

PROGRAM AGENDA

Thursday October 31

10:15 AM - 11:45 AM PARALLEL SESSIONS (cont'd)

Track 3 Colloquium Session

LaSalle

Innovative Applications of Modern NMR Spectroscopy

Discussion Leader: James Small, Merck

- ▶ Applying Hyperpolarization to Challenges in NMR
Sean Bowen, Merck
- ▶ Studying Flexibility in Beyond Rule of 5 Space
Pablo Trigo Mouriño, Merck
- ▶ NMR Applications in Polysaccharide Vaccine Development
Chengli Zong, Merck

12:00 PM – 1:15 PM

SPONSORED LUNCH & ROUNDTABLE DISCUSSION

Princeton I & II

Sponsored by New Objective

Discussion Leader: Emily Ehrenfeld, New Objective

- ▶ Cancer Metabolism
Shawn Davidson, Princeton University

THURSDAY, OCTOBER 31



7th ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis

August 23-26, 2020 • São Paulo, Brazil

Program Chair
Carlos Kiffer
EPM / UNIFESP

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PROGRAM AGENDA

Thursday October 31

1:30 PM – 3:00 PM

PARALLEL SESSIONS

<p>Track 12 Symposium Session <i>Princeton I & II</i></p>	<p>Track 13 Colloquium Session <i>Villanova Amphitheater</i></p>
<p>Presentations from the Edge: Young Scientist Session <i>Discussion Leaders: Naidong Weng, Janssen Research & Development; Chuping Luo, Advanced Materials Technology</i></p> <ul style="list-style-type: none"> ▶ High Resolution Mass Spectrometry and Isotope Tracing to Probe Lipid Metabolism <i>Erik Allman, Penn State University</i> ▶ Sensitive Antibody Free Strategies for Targeted Protein Quantification in Biomatrices <i>Bo An, GlaxoSmithKline</i> ▶ Development of A Streamlined Workflow for Quantitative Analysis of Antisense Oligonucleotide (ASO) Therapeutics <i>Fengjian Shi, Biogen</i> 	<p>Innovator Session <i>Sponsored by Spooner Bioanalytical Solutions</i> <i>Discussion Leaders: Mark Cancilla, Merck and Daniel Spellman, Merck</i></p> <ul style="list-style-type: none"> ▶ Biomeme’s Handheld qPCR Platform: Clinical and Pharmaceutical Implications <i>Ryan Ragland, Biomeme Inc.</i> ▶ Commercializing SLIM Ion Mobility for the Masses <i>Daniel DeBord, MOBILion Systems, Inc</i> ▶ Automated Methods and Software for Intact Biomolecule MS Analysis <i>Mark Hail, Novatia</i>

3:00 PM

CLOSING REMARKS & ADJOURN

Princeton I & IIT

Timothy Olah, Bristol-Myers Squibb
Neil Spooner, Spooner Bioanalytical Solutions
Mike Lee, Milestone Development Services

THURSDAY, OCTOBER 31



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