

21ST ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis



Where Technology and Solutions Meet

**United to Beat Disease:
Partners in Healthcare, Partners in Science,
Partners in Technology and Innovation**

MEETING PROGRAM

October 15 - 18, 2018
Sheraton Bucks County
Langhorne, PA

OptiFlow LC-MS/MS Quant Solution

Microflow Sensitivity, Analytical Flow Usability



M5
MicroLC
System

QTRAP®
LC-MS/MS
with OptiFlow™
Turbo V
Source

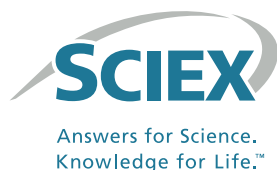
Introducing the Intelligent Union of Sensitivity, Ease-of-use, and Robustness for Quantitation.

The new OptiFlow Quant Solution from SCIEX provides the sensitivity benefits of microflow separations, but with the reliability and usability expected from traditional analytical flow assays, giving you:

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WELCOME

Inspiration. Collaboration.

October 15, 2018

Dear Colleagues:

On behalf of the organizing committee and our sponsors, it is our pleasure to welcome you to the 21st annual Symposium on Clinical and Pharmaceutical Solutions through Analysis (CPSA USA 2018). 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 chair, All Kloss, has followed Suzanne Cordovado and Emily Ehrenfeld's, vision from last year's annual meeting and developed the theme for CPSA USA 2018: United to Beat Disease: Partners in Healthcare, Partners in Science, Partners in Technology and Innovation.

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 Hui Zhang from Pfizer. Our Plenary Lecture on Tuesday will feature Florian Eichler of Massachusetts General Hospital and Harvard Medical School with "Transformative Partnerships in Rare Neurological Diseases: the Case of Adrenoleukodystrophy." Kevin Bateman from Merck, will deliver the Keynote Lecture on Wednesday, "Smart Trials: Moving from Site-Centric to Patient-Centric Clinical Trials."

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. 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,

A handwritten signature in black ink, appearing to read 'Mike S. Lee'.

Mike S. Lee
CPSA Founder

A handwritten signature in black ink, appearing to read 'Alla Kloss'.

Alla Kloss
2018 Program Chair

2018 ORGANIZING COMMITTEE

PROGRAM CHAIR

Alla Kloss
Sanofi

SYMPOSIA & SESSIONS

Susan Abbatiello
Thermo Scientific

Dave Abramowitz
SCIEX

Bradley Ackermann
Eli Lilly & Company

Mark Arnold
Covance

Lorin Bachmann
Virginia Commonwealth
University

Kevin Bateman
Merck

Chad Briscoe
PRA Health Sciences

John Butler
Agilent Technologies

Mark Cancellia
Merck

Helene Cardasis
Thermo Scientific

Johnny Cardenas
SCIEX

Donald Chace
Medolac Laboratories

Michelle Clasquin
Agius

Suzanne Cordovado
Centers for Disease Control
& Prevention

Shawn Davidson
Princeton University

Dave Detlefsen
Novatia

Nicole Donnelly
PharmaCadence Analytical
Services

Emily Ehrenfeld
New Objective

Ayman El-Kattan
Pfizer

Joe Fox
SCIEX

Patrick Fromal
Shimadzu

Timothy Garrett
University of Florida

Hannah Glader
Alturas Analytics

Mark Hail
Novatia

Mark Hayward
Active Ingredient Technologies

Lucinda Hittle
Merck

Scott Hottenstein
GlaxoSmithKline

Qin Ji
Bristol-Myers Squibb

Wenying Jian
Janssen Research &
Development

John Kellie
GlaxoSmithKline

Kelli Jonakin
SCIEX

Barry Jones
Q2 Solutions

Jonathan Josepchs
Thermo Fisher Scientific

Olga Kavetskaia
Pfizer

Richard King
PharmaCadence Analytical
Services

Michael Lassman
Merck

Yurong Lai
Bristol-Myers Squibb

Ken Lewis
OpAns

Wenkui Li
Novartis

Guowen Liu
Agius Pharmaceuticals

Linlin Luo
Bristol-Myers Squibb

Joshua Mann
SOPHiA GENETICS

Nicole Matz
PRA Health Sciences

Eric Milgram
PepsiCo

Ganesh Moorthy
Children's Hospital of
Philadelphia

Shane Needham
Alturas Analytics

Randall Nelson
Arizona State University

Timothy Olah
Bristol-Myers Squibb

Dave Pirman
Agius Pharmaceuticals

Joanna Pols
Merck

Robyn Rourick
Genentech

Nalini Sadagopan
Agilent Technologies

Jim Shen
Bristol-Myers Squibb

Petia Shipkova
Bristol-Myers Squibb

Joe Siple
New Objective

James Small
Merck

Daniel Spellman
Merck

Neil Spooner
Spooner Bioanalytical
Solutions

Matthew Szapacs
GlaxoSmithKline

Stephen Tomisich
Trajan Scientific & Medical

Gary Valaskovic
New Objective

Roy Vaz
Sanofi

Sihe Wang
Cleveland Clinic

Helen Weng
Frontage Laboratories

Naidong Weng
Janssen Pharmaceuticals

Clark Willard
inVentiv Health

Enaksha Wickremsinhe
Eli Lilly & Co.

Eric Woolf
Merck

Sophia 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

LOGISTICS & MANAGEMENT

Logistics & Communications

Carla Marshall-Waggett
New Objective

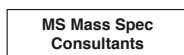
Management & Correspondence

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.



EXHIBITION

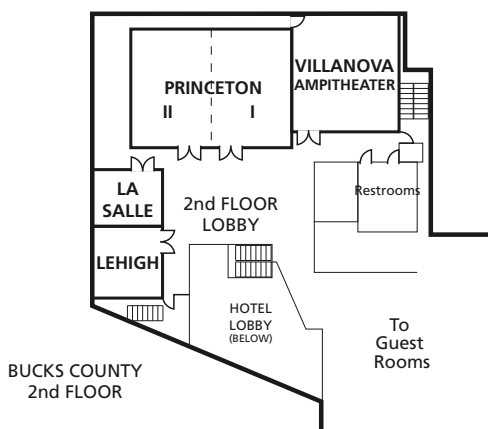
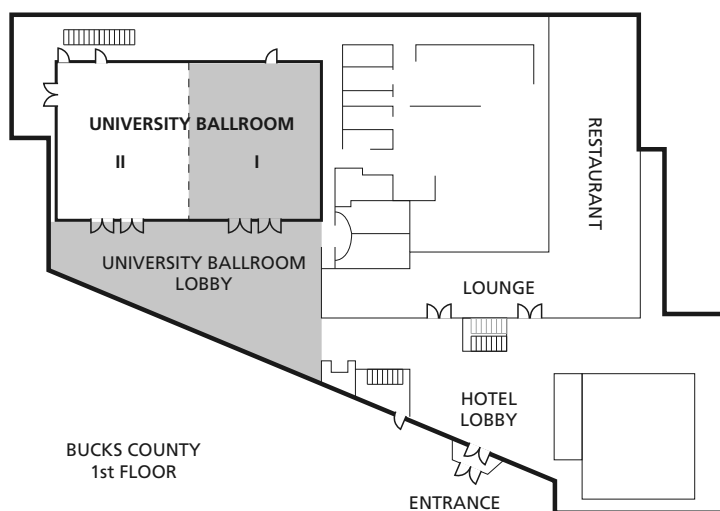
Wednesday October 17

EXHIBITORS	BOOTH
Agilent Technologies	26
Cambridge Isotope Labs	6
Chinese American Chromatography Association (CACA)	18
Elucidata	13
ES Industries	21
Frontage Laboratories	9
IMCS	14
IonSense	4
MAC-MOD Analytical	12
MS Mass Spec Consultants	22
Molecular Discovery	17
New Objective	2
Novatia	28
Novilytic	7
OpAns	8
PharmaCadence	27
PRA Health Sciences	20
Primera	11
ProLab Instruments	1
Scientific Instrument Services (SIS)	3
SCIEX	15
Shimadzu Scientific Instruments	25
Sound Analytics	24
Spooner Bioanalytical Solutions	10
Thermo Scientific	23
Trajan	5
Wiley	19

EXHIBIT LOCATIONS & HOTEL LOCATIONS

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

Booths 1 - 14 University Ballroom I
 Booths 15 - 27 University Ballroom Lobby



SHORT COURSES & EVENTS

Monday October 15

7:30 AM - 8:30 AM

REGISTRATION & CONTINENTAL BREAKFAST

2nd Floor Lobby

8:30 AM - 4:00 PM

SHORT COURSES

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,

Princeton II

Bioanalysis of Mix Modalities via Hybrid and Orthogonal Approaches

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

Lehigh

Building a Better Clinical Mass Spectrometry Lab

Instructors: Don Chace, Medolac Laboratories; Timothy Garrett, University of Florida; Mark Hayward, Active Ingredient Technologies; Kenneth Lewis, OpAns

LaSalle

Human Pharmacokinetic Prediction and Approaches to Identify Rate Determining Step of Drug Absorption and Elimination: Industrial Perspective

Instructors: Ayman El-Kattan, Pfizer and Yurong Lai, Gilead

University Grille

12:00 pm - 4:30 pm

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; Timothy Olah, Bristol-Myers Squibb; Enaksha Wickremsinhe, Eli Lilly & Co.

Villanova Amphitheater

Integrating Technologies for High Throughput, Industrialized Drug Discovery

Instructor: Abhishek Jha, Elucidata

7:30 AM - 9:30 AM

CPSA 5K EVENT CPSA Charitable Foundation

*Makefield Highlands Golf Club
Yardley, PA*

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

10:00 AM - 3:00 PM

CPSA OPEN EVENT CPSA Charitable Foundation

*Makefield Highlands Golf Club
Yardley, PA*

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

12:30 PM - 4:30 PM

MOLECULAR DISCOVERY USERS MEETING: WEBMETABASE 4.0 WORLD WIDE PREMIER

University I & II

Discussion Leader: Ismael Zamora, Molecular Discovery

4:30 PM - 5:30 PM

EXECUTIVE ROUNDTABLE: WHERE TECHNOLOGY AND SOLUTIONS MEET BUSINESS

University I & II

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

Looking at science topics through a business lens

MEETINGS & EVENTS

Monday October 15

6:00 PM - 9:00 PM

University I & II

RECEPTION & SPONSOR'S DINNER

Hosted by SCIEX

Opening Remarks

Alla Kloss, Sanofi; Mike Lee, Milestone Development Services

CPSA Institute

*Naidong Weng, Janssen Research & Development; Timothy Garrett, University of Florida;
Neil Spooner, Spooner Bioanalytical Solutions*

CPSA Charitable Foundation

Alla Kloss, Sanofi and Emily Ehrenfeld, New Objective

Introducing ALD Connect:

Raising Awareness, Creating Community, & Empowering Patients to Find a Cure for ALD

Florian Eichler, Harvard Medical School and Mass General Hospital

Kathleen O'Sullivan-Fortin, ALD Connect

Jesse Torrey and Jack Torrey: Connect to the Patients

Distinguished Lecture Series

Hosted by SCIEX

The Next Generation HT BioAnalytical Platform for Drug Discovery: ADE-OPP-MS

Hui Zhang, Pfizer

MONDAY, OCTOBER 15



2nd ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis

February 5-8, 2019 • London, U.K.

Program Co-Chair

Neil Spooner

Spooner Bioanalytical Solutions

Program Co-Chair

Ismael Zamora

Molecular Discovery

Plenary Speaker

Hitesh Pandya

GlaxoSmithKline

CPSA EUROPE FOCUS: TECHNOLOGY FOR THE PATIENT

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

www.cpsa-europe.com

Where Technology and Solutions Meet

PROGRAM AGENDA

Tuesday October 16

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

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

Alla Kloss, Sanofi

9:00 AM - 9:45 AM

PLENARY LECTURE

University I & II

**Transformative Partnerships in Rare Neurological Diseases:
The Case of Adrenoleukodystrophy**

Florian Eichler, Harvard Medical School, Massachusetts General Hospital

TUESDAY, OCTOBER 16



5th ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis

March 11-13, 2019 • Gainesville, FL

Program Chair

Timothy Garrett

University of Florida

CPSA METABOLOMICS FEATURES

Symposia • Roundtables • Analysis Trends • New Technology • Expo • Student Session

Hosted by the University of Florida

www.cpsa-metabolomics.com

Where Technology and Solutions Meet. Where Discovery Meets the Clinic.

PROGRAM AGENDA

Tuesday October 16

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>Leveraging Government/Industry Partnerships to Build a Better Bassinet in Newborn Screening <i>Discussion Leader: Suzanne Cordovado, Centers for Disease Control and Prevention</i></p> <ul style="list-style-type: none"> ▶ CDC's Newborn Screening Translation Research Initiative: An Ongoing Public-Private Partnership through the CDC Foundation <i>Robert Vogt, Centers for Disease Control and Prevention</i> ▶ Molecular Testing and DNA Sequencing in Newborn Screening: Working with Partners to Ensure Accurate Testing from Dried Blood Spots <i>Suzanne Cordovado, Centers for Disease Control and Prevention</i> ▶ Past, Present and Future of Newborn Screening for Metabolic Disorders: Global Harmonization of Screening Results <i>Kostantinos Petritis, Centers for Disease Control and Prevention</i> 	<p>Metabolomics to Biomarkers: Seeing Disease Clearly <i>Discussion Leaders: Michelle Clasquin, Pfizer and David Pirman, Agios Pharmaceuticals</i></p> <ul style="list-style-type: none"> ▶ Metabolomics in Basic Biomedical Research <i>Caroline A. Lewis, Whitehead Institute for Biomedical Research</i> ▶ Probing Metabolic Heterogeneity Using Imaging Mass-Spectrometry <i>Shawn M. Davidson, Princeton University</i> ▶ Transaminase Inhibition by 2-Hydroxyglutarate Impairs Glutamate Biosynthesis and Redox Homeostasis in Glioma <i>Sam McBrayer, Dana-Farber Cancer Institute</i>
<p>Track 3 Colloquium Session <i>Villanova Amphitheater</i></p>	<p>Track 4 Colloquium Session <i>Lehigh</i></p>
<p>A Private Endeavour to Deliver the Future Analytical Tools for All; Foolhardy or Grand? <i>Discussion Leader: Stephen Tomisich, Trajan Scientific & Medical</i></p> <p>Investing in the Workflow Solutions of the Future Smart Chemistries; Selective Sample Processing; Faster, Cheaper, Better Analytically Credible Micro-Sampling Tools Workflow Automation, Centralized vs Remote, Sampling vs POCT</p> <p><i>Stephen Tomisich, Trajan Scientific & Medical</i> <i>Andrew Gooley, Trajan Scientific & Medical</i> <i>General Discussion</i></p>	<p>Joint Session with Chinese American Chromatography Association (CACA) <i>Discussion Leaders: Chuping Luo, Advanced Materials Technology; Naidong Weng, Janssen Research & Development</i></p> <ul style="list-style-type: none"> ▶ A Closer Look at the Retention Mechanism in Hydrophilic Interaction Chromatography (HILIC) <i>Yong Guo, Fairleigh Dickinson University</i> ▶ The Advancement and Application of Hydrophilic Interaction Chromatography (HILIC) Technique in Today's Bioanalytical Science <i>Yang Lu, Frontage Laboratories</i> ▶ Recent Advances and Optimization in Reversed Phase Separation Technology for mAb Analysis <i>Chuping Luo, Advanced-Materials-Tech</i>

TUESDAY, OCTOBER 16

Is accuracy and precision important to your blood work?
Does hematocrit impact the quantitation of your analysis?
Are you looking at patient centric sampling?

At Trajan, our mission is to provide easy-to-use tools that enable the remote and minimally invasive collection of biological samples, that are affordable and preserve sample integrity, whilst being simply integrated in to current laboratory workflows.

Talk with us around your sampling needs, as we are able to deliver full support from product design, system integration, manufacturing, logistics and go-to market strategies.

Join us on Tuesday 16th October 10:00 - 11:45am

A private endeavor to deliver the future analytical tools for all; foolhardy or grand?

Discussion Leader: Stephen Tomisich, Trajan Scientific and Medical

- Investing in the workflow solutions of the future
- Smart chemistries; selective sample processing; faster, cheaper, better
- Analytically credible microsampling tools
- Workflow automation, centralized vs remote, sampling vs POCT

Intervention



- Personal choice
- Clinician driven change

Diagnose



- Interpretation of the results and what they mean
- Big data based on GOOD data

Test



- Qualified laboratory services
- Workflow integration

Microsampling



- Sample integrity
- Ease of use
- Accessible and affordable

It's about enabling samples to be taken that would or could not otherwise be taken, to drive information rich decision making.

Quadrupole Time-of-Flight
Liquid Chromatograph Mass Spectrometer

LCMS-9030



Effortless Performance

Conduct Critical Qualitative and Quantitative Analysis with Genuine Confidence and Ease

Shimadzu's research-grade **LCMS-9030 quadrupole time-of-flight (Q-TOF) mass spectrometer** combines the engineering DNA from our proven triple quadrupole (LC-MS/MS) platform with powerful, new TOF architecture to transform high mass accuracy workflows. The result is a system that delivers high-resolution, accurate-mass detection with incredibly fast data acquisition rates.

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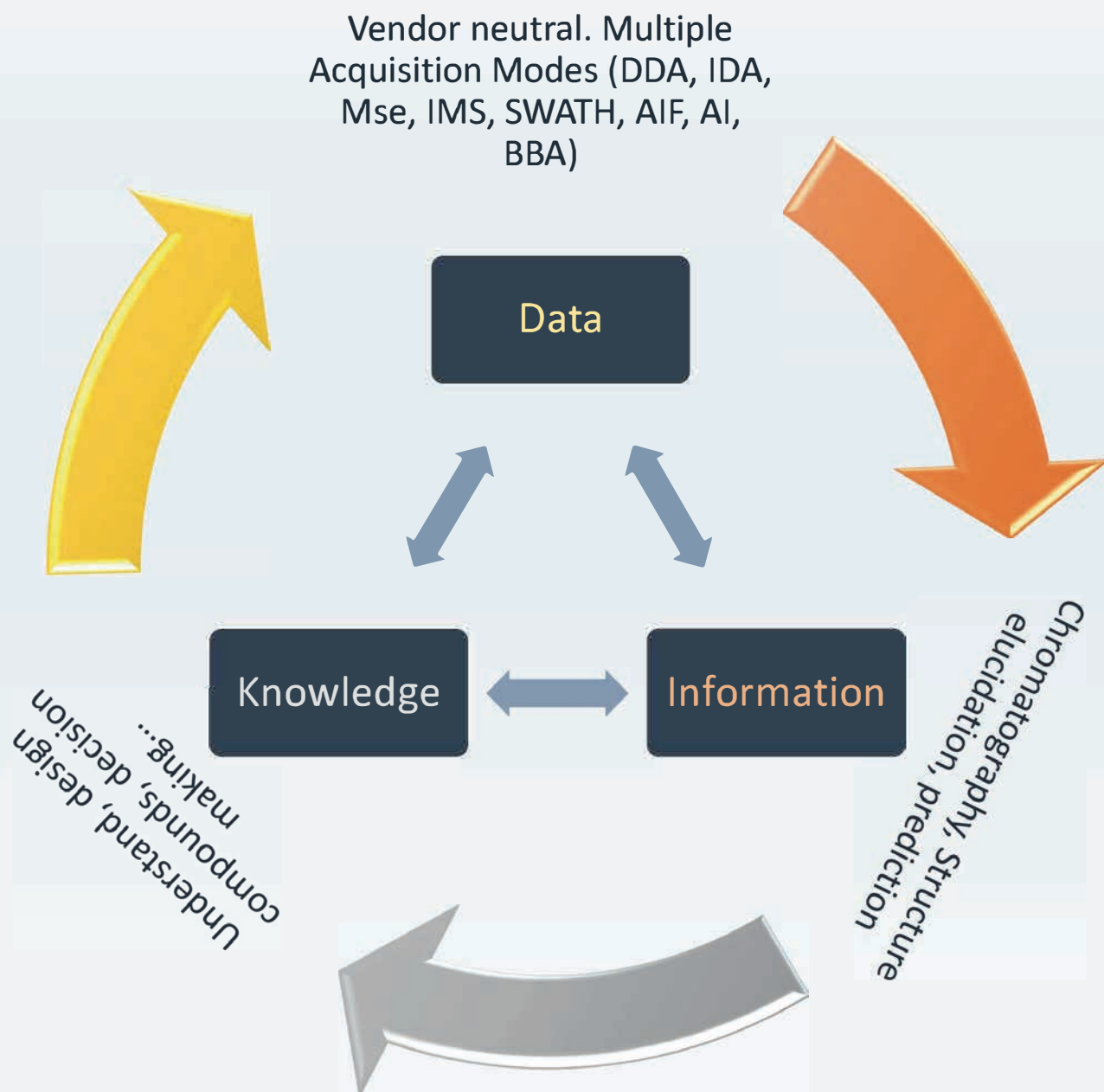


For all mAb quality attributes, you need confidence in your answers. You need to be Agilent sure.

mAbs can have numerous quality attributes that can impact drug safety and/or efficacy. Confidently identifying CQAs is a crucial and challenging step in biopharmaceuticals development. For all your attribute characterization challenges, Agilent can help you turn your unknowns into answers. Renowned for accuracy and reliability, Agilent offers a comprehensive set of technologies—instruments, columns, databases, methods, and more—complete solutions so you can confidently handle even your most complex mAb challenges.

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- Structure elucidation for bio and chemical research in small and peptide molecules
- Lipidomics analysis

PROGRAM AGENDA

Tuesday October 16

12:00 PM – 1:00 PM

University I & II

SPONSORED LUNCH & ROUNDTABLE DISCUSSION

Sponsored by Shimadzu Scientific Instruments

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 & Company.; Matthew Szapacs, GlaxoSmithKline

3:15 PM – 4:45 PM

PARALLEL SESSIONS

<p>Track 5 Symposium Session <i>University I</i></p>	<p>Track 6 Colloquium Session <i>University II</i></p>
<p>Meet All Omics <i>Discussion Leader: Monica Lane, Sanofi</i></p> <ul style="list-style-type: none"> ▶ Multi-omic Study to Identify Novel Biomarkers of Pompe Disease <i>Kelly George, Sanofi</i> ▶ Utilization of High-Throughput LC-MS and CE-MS in Plasma Biomarker Discovery for Infectious Diseases <i>J. Will Thompson, Duke University</i> ▶ Fast Sensitive Method for Trisaccharide Biomarker Detection in Mucopolysaccharidosis <i>Alexei Belenky and Drew Tietz, Sanofi</i> 	<p>Biomarkers <i>Discussion Leaders: Wenyong Jian, Janssen Research & Development; Naidong Weng, Janssen Research & Development</i></p> <ul style="list-style-type: none"> ▶ 7-Alpha-Hydroxy-4-Cholesten-3-One (C4) as a Potential Biomarker for Glucagon Receptor (GCGR) Activation <i>Lijuan Kang, Janssen</i> ▶ Impacts of Biomarker Bioanalysis on Drug Development And Translational Medicine <i>Yue Zhao, Bristol-Myers Squibb</i> ▶ Biomarkers and the New BMV Guidance <i>Barry Jones, Q2 Solutions</i>
<p>Track 7 Colloquium Session <i>Villanova Amphitheater</i></p>	<p>Track 8 Colloquium Session <i>Lehigh</i></p>
<p>Metabolomics and Standardization <i>Discussion Leaders: Timothy Garrett, University of Florida</i></p> <ul style="list-style-type: none"> ▶ Approaches to Enable Longitudinal Metabolomic Data Mining in Drug Discovery <i>Dave Pirman, Agios Pharmaceuticals</i> ▶ Metabolomic and Fluxomic Biomarkers for the Fasted/ Refed Transition <i>Irwin Kurland, Albert Einstein College of Medicine</i> ▶ Development of Reference Method Systems to Improve Patient Care <i>Lorin M. Bachmann, Virginia Commonwealth University</i> 	<p>Advancing Analytical and Engineering Techniques in Pharmaceutical Sciences <i>Discussion Leaders: James Small, Merck; Yongchao Su, Merck</i></p> <ul style="list-style-type: none"> ▶ Characterizing the Impact of Modifications in CDRs of mAbs on Structure-Function by Hydrogen-Deuterium Exchange Mass Spectrometry and Functional Assays <i>Hui Wei, Bristol-Myers Squibb</i> ▶ Predictive Physical Stability Enabling Pharmaceutical Package Selection <i>Michael McNevin, Merck & Co, Inc.</i> ▶ Utilizing Imaging Techniques, such as Scanning Electron Microscopy and Energy Dispersive Spectroscopy, to Enabled Drug Development <i>James D. Ormes, Merck & Co, Inc.</i>

PROGRAM AGENDA

Tuesday October 16

4:45 PM – 5:15 PM

LET THEM EAT CAKE!

2nd Floor Lobby

Donald Chace, Medolac Laboratories

5:00 PM – 6:00 PM

SOCIAL HOUR & SPONSORED WORKSHOPS

Princeton I

WORKSHOP
Sponsored by Sound Analytics

Princeton II

**Microsampling and Patient Centric Blood Sampling and Analysis:
Practical Aspects of Implementation**
Sponsored by Spooner Bioanalytical Solutions

Villanova Amphitheater

WORKSHOP
Sponsored by Agilent Technologies

6:30 PM - 9:30 PM

SPONSOR HOSPITALITY & EVENING WORKSHOPS

University I

MICROSAMPLING SUMMIT

Hosted by New Objective and Spooner Bioanalytical Solutions

Workshop Leaders: Kevin Bateman, Merck; Qin Ji, Bristol-Myers Squibb; Olga Kavetskaia, Pfizer; Timothy Olah, Bristol-Myers Squibb; Joe Siple, New Objective; Neil Spooner, Spooner Bioanalytical Solutions; Enaksha Wickremsinhe, Eli Lilly & Co.

- ▶ **Patient Centric Sampling – It Really is Bleedin’ Obvious**
Neil Spooner, Spooner Bioanalytical Solutions
- ▶ **Bleeding at Home... Impact on Clinical Trial Patients**
Enaksha Wickremsinhe, Eli Lilly & Co.
- ▶ **“A pint of sweat, saves a gallon of blood.” (George S. Patton) Let’s Get to Work Now!**
Timothy Olah, Bristol-Myers Squibb
- ▶ **Bringing the Trial to the Patient**
Kevin Bateman, Merck



10th ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis

April 10-12, 2019 • Shanghai, China

Program Chair: **Min Liu** Merck Plenary Speaker: **Petr Vachal** Merck Keynote Speaker: **Mingqiang Zhang** Amgen

Workshops • Roundtables • Symposia • New Technology • Expo • Social Events • Student Session

www.cpsa-shanghai.com

Where Technology and Solutions Meet. Where East Meets West.

PROGRAM AGENDA

Wednesday October 17

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

8:30 AM – 10:00 AM

SYMPOSIUM SESSION & ROUNDTABLE DISCUSSION

University I & II

Lions Don't Hunt Chipmunks: The Unique and Important Role of Quantitative Mass Spectrometry for the Analysis of Tissue-Based Protein Biomarkers

Discussion Leader: Brad Ackermann, Eli Lilly & Co.

- ▶ **Hunting for Inflammatory Cytokine Expression in Atopic Dermatitis Skin Biopsies Using Multiplexed Online Immunoaffinity LC/MS/MS**
Jay Johnson, Pfizer
- ▶ **Why Assume When You Can Actually Detect? Comprehensive Insight into the Complexities of Disease and Identifying Effective Treatment**
Timothy Olah, Bristol-Myers Squibb
- ▶ **Targeted Mass Spectrometry to Quantify Drug Targets in Cancer Immunotherapy**
Dan Liebler, Protyopia/Adjunct Professor, Vanderbilt University

10:15 AM – 11:45 AM

PARALLEL SESSIONS

Track 1 Symposium Session <i>Villanova Amphitheater</i>	Track 2 Colloquium Session <i>Princeton I & II</i>
<p>Patient Centric Blood Sampling and Analysis: Let's Make this Happen! <i>Discussion Leaders: Neil Spooner, Spooner Bioanalytical Solutions; Joe Siple, New Objective</i></p>	<p>Targeting Parkinson's Disease <i>Discussion Leader: Pablo Sardi, Sanofi</i></p> <ul style="list-style-type: none"> ▶ Parkinson's Progression Marker Initiative (PPMI): Identifying Progression Biomarkers for Therapeutic Development <i>Samantha Hutten, Michael J. Fox Foundation</i> ▶ Parkinson's Disease: Time to be Precise <i>Pablo Sardi, Sanofi</i> ▶ Identifying CSF Markers of Parkinson's Disease and Progression with Mass Spectrometry <i>Daniel Chelsky, Caprion Biosciences, Inc.</i>

WEDNESDAY, OCTOBER 17

PROGRAM AGENDA

Wednesday October 17

10:15 AM – 11:45 AM

PARALLEL SESSIONS *(cont'd)*

<p>Track 3 Symposium Session <i>Lehigh</i></p>	<p>Track 4 Colloquium Session <i>LaSalle</i></p>
<p>Metabolite Identification and Databases: Industrial Workflows and Emerging Trends <i>Discussion Leader: Ismael Zamora, Molecular Discovery</i></p> <ul style="list-style-type: none"> ▶ Unlocking the potential of Ion Mobility for Drug Metabolite Identification - partnering with Lead Molecular Design <i>Mark Wrona, Waters</i> ▶ UNIFI/MassMetaSite Integration. How to Use Ion Mobility Data Using the UNFI 3rd Party API <i>Ismael Zamora, Molecular Discovery</i> ▶ Structural Elucidation in Chemistry: MS and NMR Join Forces for an Automatic Workflow <i>Elisabeth Ortega, Molecular Discovery</i> 	<p>Innovation Bootcamp <i>Discussion Leader: Lucinda Hittle</i></p>

12:00 PM -1:00 PM

University I & II

SPONSORED LUNCH & ROUNDTABLE

Sponsored by Thermo Fisher Scientific

1:15 PM – 2:15 PM

Princeton I & II

SOCIAL HOUR & SPONSORED WORKSHOPS

WORKSHOP

Leading High-Performance Nanoflow and Microflow LC-MS into the Future

Sponsored by New Objective

Bernhard Nemec, Prolab

Andrew Lee, IMCS

Abhishek Jha, Elucidata

Monica Lane, Sanofi

Michelle Robinson, Merck

Villanova Amphitheater

WORKSHOP

Sponsored by Thermo Fisher Scientific

Lehigh

WORKSHOP

Maven User Meeting

Sponsored by Elucidata

Abhishek Jha, Elucidata

PROGRAM AGENDA

Wednesday October 17

2:30 PM – 3:45 PM

PARALLEL SESSIONS

<p>Track 5 Symposium Session <i>Princeton I & II</i></p>	<p>Track 6 Colloquium Session <i>Lehigh</i></p>
<p>Clinical Biomarkers: Business or Science or the Business of Science <i>Discussion Leaders: Arkady Gusev, Novartis and Olga Kavetskaia, Pfizer</i></p> <ul style="list-style-type: none"> ▶ Introduction to Clinical Biomarkers and the Business of Science <i>Olga Kavetska, Pfizer</i> ▶ Business of Fit for Purpose: From sample management to validation to final sample analysis data <i>Iman Jilani, Pfizer</i> ▶ Business of Synergies: From clinical sites to central lab, CROs and beyond <i>Arkady Gusev, Novartis</i> ▶ LC-MS Biomarker Bioanalysis Outsourcing Business Models: Challenging the PK Precedence <i>Stephen Lowes, Q2 Solutions</i> 	<p>Frontiers of Innovation, Technology and Solutions <i>Discussion Leader: Alla Kloss, Sanofi; Ganesh S. Moorthy, Children's Hospital of Philadelphia</i></p> <ul style="list-style-type: none"> ▶ Microsampling Assays for Pediatric Clinical Trials: Opportunities and Challenges <i>Ganesh S. Moorthy, Children's Hospital of Philadelphia</i> ▶ Recent Trends with the Transfer from LBA to LC/MS Assays: Microflow LC/MS Applications for Large Biomolecules <i>Shane Needham, Alturas Analytics</i> ▶ Integrative Proteomics to Producing a Large Versatile Repertoire of Therapeutic Nanobodies <i>Yi Shi, University of Pittsburgh</i> ▶ High-Frequency Longitudinal Analysis of Macro- and Micro- Inflammation Processes Using Dried Blood Microsamples and SISCAPA Protein Panel Assays <i>Leigh Anderson, SISCAPA Assay Technologies</i>
<p>Track 7 Innovator Award Session <i>University II</i></p>	<p>Track 8 Steven A. Hofstadler Graduate Student Session <i>Villanova Amphitheater</i></p>
<p><i>Session Leaders: Mark Cancilla, Merck; Daniel Spellman, Merck</i></p> <ul style="list-style-type: none"> ▶ Fast HPLC Injections, Rethought <i>Bernhard Nemec, Prolab Instruments</i> ▶ Rapid Purification, Characterization and Manipulation of Antibodies using High Capacity Capture Membranes <i>Christian Hoppmann, Takara Bio USA</i> 	<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"> ▶ Uncovering New Fungal Natural Products and Their Biosynthetic Pathways Using FAC-MS Technology <i>Matt Robey, Northwestern University</i> ▶ Deciphering the Human Heart Proteome by Top-down Proteomics <i>Trisha Tucholski, University of Wisconsin</i> ▶ Mass-Activated Droplet Sorting for Label Free, High-Throughput Enzyme Screening at the Nanoliter Scale <i>Dan Holland-Moritz, University of Michigan</i> ▶ Improving quantitation of 25-hydroxyvitamin D in human serum using ion mobility coupled with liquid chromatography and mass spectrometry <i>Nick Oranzi, University of Florida</i>

WEDNESDAY, OCTOBER 17

PROGRAM AGENDA

Wednesday October 17

4:00 PM – 5:30 PM

Princeton I & II

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

Session Leaders: Mark Hayward, Active Ingredient Technologies; Matt Szapacs, GlaxoSmithKline

5:30 PM – 6:30 PM

EXHIBITION & SOCIAL HOUR - WHERE TECHNOLOGY AND SOLUTIONS MEET!

University I, University Ballroom Foyer

6:30 PM – 7:30 PM

University II

CPSA AWARD PRESENTATIONS & ANNOUNCEMENTS

Local ACS Discussion Groups

CPSA Announcements

CPSA Europe - Neil Spooner, Spooner Bioanalytical Solutions & Ismael Zamora, Molecular Discovery

CPSA Metabolomics - Timothy Garrett, University of Florida

CPSA Shanghai - Emily Ehrenfeld, New Objective & Naidong Weng, Janssen R&D

CPSA Analytics - Amanda Berg, New Objective & Alla Kloss, Sanofi

CPSA BRASIL - Carla Marshall-Waggett, New Objective

- ▶ **Innovator Award Presentation**
Mark Cancilla, Merck; Dan Spellman, Merck
- ▶ **Steven A. Hofstadler Graduate Student Award/Recognition**
Petia Shipkova, Merck and Emily Ehrenfeld, New Objective
- ▶ **Program Chair Recognition**
Mike Lee, Milestone Development Services
- ▶ **CPSA USA 2019 Program Chair**
Alla Kloss, Sanofi

7:30 PM - 9:00 PM

University II

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

Sponsored by New Objective

Keynote Lecture

Smart Trials: Moving from Site-Centric to Patient-Centric Clinical Trials
Kevin Bateman, Merck

Distinguished Analytical Scientist Award Presentation

Introduction and presentation of award by Matt Barfield, GlaxoSmithKline

Patient Centric Blood Sampling and Quantitative Bioanalysis – A Personal Journey
Neil Spooner, Spooner Bioanalytical Solutions

PROGRAM AGENDA

Thursday October 18

7:30 AM – 8:30 AM

REGISTRATION & CONTINENTAL BREAKFAST

2nd Floor Lobby

8:30 AM – 10:00 AM

COLLOQUIA & ROUNDTABLES

Princeton I & II

Collaborative Research Models Between CRO and Pharma

Discussion Leader: Jim Shen, Bristol-Myers Squibb

- ▶ Hitchhikers Guide to the 2018 FDA BMV Guidance: Don't Panic
Steve Lowes, Q2
- ▶ FDA's Last Frontier: 5-Year Mission to Revise the BMV Guidance
Linlin Luo, Bristol-Myers Squibb

10:15 AM - 11:45 AM

PARALLEL SESSIONS

Track 9 Symposium Session Villanova Amphitheater	Track 10 Colloquium Session Lehigh	Track 11 Colloquium Session LaSalle
<p>Bioanalytical Aspects in Biological Therapeutics Discussion Leaders: Sophia Xu, Bristol-Myers Squibb and Weifeng Xu, Bristol-Myers Squibb</p> <ul style="list-style-type: none"> ▶ Strategies and Challenges for Peptide Quantification in Regulated BA with Case Studies Yang Xu, Merck ▶ CRISPR, Cell and Gene Therapies: Bioanalytical Expectations and Challenges Robert Dodge, Novartis ▶ The Secrets to Robust Bioanalytical Method Development Jonathan Haulenbeek, Bristol-Myers Squibb 	<p>Updates on the Road to Regulation for Biomarkers Discussion Leaders: Robyn Rourick, Genentech; Brad Ackermann, Eli Lilly and Company</p> <ul style="list-style-type: none"> ▶ Biomarker Assay Validation Challenges and the Current BMV Carmen Fernandez-Metzler, PharmaCadence Analytical Services ▶ Juggling 101: Satisfying Regulatory, Client and Internal Compliance and Performance Requirements for Biomarker Assays in the CRO Environment Tom Oglesby, PPD Laboratories ▶ When Do GLP, GCLP, GCP or CLIA Apply for Biomarkers Mark Arnold, Covance 	<p>Pushing the Boundaries of Analytical Chemistry through Novel Applications Discussion Leader: James Small, Merck</p> <ul style="list-style-type: none"> ▶ Applying SepQuant DropletProbe for Rapid Tissue Distribution and On Tissue Metabolite Identification in Drug Discovery and Development Bingming Chen, Merck & Co. ▶ Problem Solving in a Pharmaceutical Forensic Services Laboratory—Who We Are; What We Do and How We Do It Janine Brouillette, Merck & Co, Inc.

12:00 PM – 1:15 PM

SPONSORED LUNCH & ROUNDTABLE DISCUSSION

Princeton I & II

Sponsored by New Objective and The University of Florida

Micro-Column Separation in Metabolomics: How Do We Grow Small?

Discussion Leader: Emily Ehrenfeld, New Objective; Timothy Garrett, University of Florida

- ▶ LC/MS-based Workflows for Targeted Protein Quantitation in Biopharmaceutical R&D: Automation, Micro and NanoFlow Chromatography and Integrated Data Analytics
Dan Spellman, Merck

PROGRAM AGENDA

Thursday October 18

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: Roy Vaz, Sanofi</i></p> <ul style="list-style-type: none"> ▶ New Strategies to Facilitate Efficient Discovery of Permeable Therapeutic Peptides <i>Tanvi Desai, Merck</i> ▶ Strategies to Address Stability Issue in Biomarker Quantitation <i>Zhuo Chen, GlaxoSmithKline</i> ▶ Mass Spectrometry Imaging Reveals Drug Disposition and Facilitates Biomarker Discovery <i>Cristina Silvescu, Bruker</i> 	<p>Alternative Instrumentation <i>Discussion Leaders: Kevin Bateman, Merck and Rick King, PharmaCadence Analytical Services</i></p>

3:00 PM

ADJOURN

THURSDAY, OCTOBER 18



4th ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis

May 6-9, 2019 • Boston, MA

Program Co-Chair
Amanda Berg
New Objective

Program Co-Chair
Alla Kloss
Sanofi

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2010

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