

20TH ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis



Where Technology and Solutions Meet

**Enabling Personalized Medicine:
Connecting People, Disciplines and Technology**

MEETING PROGRAM

October 23 - 26, 2017
Sheraton Bucks County
Langhorne, PA

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WELCOME

Inspiration. Collaboration.

October 23, 2017

Dear Colleagues:

On behalf of the organizing committee and our sponsors, it is our pleasure to welcome you to the 20th annual Symposium on Clinical and Pharmaceutical Solutions through Analysis (CPSA USA 2017). 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 chairs, Suzanne Cordovado and Emily Ehrenfeld, have followed Chad Briscoe and Naidong Weng's, vision from last year's annual meeting and developed the theme for CPSA USA 2017: Enabling Personalized Medicine: Connecting People, Disciplines and Technology.

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 Distinguished Lecture, once again generously sponsored by SCIEX. Our Plenary Lecture on Tuesday will feature Kyriakie Sarafoglou of the University of Minnesota with "Screening, Diagnosis and Treatment of Newborns with Congenital Adrenal Hyperplasia: Opportunities for Improvements." Carla Cuthbert of the Centers for Disease Control and Prevention, will deliver the Keynote Lecture on Wednesday, "Bringing Precision Medicine to Public Health: The Role of Newborn Screening."

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

A handwritten signature in black ink, appearing to read "Suzanne Cordovado".

Suzanne Cordovado

A handwritten signature in black ink, appearing to read "Emily Ehrenfeld".

Emily Ehrenfeld

2017 ORGANIZING COMMITTEE

PROGRAM CO-CHAIRS

Suzanne Cordovado
Centers for Disease Control & Prevention

Emily Ehrenfeld
New Objective

SYMPOSIA & SESSIONS

Susan Abbatiello
Thermo Scientific

Dave Abramowitz
SCIEX

Bradley Ackermann
Eli Lilly & Company

Mark Arnold
Covance

Lorin Bachmann
Virginia Commonwealth University

Kevin Bateman
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Joe Fox
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Patrick Fromal
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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
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Wenying Jian
Janssen Research & Development

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Jonathan Josephs
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Alla Kloss
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Michael Lassman
Merck

Yurong Lai
Bristol-Myers Squibb

Ken Lewis
OpAns

Wenkui Li
Novartis

Guowen Liu
Agiros Pharmaceuticals

Linlin Luo
Bristol-Myers Squibb

Nicole Matz
PRA Health Sciences

Eric Milgram
PepsiCo

Shane Needham
Alturas Analytics

Randall Nelson
Arizona State University

Timothy Olah
Bristol-Myers Squibb

Joanna Pols
Merck

Robyn Rourick
Genentech

Nalini Sadagopan
Agilent Technologies

Jim Shen
Bristol-Myers Squibb

Petia Shipkova
Bristol-Myers Squibb

Joe Siple
Drummond Scientific

James Small
Merck

Daniel Spellman
Merck

Neil Spooner
Spooner Bioanalytical Solutions

Leigh Sullivan
McKinley Scientific

Matthew Szapacs
GlaxoSmithKline

Gary Valaskovic
New Objective

Roy Vaz
Sanofi

Sihe Wang
Cleveland Clinic

Helen Weng
Frontage Laboratories

Naidong Weng
Janssen Pharmaceuticals

Clark Willard
inVentiv Health

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

Communications & Media

Carla Marshall-Waggett
New Objective

Martin Steel
McKinley Scientific

Leigh Sullivan
McKinley Scientific

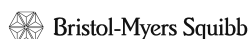
Management & Correspondence

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 25

EXHIBITORS

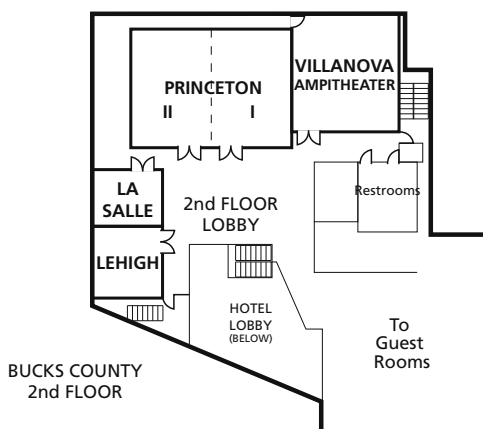
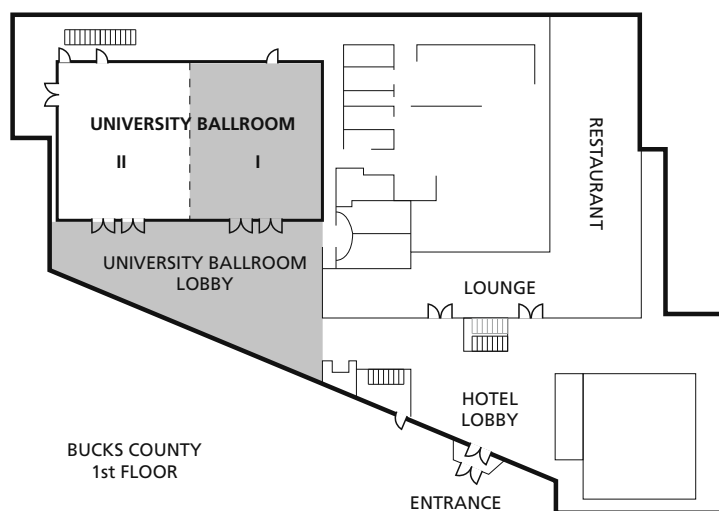
BOOTH

Agilent Technologies	27
Cambridge Isotope Labs	19
Capitainer	10
ES Industries	17
EVOSEP	6
Frontage Laboratories	11
iChrom Solutions	13
IMCS	7
MAC-MOD Analytical	12
McKinley Scientific	3
Merrill Lynch	25
Molecular Discovery	1
MS Mass Spec Consultants	21
New Objective	2
Novatia	9
Novilytic	5
PRA Health Sciences	8
SCIEX	15
Shimadzu Scientific Instruments	26
SiO ² Medical Products	18
Snōtra Laboratories	20
Sound Analytics	14
Thermo Scientific	24
Trajan	4
Wiley	22

EXHIBIT 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 23

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

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; Tim 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, Bristol-Myers Squibb

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

7:30 AM - 9:30 AM

CPSA 5K EVENT CPSA Charitable Foundation

Tyler State Park
Newtown, PA

Organizers: Nicole Matz, PRA Health Science; 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; Paul Corcoran, McKinley Scientific; Clark Willard, inVentiv Health Clinical Lab

12:00 PM - 4:00 PM

ADVANCED TRAINING IN MASSMETASITE / WEBMETABASE / MASSCHEMSITE STRUCTURE AND ELUCIDATION TOOLS

Villanova Amphitheater

Discussion Leader: Ismael Zamora, Molecular Discovery

4:30 PM - 5:30 PM

EXECUTIVE ROUNDTABLE: WHERE TECHNOLOGY AND SOLUTIONS MEET BUSINESS

University I & II

Sponsored by McKinley Scientific

Discussion Leaders: Lucinda Hittle, Merck; Emily Ehrenfeld, Mozaic Solutions

Panel Discussion: Donald Chace, Medolac Laboratories; Joanna Pols, Regeneron; Robyn Rourick, Genentech; Roy Vaz, Sanofi; Eric Yang, GlaxoSmithKline; Yi Zhang, SCIEX

MEETINGS & EVENTS

Monday October 23

6:00 PM - 9:00 PM

University I & II

RECEPTION & SPONSOR'S DINNER

Hosted by SCIEX

Opening Remarks

Suzanne Cordovado, Centers for Disease Control & Prevention; Emily Ehrenfeld, New Objective; Mike Lee, Milestone Development Services

CPSA Charitable Foundation

Paul Corcoran, McKinley Scientific; Shane Needham, Alturas Analytics; Emily Ehrenfeld, Mozaic Solutions

CPSA Institute

Naidong Weng, Janssen Research & Development; Timothy Garrett, University of Florida

Distinguished Lecture Series

Hosted by SCIEX

Metabolomics: Discovery, Innovation, and Diagnostic Potential

Timothy Garrett, University of Florida

Untargeted metabolomics refers to the systematic measurement of all small molecules found in a biological sample, including endogenous metabolites and exogenous compounds from food, medications and environmental exposures and represents a key opportunity for personalized diagnostics. Innovations in compound identification, analysis and interpretation will lead to the next expansion of clinical diagnostics. I describe analyses using imaging mass spectrometry, direct analysis of tissues, and traditional LC-MS approaches we use to help understand biological phenomena.

MONDAY, OCTOBER 23



INAUGURAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis

February 7-8, 2018 • London, U.K.

Program Co-Chair

Neil Spooner

Spooner Bioanalytical Solutions

Program Co-Chair

Ismael Zamora

Molecular Discovery

Plenary Speaker

Axel Pähler

Roche

CPSA EUROPE FEATURES

Symposia • Roundtables • Analysis Trends • New Technology
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PROGRAM AGENDA

Tuesday October 24

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

Suzanne Cordovado, Centers for Disease Control & Prevention; Emily Ehrenfeld, New Objective

9:00 AM - 9:45 AM

PLENARY LECTURE

University I & II

Screening, Diagnosis and Treatment of Newborns with Congenital Adrenal Hyperplasia: Opportunities for Improvements

Kyriakie Sarafoglou, University of Minnesota

TUESDAY, OCTOBER 24

Want to see yourself at CPSA? Here's how - Send your photos to CPSA Selfies!

- Take photos... lots of photos on your phone, tablet, or camera
- Email your photos to CPSAselfies@gmail.com
- Be sure to include a caption and/or the names of everyone in the photos



Visit the Image Gallery at www.cpsa-usa.com
to see and share your photos with friends, family and colleagues

PROGRAM AGENDA

Tuesday October 24

10:00 AM - 11:45 AM

PARALLEL SESSIONS

Track I Symposium Session <i>Princeton I</i>	Track II-a Colloquium Session <i>Princeton II</i>	Track II-b Colloquium Session <i>Villanova</i>
ormatics in the Clinical Laboratory <i>Discussion Leader: Timothy Garrett, University of Florida</i> <ul style="list-style-type: none"> ▶ Mass Spectrometry Innovations for Evaluating the Metabolic Signature of Parkinson's Disease and Deep Brain Stimulation <i>Emily Gill, University of Florida</i> ▶ Multiomic Data Integration <i>Stephan Kang, Intero Life Sciences</i> ▶ Ion Mobility/Mass Spectrometry for Metabolomics and Clinical Analysis <i>Richard Yost, University of Florida</i> 	Data-Driven Decision Making in Non-Clinical Drug Development <i>Discussion Leader: Chad Briscoe, PRA Health Services</i> <ul style="list-style-type: none"> ▶ What Data is Required and How it is Used in Non-Clinical Regulatory Decisions <i>Chet Bowen, GlaxoSmithKline</i> ▶ Data Driven Decision Making for Non-Clinical Studies <i>Rick Briscoe, Merck</i> ▶ Ligand Binding Assay Formats in the Context of Reagent Availability – Discovery to IND Enabling Tox Journey <i>Jonathan Haulenbeek and Johanna Mora, Bristol-Myers Squibb</i> 	Introducing El-Maven: Drug Discovery, Metabolomics and Flux <i>Discussion Leader: Abhishek Jha, Elucidata</i> <ul style="list-style-type: none"> ▶ Rewired Metabolism of T-cells upon mTOR Inhibition: An Integrated Omics Approach <i>Darren Dumlao, Pfizer</i> ▶ MIMOSA: Characterizing the Flux in the TCA Cycle <i>Richard Kibbey, Yale University</i> ▶ Polly: A Cloud Based, Comprehensive Metabolomic Flux Platform <i>Abhishek Jha, Elucidata</i> ▶ Panel Discussion: Challenges and Opportunities of Integrating Call Metabolism in Drug Discovery <i>John Janiszewski, Pfizer</i>

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

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



4th ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis

March 19-21, 2018 • Gainesville, FL

Program Chair **Timothy Garrett** *University of Florida*

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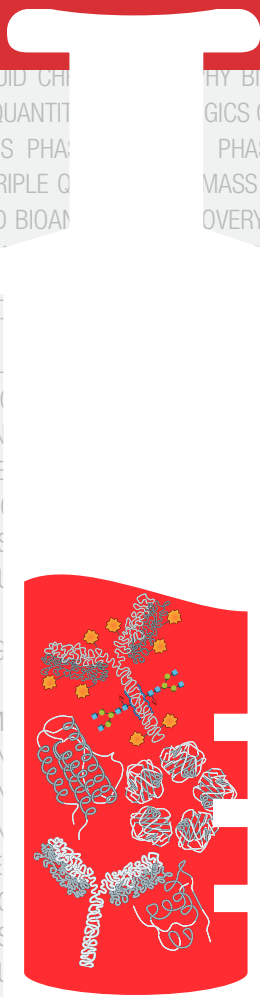
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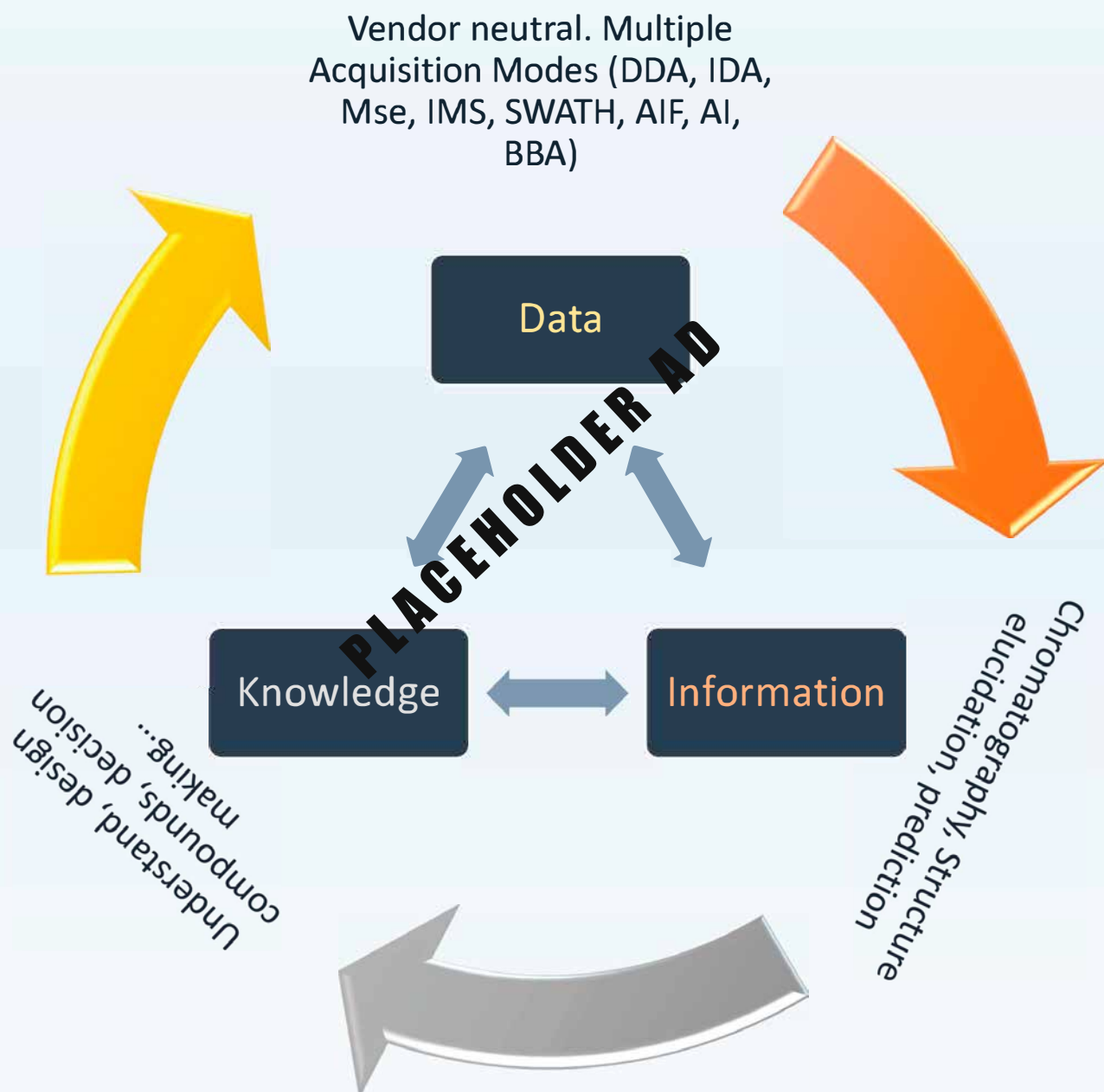
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- Structure elucidation for bio and chemical research in small and peptide molecules
- Lipidomics analysis

PROGRAM AGENDA

Tuesday October 24

3:15 PM – 4:45 PM

PARALLEL SESSIONS

Track IV Symposium Session <i>University I</i>	Track V-a Colloquium Session <i>University II</i>
Marriage of Biochemistry and Molecular: Clarifying or Confusing <i>Discussion Leaders: Don Chace, Medolac Laboratories; Suzanne Cordovado, Centers for Disease Control and Prevention</i> Panelists: <i>Tim Garrett, University of Florida</i> <i>Alla Kloss, Sanofi</i> <i>Carla Cuthbert, Centers for Disease Control and Prevention</i> <i>Binodh DeSilva, Bristol-Myers Squibb</i> <i>Kostas Petritis, Centers for Disease Control and Prevention</i> <i>Kyriakie Sarafoglou, University of Minnesota</i>	Importance of Chromatography in Applied Sciences – Current Trends, Education, and Career Opportunities <i>Discussion Leaders (on behalf of Chinese American Chromatography Assoc.): Yi He, John Jay College of Criminal Justice, CUNY & Naidong Weng, Janssen Research & Development</i> <ul style="list-style-type: none"> ▶ Advantages of Superficial Porous Particles in Chromatography <i>Chuping Luo, Advanced-Materials-Tech</i> ▶ Current Applications and New Trends of Liquid Chromatography – Mass Spectrometry in Forensic Toxicology <i>Marta Concheiro-Gisan, John Jay College, NY</i> ▶ Applying Chromatography to Resolve Real-world Pharmaceutical Challenges – A 30 Year Journey of An Accidental Chromatographer <i>Naidong Weng, Janssen Research & Development</i>
Track V-b Colloquium Session <i>Villanova Amphitheater</i>	Track V-c Colloquium Session <i>Lehigh</i>
Bioanalytical Considerations in Biological Therapeutics <i>Discussion Leaders: Sophia Xu, Bristol-Myers Squibb and Weifeng Xu, Bristol-Myers Squibb</i> <ul style="list-style-type: none"> ▶ Insulin Glargine: Applying LC-MS to Assess Metabolite PK in Support of Biosimilar Studies <i>Yang Xu, Merck</i> ▶ Large Molecule Bioanalysis: Special Considerations for ADC and Biosimilars <i>Xiaoyan Cai, Wuxi AppTec</i> ▶ Critical Reagents in Bioanalysis: How Do We Know What We Are Measuring? <i>Jonathan Haulenbeek, Bristol-Myers Squibb</i> ▶ Immunogenicity Assay Design and Optimization for Support in Clinical Studies <i>Sharon Arrol, Alexion</i> ▶ Challenge to Current Acid-Dissociation Based Neutralizing Antibody Extraction and Detection and How We Can Solve It <i>Weifeng Xu, Bristol-Myers Squibb</i> 	Structure Identification <i>Discussion Leaders: David Detlefsen and Mark Hail, Novatia</i>

TUESDAY, OCTOBER 24

PROGRAM AGENDA

Tuesday October 24

4:45 PM – 5:15 PM

2nd Floor Lobby

LET THEM EAT CAKE!

Donald Chace, Medolac Laboratories

5:00 PM – 6:00 PM

Princeton I

SOCIAL HOUR & SPONSORED WORKSHOPS

WORKSHOP

Sponsored by SCIEX

Princeton II

So You Want to Start a Business?

Sponsored by McKinley Scientific

Workshop Leaders: Josh Mann, Meso Scale Discovery and Tim Garrett, University of Florida

Villanova Amphitheater

Patient Centric Blood Sampling and Analysis: What is it and will it become a reality?

Sponsored by Spooner Bioanalytical Solutions

Workshop Leader: Neil Spooner, Spooner Bioanalytical Solutions

Lehigh

WORKSHOP

Sponsored by Agilent Technologies

6:30 PM - 9:30 PM

University I

SPONSOR HOSPITALITY & EVENING WORKSHOPS

MICROSAMPLING SUMMIT

Sponsored by McKinley Scientific and Eli Lilly & Co.

Workshop Leaders: Qin Ji, Bristol-Myers Squibb and Olga Kavetskaia, Pfizer

Panelists: Tim Garrett, University of Florida; Wenkui Li, Novartis; John Lin, Frontage Laboratories; Laura Patrone, SK Life Science; Neil Spooner, Spooner Bioanalytical Solutions; Enaksha Wickremsinhe, Eli Lilly & Company; Yang Xu, Merck

University II

COMPLETE BIOPHARMA CHARACTERIZATION

Sponsored by Thermo Fisher Scientific

Workshop Leader: Jonathan Josephs



9th ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis

April 18 - 20, 2018 • Shanghai, China

Program Chair: **Cornelis Hop** Genentech

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PROGRAM AGENDA

Wednesday October 25

7:30 AM – 8:30 AM

REGISTRATION & CONTINENTAL BREAKFAST

University Ballroom Lobby

7:30 AM - 8:30 AM

4 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

Development of New Biomarkers: A Focus on Disease Progression Biomarkers

Discussion Leader: Alla Kloss, Sanofi

- ▶ **Advancements in Protein Turnover Measurements and Protein Fractional Synthesis Quantification Utilizing Metabolic Labeling with Stable Isotope Tracers and High Resolution Mass Spectrometry**
Thomas Angel, GlaxoSmithKline
- ▶ **An Integrated Mass Spectrometry-Based Analysis Pipeline for Determining Clinical Biomarker Signatures**
Monica Lane, Sanofi
- ▶ **Kidney Toxicity Biomarkers**
Wen Jianzhong, Merck

10:15 AM – 11:45 AM

PARALLEL SESSIONS

Track VI Symposium Session <i>Villanova Amphitheater</i>	Track VII-a Colloquium Session <i>Princeton I / II</i>
A Bird's Eye View from the Top: Analysis of Intact Proteins by Mass Spectrometry for In-Life Sample Sets <i>Discussion Leaders: Wenying Jian, Janssen Research & Development; John Kellie, GlaxoSmithKline</i> <ul style="list-style-type: none"> ▶ Comparison of HRMS Instrumentation for Intact PK Analysis of Biotherapeutics <i>Lisa Anne O'Callaghan, Merck Research Laboratories</i> ▶ Simultaneous Catabolite Identification and Quantitation of Therapeutic Proteins at the Intact Level <i>Wenying Jian, Janssen Research & Development</i> ▶ Subunit-Level and Intact Analyses of Antibodies from In-Life Samples: LC-MS Methods for Pharmacokinetic Quantitation, Critical Quality Attributes, and Biotransformation <i>John F Kellie, GlaxoSmithKline</i> 	Emotional Intelligence in the Workplace <i>Discussion Leader: Lucinda Hittle, Merck</i> <p>We have learned to recite the alphabet backwards from memory and even built towers out of 3"x5" index cards. This year, our session will focus on small group discussion of Emotional Intelligence in the Workplace. The audience will actively participate in a brief individual assessment, then divide into 4 groups to discuss the 4 aspects of Emotional Intelligence: Self-awareness, Self-management, Social Awareness and Relationship Management. We will then have a report back to the group to discuss and provide an opportunity for further reflection. The session is based on the excellent book by Travis Bradberry and Jean Greaves Emotional Intelligence 2.0</p>

(Parallel Sessions cont'd)

WEDNESDAY, OCTOBER 25

PROGRAM AGENDA

Wednesday October 25

10:15 AM – 11:45 AM

PARALLEL SESSIONS (cont'd)

Track VII-b Symposium Session <i>Lehigh</i>	Track VII-c Colloquium Session <i>LaSalle</i>
Metabolite Identification and Databases: Industrial Workflows and Emerging Trends <i>Discussion Leader: Ismael Zamora, Molecular Discovery</i> <ul style="list-style-type: none"> ▶ Characterization of Metabolites of Different Molecular Modalities Using an Integrated LC/MS/MS and MassMetaSite/WebMetaBase™ Approach <i>Silvi Chacko, Bristol-Myers Squibb</i> ▶ Woulda-Coulda-Shoulda Acquired that Therapeutic Peptide Metabolite Identification Data <i>Christopher Kochansky, Merck</i> ▶ LC-HRMS vs NMR: The Dawn of Structure Elucidation <i>Elisabeth Ortega, Lead Molecular Design</i> 	Patient Centric Blood Sampling and Analysis: Let's Make this Happen! <i>Discussion Leader: Neil Spooner, Spooner Bioanalytical Solutions; Joe Siple, New Objective</i> <p>Following-on from Tuesday evening's workshop, this Colloquium will bring together technology companies and thought leaders that are interested in positively moving the agenda forward. Let's expedite the time frame for developing and establishing patient centric blood sampling and analysis approaches with the public, media, regulators, etc., in order to increase the likelihood of acceptance of these technologies and the data arising from them.</p>

12:00 PM -1:00 PM

University I & II

SPONSORED LUNCH & ROUNDTABLE

Sponsored by Thermo Fisher Scientific

LC-MS Analysis of mAb and Bi-specifics in Plasma and Tissues: 1 ng/mL Sensitivity without Antibody Enrichment

Jun Qu, University at Buffalo

1:15 PM – 2:15 PM

Princeton I

Princeton II

Villanova Amphitheater

SOCIAL HOUR & SPONSORED WORKSHOPS

WORKSHOP

Sponsored by SCIEX

WORKSHOP

PicoChip and Metabolomics: What's heat got to do with it?

Sponsored by New Objective

Timothy Garrett, University of Florida; Amanda Berg, New Objective; Emily Ehrenfeld, New Objective

WORKSHOP

Sponsored by Thermo Fisher Scientific

WEDNESDAY, OCTOBER 25

PROGRAM AGENDA

Wednesday October 25

1:15 PM – 2:15 PM

Lehigh

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

WORKSHOP

Elucidata User Group Meeting

Sponsored by Elucidata

- ▶ Application of Flux in Drug Discovery
Thomas Roddy, Agios Pharmaceuticals
- ▶ Democratizing Flux Capabilities through PollyPhi
Abhishek Jha, Elucidata

2:30 PM – 3:30 PM

PARALLEL SESSIONS

Track VIII Innovator Award Session <i>University II</i>	Track IX Steven A. Hofstadler Graduate Student Session <i>Villanova Amphitheater</i>
<p><i>Discussion Leaders: Mark Cancilla, Merck; Daniel Spellman, Merck</i></p> <ul style="list-style-type: none"> ▶ Garbage in garbage out: how automated sample preparation can enable superior mass spec results <i>Steve Murphy, Agilent Technologies, Inc.</i> ▶ Multivariate solid phase extraction optimization using automated dispersive pipette extraction on robotic liquid handling system <i>L. Andrew Lee, Integrated Micro-Chromatography Systems, LLC (IMCS)</i> ▶ High-speed microfluidic CE-MS and CE-HPMS technology, and their opportunities in the pharma, biopharma and clinical domains <i>Chris Brown, 908 Devices Inc.</i> ▶ Nominated Vendor/ Sponsor Talk 	<p><i>Sponsored by New Objective</i></p> <p>Inspiring Career Paths in the Sciences for Young Scientists</p> <p><i>Discussion Leader: Petia Shipkova, Bristol-Myers Squibb</i></p> <ul style="list-style-type: none"> ▶ Online Hydrophobic Interaction Chromatography-Mass Spectrometry for Top-down Protein Analysis <i>Bifan Chen, University of Wisconsin</i> ▶ Characterization of Protein-Protein Interactions by Protein Cross-linking Capillary Electrophoresis at Increased Throughput <i>Claire Ouimet, University of Michigan</i> ▶ Quantitative Top Down Proteomics Temporally Defines Complexity of Aging Biomarkers <i>Peter Doubleday, Northwestern University</i> ▶ An Integrative Approach for Determining Biomarkers and Etiology of a Disease Leading to Mass Die Offs of Aquatic Life in South Africa <i>Jeremy Koelmel, University of Florida</i>

WEDNESDAY, OCTOBER 25

PROGRAM AGENDA

Wednesday October 25

3:45 PM – 4:15 PM

Princeton I & II

CPSA AWARD PRESENTATIONS & ANNOUNCEMENTS

Sponsored by McKinley Scientific and New Objective

- ▶ 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 - Xiao-Yan Cai, WuXi AppTec & Naidong Weng, Janssen R&D*
 - CPSA Analytics - Nathan Yates, University of Pittsburgh*
 - CPSA BRASIL - Carla Marshall-Waggett, New Objective & Martin Steel, McKinley Scientific*
- ▶ Innovator Award Presentation
 - Kevin Bateman, Merck*
- ▶ Steven A. Hofstadler Graduate Student Award/Recognition
 - Presented by the Mentors*
- ▶ Program Chair Recognition
 - Mike Lee, Milestone Development Services*
- ▶ CPSA USA 2018 Program Chair
 - Suzanne Cordovado, Centers for Disease Control & Prevention; Emily Ehrenfeld, New Objective*

4:15 PM – 5:45 PM

Princeton I & II

KEYNOTE LECTURE PRESENTATION OF THE DISTINGUISHED ANALYTICAL SCIENTIST AWARD

Sponsored by McKinley Scientific and New Objective

Keynote Lecture

Bringing Precision Medicine to Public Health: The Role of Newborn Screening
Carla Cuthbert, Centers for Disease Control and Prevention

Distinguished Analytical Scientist Award Presentation

Introduction and presentation by Renuka Pillutla, Bristol-Myers Squibb

**Don't Gamble with Bioanalysis in Enabling Precision Medicine:
Bioanalysis – Empowered by Innovation Shaped by Regulation**
Binodh DeSilva, Bristol-Myers Squibb

5:45 PM – 6:45 PM

EXHIBITION & SOCIAL HOUR - *WHERE TECHNOLOGY AND SOLUTIONS MEET!*

University I, University Ballroom Lobby, 2nd Floor Lobby,

6:45 PM – 9:00 PM

University II

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

Hosted by Bernard Hirsh, Merrill Lynch

Session Leaders: Mark Hayward, ITSP; Nicole Donnelly, PharmaCadence Analytical Services; Matt Szapacs, GlaxoSmithKline

PROGRAM AGENDA

Thursday October 26

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 Pharma and CRO

Discussion Leader: Jim Shen, Bristol-Myers Squibb

- ▶ Outsourcing Bioanalysis of Clinical Biomarkers: Challenges and Opportunities
Yue Zhao, Bristol-Myers Squibb
- ▶ Collaborating with Pharmaceutical Companies between 1 and 100,000 Employees: the CRO Perspective
Liam Moran, Charles River Laboratories
- ▶ Be Careful What You Wish for... A Personal, CRO Perspective on CRO-Pharma Collaborations
Chad J. Briscoe, PRA Health Sciences

10:15 AM - 11:45 AM

PARALLEL SESSIONS

Track VIII Symposium Session <i>Villanova Amphitheater</i>	Track IX Colloquium Session <i>Lehigh</i>
The Road to Regulation for Biomarker Qualification <i>Discussion Leader: Robyn Rourick, Genentech</i> <ul style="list-style-type: none"> ▶ Progress in Analytical Assay Validation for Biomarker Qualification: A Joint FDA/Critical Path Initiative <i>Steven Piccoli, Neoteric Consulting</i> ▶ Best Practices for Biomarker Methods Validation for LC/MS, AAPS White Paper Perspective <i>Carmen Fernandez-Metzler, PharmaCadence</i> <p><i>Panel Discussion:</i> <i>Mark Arnold, Covance</i> <i>Chad Briscoe, PRA Health Sciences</i> <i>Don Chace, Medolac Laboratories</i> <i>Carmen Fernandez-Metzler, PharmaCadence</i> <i>Steven Piccoli, Neoteric Consulting</i></p>	From Large to Small Molecules – Molecular-Level Characterization Strategies of API, Metabolites, Degradants and Everything in Between! <i>Discussion Leader: James Small, Merck</i> <ul style="list-style-type: none"> ▶ Probing the Relationship Between Small Molecule Drug Metabolites and Oxidative Degradants – Is there Really Something to Learn Here? <i>James Small, Merck</i> ▶ Sulfur-Centered Radicals and Degradation Mechanisms of Proteins – New Perspectives in the Regulation of Proteins and the Formation of Biologically Active Substances <i>Olivier Mozziconacci, Merck</i>

THURSDAY, OCTOBER 26

PROGRAM AGENDA

Thursday October 8

12:00 PM – 1:15 PM

Princeton I & II

SPONSORED LUNCH & ROUNDTABLE DISCUSSION

Sponsored by New Objective and The University of Florida

My History in Analytical Technology in Biomarkers

Naidong Weng, Janssen Research & Development

1:30 PM – 3:00 PM

PARALLEL SESSIONS

Track X

Symposium Session

Princeton I / II

Presentations from the Edge: Young Scientist Session

Discussion Leaders: Roy Vaz, Sanofi and Alla Kloss, Sanofi

*Michelle Robinson, Merck
Timothy Sikorski, GlaxoSmithKline
Kristen Randall, Sanofi*

Track XI

Colloquium Session

Villanova Amphitheater

Alternative Instrumentation

Discussion Leaders: Kevin Bateman, Merck and Rick King, PharmaCadence Analytical Services

3:00 PM

ADJOURN

THURSDAY, OCTOBER 26



5th ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis

August 13-16, 2018 • São Paulo, Brazil

Program Chair

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