

Clinical & Pharmaceutical Solutions through Analysis



Innovative Approaches to Reduce Attrition and Predict Clinical Outcomes

April 20 - 23, 2016 Renaissance Shanghai Pudong Hotel Shanghai

MEETING PROGRAM

Where Technology and Solutions Meet
Where East Meets West

寻求科学的答案,探索生命的奥秘!



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WELCOME

Inspiration to Application

April 20, 2016

Dear Colleague,

On behalf of the organizing committee and our sponsors, we welcome you to the 7th Annual Shanghai Symposium on Clinical & Pharmaceutical Solutions through Analysis (CPSA Shanghai 2016). It is a pleasure to once again host this unique event in Shanghai.

The goal of the CPSA Shanghai annual meetings is to provide in-depth reviews of innovative technology and industry practices through open discussion of industry related issues and needs. The diversified symposia and sponsored events are designed with the intent to be highly interactive where scientists openly share their experiences and visions in a collegial setting. The program will highlight speakers and sessions that provide firsthand experiences with new technologies as well as critical insights into industrial workflows and regulatory issues.

The symposium sessions, workshops and events reflect the theme of this year's annual meeting "Innovative Approaches to Reduce Attrition and Predict Clinical Outcomes." Traditions – universal for CPSA events worldwide – continue in Shanghai as pre-conference workshops, the Executive Roundtable, Welcome Reception and Sponsors Dinner, Distinguished Lecture Series and Social Event, Poster Session, CPSA EXPO, Innovator Award Session, and Young Scientist Excellence Awards help make our annual meeting a most unique and premier international event. We also continue with traditions from previous annual meetings and endeavor to connect everyone, not only as friends, but also as scientists across different disciplines in drug R&D.

Imagination and stimulating discussion are central to each CPSA function and session – or as we say around the world – CPSA is user friendly! We aim to bring scientists together from both East and West; and thus, CPSA Shanghai 2016 continues to foster our unique meeting tradition that encourages the diverse thinking, understanding, and relationships. Our hope is for attendees to actively participate in the conference and to become inspired with new ideas, new relations, and new collaborations.

Special thanks are extended to our sponsors who all share their sincere belief that CPSA Shanghai is indeed the premier international event to meet experts in the field and to openly discuss our industry's most fundamental challenges. Each sponsor shares the passion and commitment for the sciences – on an international scale.

Enjoy the annual meeting - Where Technology and Solutions Meet.... and of course, where East meets West!

Mike S. Lee, Ph.D. CPSA Founder

Kelly Dong, Ph.D. 2016 Program Chair



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PROGRAM CHAIR

Kelly Dong GlaxoSmithKline

China

ORGANIZING COMMITTEE

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Suma Ramagiri

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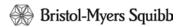
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SPONSORS

Thank You!

The CPSA Shanghai 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 pharmaceutical R&D in the hopes of inspiring significant advances in the field.





NEW OBJECTIVE





































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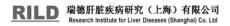
EXHIBITORS

Thank You!

We would like to extend ours sincere thanks to the exhibitors who made this year's annual CPSA Shanghai conference possible. It is with the support and commitment of these companies and people that technology can meet solutions! We hope to see you all in 2016!































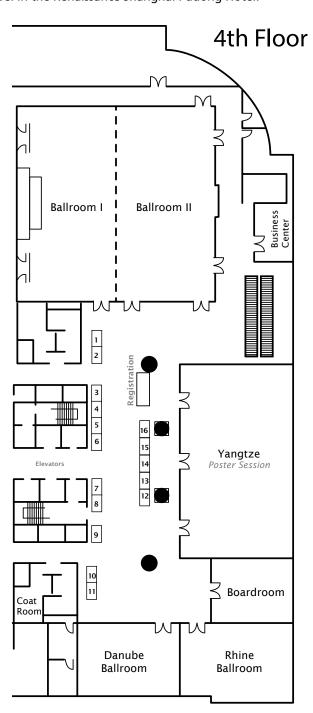






FLOOR PLAN

The CPSA Shanghai symposia, roundtables, poster session, EXPO and workshops will be held on the 4th Floor Lobby Level in the Renaissance Shanghai Pudong Hotel.



EXPO HOURS

The CPSA Shanghai 2016 Exposition will be open on the following schedule, but many company representatives will be on hand throughout the conference.

THURSDAY 11:00 AM - 2:00 PM FRIDAY 11:00 AM - 2:00 PM

EXHIBITORS

Booth#	Company
10	Antpedia
13	ChemPartner
14	Covance
16	ES Industries
12	Frontage Laboratories
1	InfoClinika
11	Instrument.com.cn
5	McKinley Scientific
4	New Objective
15	Novilytic
7	QuanYang
6	RILD
3	SCIEX
9	Tegent
2	Thermo Fisher
8	XenoTech

FOR EXHIBITORS

Move-in: Wednesday, 7:00 pm - 9:00 pm Move-out: Friday, 5:00 pm - 7:00 pm



WORKSHOPS

Wednesday APRIL 20

10:00 AM Registration Open

Renaissance Shanghai Pudong 4th Floor Lobby

1:00 PM - 4:00 PM PRE-CONFERENCE WORKSHOP

Ballroom I Sponsored by SCIEX

► Advantages of Novel Data Acquisition Strategies for Accurate Metabolite Identification

Kerong Zhang, SCIEX

▶ Practical Considerations of Large Molecule Bioanalysis in Complex Matrices Shaw Xia, SCIEX

4:00 PM - 6:00 PM EXECUTIVE ROUNDTABLE

Ballroom I The Balance of Scientific Integrity and Regulatory Burden in Drug Discovery and Development

Chair: Naidong Weng, Janssen Research & Development

► DMPK and Asia Outsourcing

Ajai Chaudhary, Merck

► CRO Bioanalysis

Xinping Fang, WuXi AppTec

► Medicinal Chemistry and External Lead Discovery Peter Meinke, Merck

► EBF and Pharmaceutical Bioanalysis

Philip Timmerman, Janssen Research & Development

► Instrument Sector Hua-Fen Liu, SCIEX

6:00 PM - 9:00 PM OPENING RECEPTION

Plan to attend the opening festivities. Greet old friends, meet new friends, and get an

overview of the week's events and activities.

Hosted by SCIEX

Welcome to CPSA Shanghai 2016!

Ballroom II



Thursday APRIL 21

7:30 AM Registration Open

Renaissance Shanghai Pudong 4th Floor Lobby

8:30 AM – 9:00 AM OPENING REMARKS

Ballrooms I & II Welcome

Mike Lee, Milestone Development Services

Objectives, Format, and Opening Remarks

Kelly Dong, GlaxoSmithKline - Program Chair

9:00 AM - 9:45 AM PLENARY LECTURE

Ballrooms I & II Quantitative Systems Pharmacology – A Key Approach to Reduce Attrition in Drug

Discovery and Development

Valeriu Damian, GlaxoSmithKline

9:00 AM – 5:00 PM Poster Hall Open

Yangtze Ballroom Posters will be available all day today and Friday

10:15 AM – 11:45 AM JOINT ADME/BA SYMPOSIUM & ROUNDTABLE

Ballrooms I & II Innovative Approaches to Reduce Attrition

Chairs: Sylvia Zhao, Novartis and Fan Jin, Covance

▶ Early Reading of Drug-Drug Interactions by Using Endogenous Biomarkers and Recommendation of IQ Bioanalytical Subteam on Use of 4ß-Hydroxycholesterol for P450 3A4/5 DDI

Naidong Weng, Janssen Research & Development

- ▶ Bioanalytical Strategies to Help Drive Drug Development Joseph Bower, Covance
- ► Bioanalytical Strategy for Antibody Drug Conjugates

 Mary Hu, Shanghai Miracoge

11:00 AM - 2:00 PM CPSA SHANGHAI EXPO - WHERE TECHNOLOGY AND SOLUTIONS MEET!

4th Floor Lobby Meet and mingle with vendors offering the latest in technology and services



Thursday APRIL 21

11:30 AM - 12:30 PM	POSTER SESSION	YOUNG SCIENTIST	FXCFLLENCE	ΔWΔRD RFVIFW

Yangtze Ballroom

Young Scientist Excellence Committee Members: Luke Bi, Covance; Joseph Bower, Covance; Xiao Ding, Genentech; Jonathan Josephs, Thermo Fisher Scientific; Fred Li, Hua Medicine; Min Liu, Merck; Qun Lu, Celgene; Marjoleen Nijsen, AbbVie; Suma Ramagiri, SCIEX; Jasminder Sahi, Sanofi; Gary Valaskovic, New Objective; Sihe Wang, Cleveland Clinic; Naidong Weng, Janssen; Mingdan Wu, WuXi AppTec; Jeff Zhang, Novartis; Tianyi Zhang, Frontage Laboratories; Sylvia Zhao, Novartis

12:00 PM - 1:00 PM **LUNCH & LEARN WORKSHOPS**

Ballroom I Workshop

Sponsored by SCIEX

► Accurate Metabolite Identification using SWATH™, A Data Independent Acquisition and SelexION™ Gas Phase Separation

Shaw Xia, SCIEX

Ballroom II Workshop

Sponsored by McKinley Scientific

1:30 PM - 3:00 PM **PARALLEL SESSIONS** TRACKS 1 - 4

Track 2 Track 1 **Small Molecule Bioanalysis Drug Metabolism** Ballroom II Ballroom I Chairs: Dafang Zhong, Shanghai Institute of Materia Medica Chairs: Xiao Ding, Genentech and Luke Bi, Covance and Jeff Zhang, Novartis

▶ Metabolism and Pharmacokinetics of Vicagrel, A Novel Thienopyridine P2Y12 Inhibitor, Compared with

Dafang Zhong, Shanghai Institute of Materia Medica

▶ Metabolite Profiling of Artemisinin-Based Combination Drugs

Jie Xing, Shandong University

Clopidogrel in Humans

- ▶ Rapid Identification of Biotransformation-Mediated Modification of Endogenous Proteins and Biologics Using HRMS, Background Subtraction and PEAKS Mingshe Zhu, Bristol-Myers Squibb
- ▶ In Vitro ADME Evaluation for Supporting IND Submission: Guidance, Challenges, and Solutions Zhuohan Hu, Fudan University

- ▶ Application of LC-AMS for the Determination of Absolute Bioavailability of Taselisib in Human Xiao Ding, Genentech
- ▶ Bioanalytical Challenges and Strategies for Analysis of Unstable Small Molecules

Hongliang Jiang, Hua Zhong Sci Tech University

► Addressing Matrix Effect Issues in Clinical **Bioanalysis**

Luke Bi, Covance

Parallel Sessions Continued...



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1ST ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis

Where Technology and Personalized Medicine Meet



Cloud Platforms for Scientific Analysis



Program Chair

Nathan Yates University of Pittsburgh Plenary Speaker

Andrey Bondarenko

InfoClinika

This unique event is highly interactive and dedicated to the needs of the patient. The program features updated perspectives and experiences on clinical and pharmaceutical analysis. Imagination and stimulating discussion are central to each CPSA Analytics session and event.

JOIN US FOR THE INAUGURAL EVENT!

May 19 - 20, 2016 University of Pittsburgh Pittsburgh, PA USA

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Thursday APRIL 21

1:30 PM - 3:00 PM	PARALLEL SESSIONS
1.50 1 101 5.00 1 101	I ANALLE SESSIONS

Track 3	Track 4	
Protein Biomarkers: Defining Industry Trends and Meeting Needs Through Technology	Advances in New Technologies for Pharmaceutical Development Danube Ballroom	
Rhine Ballroom		
Chairs: Nathan Yates, University of Pittsburgh and Gary Valaskovic, New Objective Protein Subtyping for the Diagnosis of Amyloidosis Sihe Wang, Cleveland Clinic	Chair: Qun Lu, Celgene ➤ Solid Form Transformation During Pharmaceutical Processing Lei Zhu, Merck	
 ▶ Is Urine a Better Biomarker Source than Blood? Youhe Gao, Beijing Normal University ▶ The Phoenix Center and National Proteomics Programs 	► High Speed Chromatography to Expedite Pharmaceutical Development Naijun Wu, Celgene	
in China Jun Qin, Beijing Proteome Research Center	► High Resolution Mass Spectrometry for Structure Elucidation of Impurity and Degradation Products in Pharmaceutical Industry Wendy Zhong, Merck	



1st Annual Symposium on Clinical & Pharmaceutical Solutions through Analysis

Cloud Platforms for Scientific Analysis

May 19 - 20, 2016 • Pittsburgh, PA USA

Program Chair

Nathan Yates University of Pittsburgh Plenary Speaker

Andrey Bondarenko
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Symposia • Roundtables • Analysis Trends • New Technology Performance Benchmarks • Mainstream Appliances • Social Events

Hosted by University of Pittsburgh

www.cpsa-analytics.com

Where Technology and Personalized Healthcare Meet



Thursday APRIL 21

3:30 PM - 5:00 PM

PARALLEL SESSIONS TRACKS 5 - 8

Track 5	Track 6	
Enabling Capabilities in Support of Drug Discovery and Development	Changing World of Biomarkers in Drug Development	
Ballroom I	Ballroom II	
Chair: Min Liu, Merck	Chair: Wenying Jian, Janssen and Naidong Weng, Janssen	
 ▶ Enabling Capabilities in Drug Discovery Petr Vachal, Merck ▶ Small Molecule Research: The Present and the Future Hong Sheng, Roche ▶ Applications and Impact of Alternative Synthetic Technologies in Lilly Research Labs Óscar de Frutos, Eli Lilly and Company 	 An Overview of the Changing World of Biomarkers in Drug Development Patrick Bennett, PPD Crystal City VI Biomarker Meeting Robert Dodge, Bristol-Myers Squibb Biomarker Challenges and Innovative Approaches to Predict Clinical Outcomes Jialin Mao, Genentech 	
Track 7 Young Scientist Excellence Award Session	Track 8 Bioanalytical Application in Biosimilar Preclinical and Clinical Development	
Rhine Ballroom	Danube Ballroom	
Chairs: Mingdan Wu, Wuxi AppTec and Jeff Zhang, Novartis Young Scientist Excellence Committee Members: Luke Bi, Covance; Joseph Bower, Covance; Xiao Ding, Genentech; Jonathan Josephs, Thermo Fisher Scientific; Fred Li, Hua Medicine; Min Liu, Merck; Qun Lu, Celgene; Marjoleen Nijsen, AbbVie; Suma Ramagiri, SCIEX; Jasminder Sahi, Sanofi; Gary Valaskovic, New Objective; Sihe Wang, Cleveland Clinic; Naidong Weng, Janssen; Tianyi Zhang, Frontage Laboratories; Sylvia Zhao, Novartis	Chairs: Xiao-Yan Cai, WuXi AppTec and Yi Du, HuaHai Pharmaceutical Co., Ltd.	

6:00 PM

CPSA SOCIAL

Yangtze Ballroom

Cocktails & Karaoke at CPSA

Sponsored by McKinley Scientific

Whether you like to command the stage or cheer from the audience, it's hard to have a forgettable time of karaoke. Xiao-Yan Cai of Wuxi AppTec, with her dance partner Mike Lee, will open the dance floor to begin the evening's festivities!

Join colleagues and friends – old and new – to relax and unwind!

See Martin at McKinley Scientific booth to request your song!



Friday APRIL 22

7:30 AM Registration Open

Renaissance Shanghai Pudong 4th Floor Lobby

8:30 AM – 9:15 AM PLENARY LECTURE

Ballrooms I & II Differential Mass Spectroscopy:

Biomarker Discovery from Basic Research to the Clinic

Nathan Yates, University of Pittsburgh

9:00 AM – 5:00 PM Poster Hall Open

Yangtze Ballroom Posters will be available all day today

9:30 AM – 11:00 AM JOINT ADME/BA SYMPOSIUM & ROUNDTABLE

Ballrooms I & II Preparing For A Successful First Into Human (NBE Perspective)

Chairs: Jing Lin, Sunovion and Marjoleen Nijsen, AbbVie

- ► Innovative Translational Modeling to Build Confidence in PoC Marjoleen Nijsen, AbbVie
- ➤ Translation of Preclinical In Vivo and In Vitro Data to Predict Clinical Exposures and Drug-Drug Interactions for a Novel NAMPT Inhibitor

 Bianca Liederer, Genentech
- ► Mechanism-Based PK/PD Modeling in Drug Development Sylvia Zhao, Novartis

11:00 AM - 2:00 PM CPSA SHANGHAI EXPO - WHERE TECHNOLOGY AND SOLUTIONS MEET!

4th Floor Lobby Meet and mingle with vendors offering the latest in technology and services

11:30 AM - 12:30 PM POSTER SESSION / YOUNG SCIENTIST EXCELLENCE AWARD REVIEW

Yangtze Ballroom Chairs: Mingdan Wu, Wuxi AppTec and Jeff Zhang, Novartis

Young Scientist Excellence Committee Members: Luke Bi, Covance; Joseph Bower, Covance; Xiao Ding, Genentech; Jonathan Josephs, Thermo Fisher Scientific; Fred Li, Hua Medicine; Min Liu, Merck; Qun Lu, Celgene; Marjoleen Nijsen, AbbVie; Suma Ramagiri, SCIEX; Jasminder Sahi, Sanofi; Gary Valaskovic, New Objective; Sihe Wang, Cleveland Clinic; Naidong Weng, Insperse Tianui Thank Frontiers Inhorstories; Sulvia Than New Tianui Thank Frontiers Inhorstories; Sulvia Thank New Tianui Thank T

Janssen; Tianyi Zhang, Frontage Laboratories; Sylvia Zhao, Novartis

12:00 PM - 1:00 PM LUNCH & LEARN WORKSHOPS

Ballroom I Defining Needs and Solutions to Enable Success with High-Performance Mass Spectrometry

Nathan Yates, University of Pittsburgh; Naidong Weng, Janssen R&D; Gary Valaskovic, New Objective

Sponsored by New Objective

Ballroom II Advances in Blood Collection and Plasma Preparation for Clinical Trials

Timothy Schlabach, Novilytic Sponsored by Novilytic



Friday APRIL 22

1:30 PM - 3:00 PM

PARALLEL SESSIONS TRACKS 9 - 12

Track 9	Track 10	
Prediction of Clinical Dose	Biomolecule Bioanalysis	
Ballroom I	Ballroom II	
Chairs: George Liu, Novartis and Jiansong Yang, MOSIM	 Chairs: Eric Liang, Novartis and Dongbei Li, WuXi AppTec ▶ Important Considerations and Case Studies for Anti-Drug Antibody Assay Development Dongbei Li, WuXi AppTec Bioanalytical Services ▶ Large Molecule Quantification by LC-MS and Case Studies Tianyi "Tee" Zhang, Frontage ▶ Analytical Considerations for Bi-Specific Antibodies and Antibody Drug Conjugates James Munday, Covance 	
 ▶ Dosing in Children: Prediction and Optimization Wei Zhao, Shandong University ▶ Ethnic Differences and Precise Medicine in Clinical Drug Development and Medical Practice Charles Xie, Boehringer Ingelheim ▶ A Systems Pharmacology Model for Predicting Effects of Factor Xa Inhibitor in Healthy Subjects: Assessment of PK and Binding Kinetics Xuan Zhou, Novartis 		
Track 11 Protein Biomarkers and Proteomic Quantification: Addressing Needs from Pharmaceuticals to Clinical Application	Track 12 Pharmaceutical Development	
Rhine Ballroom	Danube Ballroom	
Chairs: Nathan Yates, University of Pittsburgh and Gary Valaskovic, New Objective	Chairs: Deepak Hegde, GlaxoSmithKline and Fred Li, Hua Medicine	
 ▶ Bioanalytical Strategies for Serum Apolipoprotein A-1: A Biomarker for Cardiovascular Disease Risk Wenying Jian, Janssen Pharmaceutical Research and Development and Ian A. Blair, University of Pennsylvania ▶ Technological Advancements to Decode Complex Biomarker Analysis and its Contribution to Drug Discovery & Development Hua-Fen Liu, SCIEX ▶ TBA Catherine Wong, National Center for Protein Science ▶ The Use of High Resolution Accurate Mass (HRAM) to Maximize Selectivity in Quantitative Analysis Jonathan Josephs, Thermo Fisher Scientific 	 Preformulation – Key to efficient and effective formulation design Feng Tao, Zai Lab Drug Substance (API) for Early Drug Development Jun Lu, GlaxoSmithKline R&D Formulation Selection Matrix in Early Clinical Development Anand Kulkarni, Bioduro 	



Friday APRIL 22

3:30 PM - 5:00 PM PARALLEL SESSIONS TRACKS 13 - 16

Track 13	Track 14	
Quantitative System Pharmacology	Challenges and Opportunities for Biomarkers in Scientific Space	
Ballroom I	Ballroom II	
Chairs: Valeriu Damian, GlaxoSmithKline and Peiming Ma, GlaxoSmithKline ➤ Application of QSP Modeling to Support Drug Development Projects Oleg Demin, Institute for Systems Biology Moscow ➤ Mechanistic Physiological PhysioPD™ Models in Drug Development: A Proven Quantitative Systems Pharmacology (QSP) Approach Ananth Kadambi, Rosa & Co. LLC ➤ Practical Applications of DILIsym, A Simulation Tool for Drug-Induced Liver Injury Brett Howell, DILIsym Services, Inc.	 Chairs: Wenying Jian, Janssen and Naidong Weng, Janssen Metabolomics in the Search for Pancreatic Cancer Biomarkers Huichang Bi, Sun Yat-sen University Advanced Technology for Mass Spectrometry Based Small Molecule Biomarker Quantitation Allan Xu, Keystone Bioanalytical Quantification of 14 Bile Acids Using UHPLC-HRAM Min Meng, Covance 	
Track 15	Track 16	
Innovator Award Session Rhine Ballroom	Scientific Validation Danube Ballroom	
Innovator Award Committee: Robert Dodge, Bristol-Myers Squibb; Yi Du, HuaHai Pharmaceutical Co., Ltd.; Xianyu Jiang, WuXi; Wenzhe Lu, Roche; Yi-Min She, Shanghai Center for Plant Stress Biology	 Chairs: Philip Timmerman, Janssen Research & Development ▶ The Principles of Tiered Approach and Scientific Validation: History and EBF Recommendation Philip Timmerman, Janssen Research & Development on behalf of the EBF ▶ Bioanalytical Support of Early Development Studies at WuXi: A Perspective Xinping Fang, WuXi AppTec ▶ Perspective on Translating Tiered Approach and Science Validation into LBA Joseph Bower, Covance Panel Discussion 	



Friday APRIL 22

5:00 PM - 7:30 PM

CPSA SHANGHAI CLOSING GALA

Ballroom I & II

Dinner, Awards and Celebration

Sponsor's Toast

Program Chair Recognition

Mike Lee, Milestone Development Services

CPSA Shanghai 2016 – Program Chair Announcement

Kelly Dong, GlaxoSmithKline

Innovator Award Presentation

Innovator Award Committee: Robert Dodge, Bristol-Myers Squibb; Yi Du, HuaHai Pharmaceutical Co., Ltd.; Xianyu Jiang, WuXi; Wenzhe Lu, Roche; Yi-Min She, Shanghai Center for Plant Stress Biology

Young Scientist Excellence Award Presentation

Chairs: Mingdan Wu, Wuxi AppTec and Jeff Zhang, Novartis

3rd Annual Symposium on Clinical & Pharmaceutical Solutions through Analysis



Pharmaceutical Innovation: Collaborating from Bench to Bedside

August 3 - 5, 2015 • São Paulo, Brazil

Program Chair

Plenary Speaker

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Plenary Speaker

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- Take photos... lots of photos on your phone, tablet, or camera
- Email all of your CPSA photos to CPSAselfies@gmail.com
- Be sure to include the names of everyone in the photos
- Make sure to check the Image Gallery at cpsa-shanghai.com to see and share your photos with friends, family and colleagues!



19th Annual Symposium on Clinical & Pharmaceutical Solutions through Analysis



Analytical Chemistry at a Crossroad: Making Data Relevant to the Patient

September 26 - 29, 2016 • Langhorne, PA USA

Program Co-Chair

Timothy Garrett University of Florida

Plenary Speaker

Scott Biller Agios Pharmaceuticals Program Co-Chair

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Where Technology and Solutions Meet

15



NOTES





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We need this to be **easy to use**...
But we don't want to give up

any **performance**."

Nathan Yates University of Pittsburgh





High-performance IS ease-of-use."

Shane Needham Alturas Analytics



Several key performance attributes are required for essential overall performance. While each may be independent of the other, the coordinated control of these parameters is essential to improving your overall analysis.

Tip Size

Proven PicoFrit[®] technology is at the core, producing sharp peaks and optimal chromatography.

Voltage

Factory installed, tested, and verified, to ensure leak-free optimal voltage contact.

Position

Easy-to-use pre-optimized for exact tip positioning right out of the box for maximized signal.

Flow Rate

Flow-rate control equals higher sensitivity.



Leaders in Flow Technology™

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