



6TH ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis

CPSA

SHANGHAI

2015

**Connecting the Dots:
Sharing Science Across Disciplines Helps Projects Progress**

April 15 - 18, 2015
Renaissance Shanghai Pudong Hotel
Shanghai

MEETING PROGRAM

*Where Technology and Solutions Meet
Where East Meets West*

因为专注，所以专业



SCIEX TripleTOF[®] 系列质谱同时 定量/定性工作流程

药物发现早期

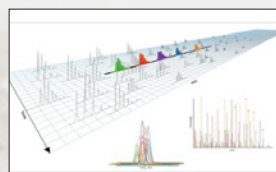
需要：测定重要的代谢
柔点信息；一次进样，
鉴定药物代谢稳定性 ...

药物发现后期

需要：鉴定预期和非预
期的低浓度代谢物

药物发展阶段

做什么：代谢物明确的
结构解析以及相关分析



SCIEX快速、全面的代谢物非数据依赖性SWATH[™]采集：

- 一次进样，获得包括低浓度和毒性代谢物的MS/MS数据信息100%覆盖，用于定性、定量分析；
- MetabolitePilot[™]软件是一个集所有功能于一体的代谢物鉴定，可快速识别和确认的代谢物鉴定与结构解析；
- PCVG去卷积算法，能明确的进行碎片归属，避免假阳性结果；
- 高分辨MRM定量有效降低干扰对测试的影响，并依然能够保持三重四极杆级别的灵敏度与线性范围；
- 更加简单轻松的方法开发。



SCIEX中国各办事处

北京办事处：北京市朝阳区酒仙桥中路24号院1号楼5楼
上海办事处：上海市田林路888号 科技绿洲一号楼102室
广州办事处：广州市体育西路109号 高盛大厦15C室
全国免费垂询电话：800 820 3488, 400 821 3897

电话：010-5808 1388
电话：021-2419 7200
电话：020-8510 0200

传真：010-5867 1390
传真：021-2419 7333
传真：020-3876 0835

网址：www.absciex.com.cn

微博：[@ABSCIEX](https://weibo.com/ABSCIEX)

WELCOME

Inspiration to Application

Dear Colleague:

On behalf of the organizing committee and our sponsors, we welcome you to the 6th Annual Shanghai Symposium on Clinical & Pharmaceutical Solutions through Analysis (CPSA Shanghai 2015) – Connecting the Dots. It is a great 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. At CPSA Shanghai 2015, 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.

Certainly, the sessions and events reflect the theme of this year's annual meeting "Connecting the Dots." Traditions – universal for CPSA events worldwide – continue in Shanghai as pre/post-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. In this year's meeting we aim even more at connecting everybody, not only as friends, but also as scientists across different disciplines in drug R&D. We want to connect you around the growing importance of PBPK and modeling, being the theme of the preconference workshop and executive round table.

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 2015 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!

Sincerely



Mike S. Lee, Ph.D.
CPSA Founder



Philip Timmerman
CPSA Shanghai 2015 Program Chair

ORGANIZING COMMITTEE

PROGRAM CHAIR

.....

Philip Timmerman
Janssen Research & Development
Belgium

ORGANIZING COMMITTEE

.....

Luke Bi
Covance
China

Chad Briscoe
PRA International
USA

Swapan Chowdhury
Takeda Pharmaceuticals
USA

Binodh DeSilva
Bristol-Myers Squibb
USA

Kelly Dong
GlaxoSmithKline
China

Alicia Du
ChemPartner
China

Todd Gillespie
Eli Lilly and Company
USA

Cornelis Hop
Genentech
USA

Zhouhan Hu
Research Institute for Liver Diseases
China

Wenying Jian
Janssen Research & Development
USA

Xianyu Jiang
WuXi AppTec
China

Fan Jin
Covance
China

David Jones
MHRA
United Kingdom

Yong-Guo "Fred" Li
Hua Medicine, Ltd.
China

Jing Lin
Sunovion
USA

Jun Liu
ChemPartner
China

Min Liu
Merck
USA

Chuang Lu
Takeda Pharmaceuticals
China

Tong Lu
Genentech
USA

Qun Lu
Celgene
China

Mario Monshouwer
Janssen Research & Development
Belgium

Marjoleen Nijssen
AbbVie
USA

Jasminder Sahi
GlaxoSmithKline
China

Jim Shen
Bristol-Myers Squibb
USA

Jan Snoeys
Janssen Research & Development
Belgium

Wei Tang
ChemPartner
China

Gary Valaskovic
New Objective
USA

Paolo Vicini
Pfizer
USA

Frances Wang
Roche
Shanghai, China

Sih Wang
Cleveland Clinic
USA

Steve Wang
WuXi AppTec
China

Naidong Weng
Janssen Research & Development
USA

Mingdan Wu
WuXi AppTec
China

Ismael Zamora
Molecular Discovery
Europe

Duxi Zhang
Wuxi AppTec
China

Jeff Zhang
Novartis
China

Tianyi Zhang
Frontage Laboratories
China

Sylvia Zhao
Novartis
China

Dafang Zhong
Shanghai Institute of Materia Medica
China

Shaolian Zhou
Novartis
China

LOGISTICS & MANAGEMENT

.....

Event Services Manager

Frank Fung
MICE Partners
China

Communications & Media
Martin Steel
McKinley Scientific
USA

Communications & Media
Carla Marshall-Waggett
New Objective
USA

Management & Correspondence
Mike Lee
Milestone Development Services
USA

SPONSORS

Thank You!

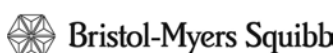
The CPSA Shanghai annual symposium is made possible by the broad-based support of industry sponsors. The passion for the analytical sciences and the accelerated discovery and development of pharmaceuticals is shared by each sponsor. As a result, the event is dedicated to promoting awareness and understanding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



NEW OBJECTIVE



Waters
THE SCIENCE OF WHAT'S POSSIBLE.™



Meeting Management

MICE PARTNERS

Media Sponsors



EXHIBITORS

Thank You!

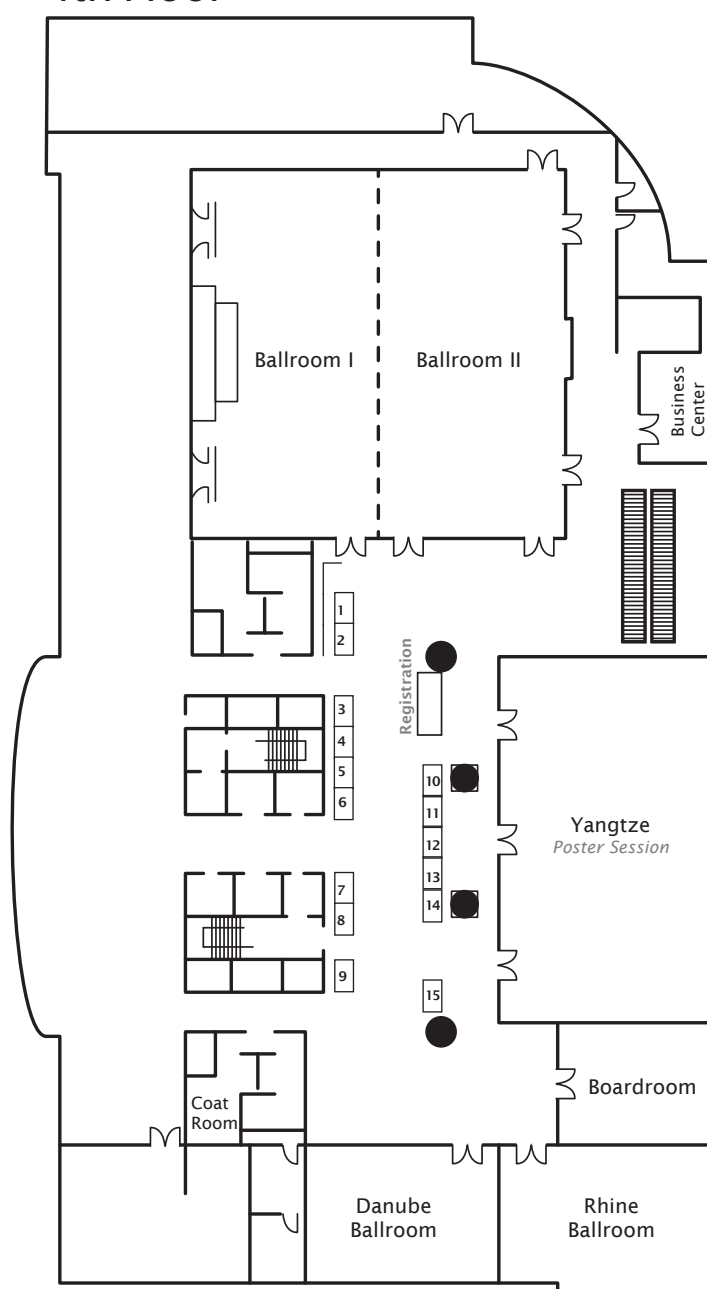
We would like to extend our sincere thanks to the exhibitors who made this year's annual CPSA Shanghai conference possible. It is with the support and commitment of these companies and people that technology can meet solutions! We hope to see you all in 2016!



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.

4th Floor



EXPO HOURS

The CPSA Shanghai 2015 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
12	Agilent Technologies
13	Antpedia
3	Covance
4	ES Industries
9	Instrument.com.cn
2	McKinley Scientific
5	Molecular Discovery
11	New Objective
15	Novilytic
7	QuanYang
6	RILD
1	SCIEX
10	Thermo Fisher
14	Waters
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 15

10:00 AM

Registration Open

.....
Renaissance Shanghai Pudong 4th Floor Lobby

1:00 PM - 4:00 PM

WORKSHOP

Ballroom I

Workshop on PBPK

Chair: Philip Timmerman, Janssen Research & Development

**Physiologically-Based Pharmacokinetic Modelling and Simulations –
Challenges Today and Future Trends**

Sheila Annie Peters, AstraZeneca

Mechanistic PBPK: Approaches to Understanding Tissue Distribution

Avijit Ghosh, Janssen Research & Development

PBPK Modeling for Non-Oral/IV Routes: Pulmonary, Dermal, Ocular

Valeriu Damian, GlaxoSmithKline

**Physiologically-Based Pharmacokinetic Modelling of Monoclonal Antibodies:
A Case Study**

Jiansong Yang, GlaxoSmithKline

**Physiologically Based Pharmacokinetic Modeling as a Tool to Predict Drug Interactions
for Antibody-Drug Conjugates**

Yuan Chen, Genentech

1:00 PM - 4:00 PM

WORKSHOP

Ballroom II

Pharmaceutical R&D and How DMPK Fits In

Chair: Jim Shen, Bristol-Myers Squibb

Session Introduction - Panelist Introduction

Jim Shen, Bristol-Myers Squibb

Introduction to DMPK

Mingdan Wu, WuXi AppTec

DMPK in Pharmaceutical Development

Zack Cheng, AstraZeneca

Contract Research and How DMPK Fits In

Duxi Zhang, WuXi AppTec

Career Options in Pharmaceutical Development

Qun Lu, Celgene

What It Is Like to Work For, or Start Up, a Small Company

Gary Valaskovic, New Objective

Career Development, Job Skills, Interview

Jing Lin, Sunovion Pharmaceuticals

PROGRAM AGENDA

Wednesday APRIL 15

WORKSHOP

Pharmaceutical R&D and How DMPK Fits In (*continued*)

Career Development, Job Skills, Resume

Min Liu, Merck

Career Development, Job Skills, PowerPoint Presentations

Jim Shen, Bristol-Myers Squibb

Roundtable Discussion on Career Development

David Abramowitz, SCIEX; Zack Cheng, AstraZeneca; Paul Corcoran, McKinley Scientific; Jing Lin, Sunovion Pharmaceuticals; Min Liu, Merck; Qun Lu, Celgene; Jim Shen, Bristol-Myers Squibb; Sihe Wang, Cleveland Clinic; Mingdan Wu, WuXi AppTec; Duxi Zhang, WuXi AppTec

4:00 PM - 6:00 PM

Ballroom I & II

EXECUTIVE ROUNDTABLE

The Value and Limitations of Modeling in Today's Drug Development:
An Industry and Regulator's Perspective

Discussion Panel:

Valeriu Damian, GlaxoSmithKline

Cornelis (Marcel) Hop, Genentech

David Jones, MHRA, UK

Mario Monshouwer, Janssen Research & Development

Hu Pei, Peking Union Medical College Hospital

Steve Yang, WuXi AppTec

Ping Zhao, USA

6:00 PM - 9:00 PM

Ballroom I & II

OPENING RECEPTION

Sponsored by SCIEX

Plan to attend the opening festivities. Greet old friends, meet new friends, and get an overview of the week's events and activities. Welcome to CPSA Shanghai 2015!

Sponsor's Toast

PROGRAM AGENDA

Thursday APRIL 16

7:30 AM

REGISTRATION OPEN

8:30 AM – 9:00 AM

OPENING REMARKS

Ballrooms I & II

Welcome

Mike Lee, Milestone Development Services

Objectives, Format, and Opening Remarks

Philip Timmerman, Janssen Research & Development - Program Chair

9:00 AM - 9:45 AM

PLENARY LECTURE

Ballrooms I & II

Trends, Success Stories, and Works in Progress with Physiologically Based Pharmacokinetic Modeling: On the Optimization of Free Exposure at the Site of Action

Avijit Ghosh, Janssen Research & Development

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

Preparing for a successful First into Human (NCE perspective)

Co-Chairs: Kelly Dong, GlaxoSmithKline and Marjoleen Nijsen, AbbVie

- ▶ **What Pharmacokinetics Can Do in Early Phase Clinical Development of Innovative Drug**
Pei Hu, Peking Union Medical College Hospital
- ▶ **AbbVie's Strategy for Human PK & FIH Dose Prediction with Retrospective Analysis**
Marjoleen Nijsen, AbbVie
- ▶ **First-Time-in-Human (FTIH) Studies: Dose Selection and Study Design**
Jiansong Yang, GlaxoSmithKline
- ▶ **Early Clinical Development: A Critical Stage to Move a Right Compound for Global Development**
Zhigang Yu, Amgen

11:00 AM - 2:00 PM

CPSA SHANGHAI EXPO - WHERE TECHNOLOGY AND SOLUTIONS MEET!

Lobby

11:30 AM - 12:30 PM

POSTER SESSION / YOUNG SCIENTIST EXCELLENCE AWARD REVIEW

Yangtze Ballroom

Young Scientist Excellence Committee Members: *Chad Briscoe, PRA International; Swapan Chowdhury, Takeda Pharmaceuticals; Todd Gillespie, Eli Lilly and Company; Cornelis Hop, Genentech; Jing Lin, Sunovion Pharmaceuticals; Qun Lu, Celgene; Jasminder Sahi, GlaxoSmithKline; Gary Valaskovic, New Objective; Sihe Wang, Cleveland Clinic; Naidong Weng, Janssen Research & Development; Ismael Zamora, Molecular Discovery; Jeff Zhang, Novartis; Sylvia Zhao, Novartis*

百万用户的共同选择

科学仪器行业专业门户网站



网上仪器展

专业的仪器导购平台
助您轻松完成仪器采购



网络讲堂

科学仪器行业的百家讲坛
每周举办多场仪器技术及应用在线研讨会



行业应用

仪器导购新方式
按行业选购仪器



仪器论坛

科学仪器行业专业的
用户在线交流平台



人才招聘

仪器及分析测试行业
专业人才招聘平台





WHEN CONSIDERING MS PERFORMANCE CLAIMS,
BE MINDFUL OF THE FINE PRINT.



It's true! In the world of pharmaceutical bioanalysis, there's more than meets the eye. There are those who make bold claims. And those who deliver greater results. In the bold claims department, you'll hear about ultra-high resolution settings that are rarely if ever achieved—or that take too long to obtain. Then there are sensitivity measurements that don't hold up over time.

What can you do to avoid the false perception trap? Shine a spotlight on the truth.

And see where it takes you at waters.com/DMPKpartner



关注沃特世微信

Waters

THE SCIENCE OF WHAT'S POSSIBLE.®

Pharmaceutical | Health Sciences | Food & Environmental | Chemical Materials

Identify. Design. Succeed.

...defining the field

Molecular Discovery's revolutionary high-throughput approach to MetID turns data into knowledge faster than ever before.

Multiple Instruments? One platform.

Identify.

Whichever instrument you have, obtain fully specific MetID in minutes. Reactive metabolites? No problem.

Design.

Visualize results in the context of the Cytochrome to aid design. Or link directly to automated design engines for suggestions on how to optimize your compounds.

Succeed.

Capture all data for enterprise-wide interrogation and analysis. Increase knowledge, increase collaboration.

Find out more at www.moldiscovery.com



互联网营销，您同样需要3S+2A

Sensitive：每天300万访问量保证绝对市场灵敏度，深度报道显著提升营销沟通信噪比

Selective：3000种分类产品，10种互联网工具，50种应用行业分类，10万高质量行业专家库，为您提供高选择性的营销推广组合

Speedy：1分钟发布，1天内您的客户全知道，助您快速传播最新资讯

Accurate：无论是电子直邮、客户通讯，还是网络研讨会、用户调查，基于细分数据库的灵活运用，帮您把握精准的客户需求信息

Automatic：自动咨询提醒和反馈系统，让您的推广和客服工作事半功倍，提升客户满意度

快来体验我们的 **3S+2A** 服务吧！



PROGRAM AGENDA

Thursday APRIL 16

12:00 PM - 1:00 PM

LUNCH & LEARN WORKSHOPS

Ballroom I

Molecular Discovery-SCIEX Collaboration to Process SWATH Data Analysis

Sponsored by Molecular Discovery

▶ SWATH Data Analysis Within the Mass-MetaSite Framework: Metabolite and Soft Spot Identification Workflows
Ismael Zamora, Molecular Discovery

▶ Comprehensive Metabolite Identification using SWATH Acquisition
Eva Duchoslav, SCIEX

Ballroom II

Applications of Novel Acquisition Modes and instrument Geometries in Time-of-Flight Mass Spectrometer for Targeted Quantitation

Sponsored by Waters Corporation

Russell Mortishire-Smith, Waters Corporation

Boardroom

Connecting the Dots and Helping Projects Progress with Asset Management

Sponsored by McKinley Scientific

Discussion Leader: Martin Steel, McKinley Scientific

THURSDAY, APRIL 16

2nd Annual Symposium on
Clinical & Pharmaceutical Solutions through Analysis



On The Way to Innovation: Pharmaceutical/Analytical Technology, Regulation and Knowledge Management

Program Chair
Rafael Barrientos
Eurofarma Laboratórios S.A.

Plenary Speaker
Nathan A. Yates
University of Pittsburgh

CPSA BRASIL FEATURES

Symposia • Roundtables • Performance Benchmarks
Commercial Technology • Mainstream Appliances • Analysis Trends

August 3 - 5, 2015
São Paulo, Brazil

www.cpsa-brasil.com

PROGRAM AGENDA

Thursday APRIL 16

1:30 PM - 3:00 PM

PARALLEL SYMPOSIA & ROUNDTABLES

<p>Traditional Chinese Medicine and Natural Product Research <i>Ballroom I</i></p>	<p><i>New Technologies for Early Bioanalytical Support</i> <i>Ballroom II</i></p>	<p>ADME/PK session: New Technologies for ADME <i>Rhine Ballroom</i></p>
<p><i>Chair: Chuang Lu, Takeda Pharmaceuticals</i></p> <ul style="list-style-type: none"> ▶ Involvement of P-gp and CYP3A In The Liver Disposition of Triptolide: Implications for Understanding Triptolide-induced Hepatotoxicity <i>Xiaomei Zhuang, Beijing Institute of Pharmacology and Toxicology</i> ▶ Role of Herb-Drug Interaction Study In The Practice of Integrative Medicine in Hong Kong: Fact and Challenges <i>Joan Z. Zuo, Chinese University of Hong Kong</i> ▶ PXR and CAR-Mediated Transcriptional Activation of CYP2B6 and UGT1A1 By Natural Constituents From Traditional Chinese Medicines <i>Lushan Yu, Zhejiang University</i> ▶ Reaction Phenotyping Of Drug Metabolizing Enzymes, The Central Piece Of Victim Drug DDI Prediction <i>Chuang Lu, Takeda Pharmaceuticals</i> 	<p><i>Chair: Tianyi Zhang, Frontage Labs</i></p> <ul style="list-style-type: none"> ▶ A Novel Selective Peptide Derivatization Strategy For Sensitivity Enhancement For LC-MS/MS Bioanalysis Of Proteins <i>Long Yuan, Bristol-Myers Squibb</i> ▶ Ultra-sensitive Method for Analysis of Midazolam in DDI Studies <i>Wenzhe Lu, Roche China</i> ▶ Bioanalytical Challenges and Strategies for Antibody-Drug Conjugate (ADC) Therapeutics <i>John Lin, Frontage Labs</i> ▶ LC-MS/MS Bioanalytical Support To Potent Therapeutic Peptides In Early Development – How To Manage Sensitivity Demands? <i>Magnus Knutsson, Ferring Pharmaceuticals</i> 	<p><i>Chair: Swapan Chowdhury, Takeda Pharmaceuticals</i></p> <ul style="list-style-type: none"> ▶ Important Role of DMPK In Drug Discovery: A Lesson Learned From Aldehyde Oxidase-Mediated Issue <i>Pan Deng, Shanghai Institute of Materia Medica</i> ▶ Revealing Novel Drug Metabolites Using Liquid Chromatography-High Resolution Mass Spectrometry: Case Studies in Drug Development <i>Shuguang Ma, Genentech</i> ▶ From Data To Information And From Information To Knowledge <i>Ismael Zamora, Pompeu Fabra University</i> ▶ How To Distinguish Drug-Related Ions From A Complex LC-MS Spectra And Chromatogram- A Background Subtraction Software Tool <i>Swapan Chowdhury, Takeda Pharmaceuticals</i>

THURSDAY, APRIL 16

PROGRAM AGENDA

Thursday APRIL 16

3:30 PM - 5:00 PM

PARALLEL SYMPOSIA & ROUNDTABLES

<p>Clinical Session: How Can Clinical PK and Bioanalysis Work Together To Contribute To Mutual Success?</p> <p><i>Ballroom I</i></p>	<p>Bioanalysis of Herbal Medicines</p> <p><i>Ballroom II</i></p>	<p>Technology Developments in the Application of Mass Spectrometry for Protein and Peptide: Are Both Technologies Complementary?</p> <p><i>Rhine Ballroom</i></p>
<p><i>Chairs: Sylvia Zhao, Novartis; Luke Bi, Covance</i></p> <ul style="list-style-type: none"> ▶ The Critical Roles Of BA/BE Studies In Drug Development <i>Jim Wei, Medpace</i> ▶ Develop A Sensitive LC/MS/MS Assay For A Peptide Drug In A SAD Study <i>Luke Bi, Covance</i> ▶ Considerations in the Design and Data Presentation of Clinical Pharmacokinetic Studies Used for Bridging Caucasian Data into Chinese Population <i>Minji Wei, Institute of Clinical Pharmacology, Peking University</i> ▶ Panel Discussion: Current Challenges in Bioanalysis and Impact on PK <i>Luke Bi, Covance</i> <i>Xiaohang Shen, Wuxi AppTec</i> <i>Chad Briscoe, PRA Health Sciences</i> 	<p><i>Chair: Zhuohan Hu, Research Institute for Liver Diseases</i></p> <ul style="list-style-type: none"> ▶ Quantification of Systematic Exposure to Herbal Compounds and Metabolites <i>Chuan Li, Shanghai Institute of Materia Medica</i> ▶ Bioanalysis and Pharmacophore of Iridoids from Chinese Herbs <i>Li Yang, Shanghai University of Chinese Medicines</i> ▶ HRMS-Based Metabolites Identification for Traditional Chinese Medicine <i>Gary Impey, SCIEX</i> 	<p><i>Chair: Wenyong Jian, Janssen Research & Development</i></p> <ul style="list-style-type: none"> ▶ Technology Developments in the Application of Mass Spectrometry for Protein and Peptide: Are Both Technologies Complementary? <i>Chair: Wenyong Jian, Janssen Research & Development</i> ▶ Studies On New Methods For Protein Quantification By High Performance Liquid Chromatography Coupled To Mass Spectrometry <i>Yangjun Zhang, Beijing Proteome Research Center</i> ▶ Bioanalysis of Peptides and Proteins In Drug Research and Development: LBA and LCMS! <i>Lieve Dillen, Janssen Research & Development</i> ▶ Challenges and Assay Strategies for Bioanalytical Assessment of Antibody-Drug Conjugates In Vivo <i>Keyang Xu, Genentech</i>

THURSDAY, APRIL 16

6:00 PM

Yangtze Ballroom

COCKTAILS &

KARAOKE AT CPSA

Unleash Your Inner Rock Star

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

PROGRAM AGENDA

Friday APRIL 17

7:30 AM

REGISTRATION OPEN

8:30 AM – 9:15 AM

PLENARY LECTURE

Ballrooms I & II

Advances In Biologic Therapeutics Development Beyond The Era of Monoclonal Antibodies
Binodh DeSilva
Bristol-Myers Squibb

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)

Chair: Fan Jin, Covance

- ▶ Ongoing Assay Design and Modification Choices throughout the Drug Development Life Cycle
Joe Bower, Covance
- ▶ Challenges of Biosimilar Method Development and Validation For Phase 3 Clinical Trials - Focusing On Appropriate Bioanalytical Assay Formats To Avoid Matrix Interference Issues In The Disease State. Using Some Examples For Humira, Herceptin and Enbrel.
James Munday, Covance
- ▶ Status/Strategy/Challenge of Biological BA in China
Haifeng Song, Chinese Military Academy of Science

11:00 AM - 2:00 PM

CPSA SHANGHAI EXPO - WHERE TECHNOLOGY AND SOLUTIONS MEET!

Lobby

11:30 AM - 12:30 PM

POSTER SESSION / YOUNG SCIENTIST EXCELLENCE AWARD REVIEW

Yangtze Ballroom

Young Scientist Excellence Committee Members: Chad Briscoe, PRA International; Swapan Chowdhury, Takeda Pharmaceuticals; Todd Gillespie, Eli Lilly and Company; Cornelis Hop, Genentech; Jing Lin, Sunovion Pharmaceuticals; Qun Lu, Celgene; Jasminder Sahi, GlaxoSmithKline; Gary Valaskovic, New Objective; Sihe Wang, Cleveland Clinic; Naidong Weng, Janssen Research & Development; Ismael Zamora, Molecular Discovery; Jeff Zhang, Novartis; Sylvia Zhao, Novartis

PROGRAM AGENDA

Friday APRIL 17

12:00 PM - 1:00 PM

LUNCH & LEARN WORKSHOPS

Ballroom I

Validation of LC/MS Instruments for Part 11 Compliance

Sponsored by SCIEX

- ▶ How to Migrate to an Integrated Compliance Strategy for Your Lab
Dave Abramowitz, SCIEX

Ballroom II

The Future of High Data Capacity Mass Spectrometry in the Analytical and Clinical Sciences Connecting Disciplines with High Performance Nanospray

Sponsored by New Objective

- ▶ CHORUS: Mass Spectrometrists Look to Cloud Computing for Data Permanence and Re-Analysis
Nathan Yates, University of Pittsburgh
- ▶ Clinical Science, Digital Fluidics, and Mass Spectrometry: What Would You Do with Infinite Speed?
Gary Valaskovic, New Objective

FRIDAY, APRIL 17

18th Annual Symposium on
Clinical & Pharmaceutical Solutions through Analysis



Getting Medicines to Patients Faster by Eliminating the Bottlenecks in Drug Discovery & Development

Program Co-Chairs

Chad Briscoe
PRA Health Services

Naidong Weng
Janssen Research & Development

Plenary Speaker
David Evans
Janssen Research & Development

Keynote Speaker
Donald Chace
Pediatrix Analytical

Distinguished Analytical Scientist
Andrew Hoofnagle
University of Washington

CPSA USA FEATURES

Short Courses • Symposia • Roundtables
Poster Session • Vendor Session • Exhibition • Workshops • Colloquium Series

October 5 - 8, 2015
Langhorne, PA USA

www.cpsa-usa.com

PROGRAM AGENDA

Friday APRIL 17

1:30 PM - 3:00 PM

PARALLEL SYMPOSIA & ROUNDTABLES

<p>Global Regulated Bioanalysis: Looking into China from the Outside</p> <p><i>Ballroom I</i></p>	<p>New Technology</p> <p><i>Ballroom II</i></p>	<p>DMPK: Developing Smart DDI Strategies For NCE and NBE</p> <p><i>Rhine Ballroom</i></p>
<p><i>Chair: Philip Timmerman, Janssen Research & Development</i></p> <ul style="list-style-type: none"> ▶ Highlights of the Bioanalysis Guidance in Chinese Pharmacopoeia 2015 <i>Prof. Dafang Zhong, Shanghai Institute of Materia Medica</i> ▶ All for One, One for All - The Chinese BMV Guidance in Perspective to other Guidelines <i>Peter van Amsterdam, Abbott</i> ▶ Integrating Internal and External Bioanalytical Support to Deliver a Diversified Pharmaceutical Portfolio <i>Eric Yang, GlaxoSmithKline</i> ▶ Outsourcing to China: Opportunities and Challenges, an Industry Perspective <i>Ajai Chaudhary, Merck & Co</i> <p><i>Panel Discussion</i> <i>Peter van Amsterdam, Eric Yang, Dafang Zhong, Ajai Chaudhary, Naidong Weng</i></p>	<p><i>Chair: Duxi Zhang, WuXi AppTec</i></p> <ul style="list-style-type: none"> ▶ Can We Solve the ADME Mystery of Traditional Chinese Medicines? A New Analytical Approach for Studying Metabolism and Disposition of Multiple Herb Components In Vivo <i>Mingshe Zhu, Bristol-Myers Squibb</i> ▶ The Application of Immunocapture LC-MS/MS to Simultaneously Quantify Biological Biomarkers and Drug Candidates <i>Jim Shen, Bristol-Myers Squibb</i> ▶ Software Driven Workflow Enhancements to Accelerate DMPK Analysis <i>Eva Duchoslav, SCIEX</i> 	<p><i>Chair: Cornelis Hop, Genentech</i></p> <ul style="list-style-type: none"> ▶ Predictions of Drug-Drug Interactions Involving Inhibitory Metabolites - A Case Study of Amiodarone <i>Yuan Chen, Genentech</i> ▶ Induction Based Drug-Drug Interaction Strategies During Preclinical and Clinical Development <i>Jasminder Sahi, GlaxoSmithKline</i> ▶ Cytochrome P450 Mediated Drug-Drug Interactions For Therapeutic Proteins And Antibody-Drug Conjugates <i>Cornelis Hop, Genentech</i>

FRIDAY, APRIL 17

PROGRAM AGENDA

Friday APRIL 17

3:30 PM - 5:00 PM PARALLEL SYMPOSIA & ROUNDTABLES

<p>Microsampling Beyond DBS An Industry And Regulators Perspective On Microsampling</p> <p><i>Ballroom I</i></p>	<p>Innovator Award Session</p> <p><i>Ballroom II</i></p>
<p><i>Chair: Philip Timmerman, European Bioanalysis Forum (EBF)</i></p> <ul style="list-style-type: none"> ▶ Microsampling: A Progress Update And Perspective From The EBF <i>Philip Timmerman, EBF</i> ▶ Latest Technology Developments on Blood/Plasma Microsampling, and the Perspectives from the IQ Consortium on Implementing DBS for Clinical Pharmacokinetic Studies <i>Eric Yang, GlaxoSmithKline</i> ▶ Reducing Pre-Clinical Blood Volumes From Macro To Micro: Toxicologists, Pharmacokineticists And Bioanalysts Unite <i>Cathy Vickers, NC3R Consortium; David Jones, MHRA</i> 	<p><i>Chairs: Kelly Dong, GlaxoSmithKline; Shaolian Zhou, Novartis</i> <i>Committee Members: Xianyu Jiang, WuXi AppTec; Jun Liu, ChemPartner; Qun Lu, Celgene Corporation; Jim Shen, Bristol-Myers Squibb; Sihe Wang, Cleveland Clinic</i></p> <ul style="list-style-type: none"> ▶ Adding Immuno-purification to a Plasma Collection Device <i>Tim Schlabach, Novilytic</i> ▶ Ease-of-use and Sensitivity with Nanospray: An Integrated Chip-Based Solution Incorporating Column Temperature Control, Long Columns, and Nebulization <i>Gary Valaskovic, New Objective</i> ▶ Development and Validation of LC-MS/MS Method for the Quantitation of Infliximab in Human Serum <i>Hui Wang, Waters Corporation</i> ▶ WebMetabase: A Tool to Exploit Metabolite Identification Information in Drug Discovery <i>Ismael Zamora, Molecular Discovery</i>

5:00 PM – 7:30 PM

Ballroom I & II

CPSA SHANGHAI CLOSING GALA

Dinner, Awards and Celebration

Sponsor's Toast

Program Chair Recognition

Mike Lee, Milestone Development Services

CPSA Shanghai 2016 – Program Chair Announcement

Philip Timmerman, Janssen Research & Development

Innovator Award Presentation

Kelly Dong, GlaxoSmithKline; Shaolian Zhou, Novartis

Young Scientist Excellence Award Presentation

FRIDAY, APRIL 17

PROGRAM AGENDA

Saturday APRIL 18

8:00 AM

REGISTRATION

9:00 AM – 11:15 AM

JOINT SESSION WITH LOCAL BIOANALYTICAL & METABOLISM DISCUSSION GROUPS
AND RDPAC PRECLINICAL FOCUS GROUP

Held at The Shanghai Institute of Materia Medica

Challenges and Opportunities of DMPK Studies in CFDA New Drug Submissions

- ▶ **Bioanalysis of Peptides and Proteins Using LC-MS**
Wenyang Jian, Janssen Research & Development
- ▶ **Understanding Stability and Biotransformation of ADCs in Drug Discovery**
Keyang Xu, Genentech
- ▶ **Role of Drug Transporters in Drug Disposition**
Peihua Sun, PharmaResources (Shanghai) Co., Ltd.

Directions to The Shanghai Institute for Materia Medica

From the Renaissance Shanghai Pudong Hotel, take a taxi to The Shanghai Institute of Materia Medica (中国科学院上海药物研究所) located at 555 Zu Chong Zhi Road, Zhang Jiang Hi-Tech Park, Pudong, Shanghai (上海市浦东张江祖冲之路555号). The cost of the taxi is around RMB 18 (\$3.00).

To take public transportation, walk to Shanghai Science and Technology Museum and take Subway Line #2 towards the airport. Get off at Zhang Jiang Hi-Tech Park (third stop). The Shanghai Institute of Materia Medica is directly across the street from the subway station.



Discover the *missing cog* in your global instrumentation and services strategy.

McKinley
S C I E N T I F I C



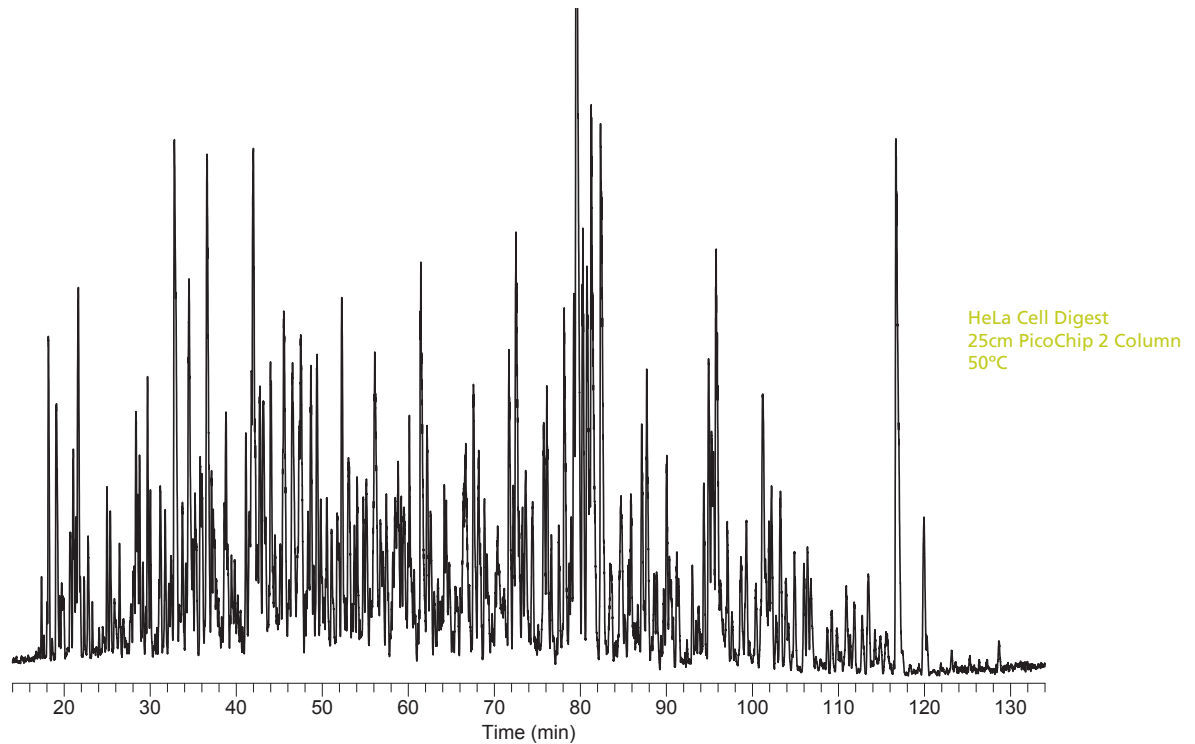
McKinley Scientific transforms the business of **global outsourcing** in the pharmaceutical and clinical life sciences by providing both standard and customized leasing options as a tool to efficient equipment management.

We use a unique strategy that uses traditional leasing as a vehicle to create access to **cutting edge** instrumentation such as LC/MS/MS, UPLC, HPLC used in research and development, clinical diagnostics and a multitude of industries where high sensitivity, resolution or separation is required for quantitation and equalization.

We have over **35 years of experience** in providing solutions in LC/MS/MS through this asset management approach. Our pre-owned instrumentation is refurbished, tested and recalibrated, delivered and installed to manufacturer specifications and carries a comprehensive warranty.

McKinley
S C I E N T I F I C

WHAT'S YOUR SPRAY DNA?™



Introducing the Next Generations of PicoChip® Columns

NEW PicoChip® XL

Extended length columns

- Analyze complex samples
- More protein IDs
- Discover more biomarkers

NEW PicoChip® Advance

Thermal control

- Suitable for quantitation
- Improves robustness
- Higher separating power



Standard PicoChip and PicoChip 2 have all of the power and performance you've come to expect!

Position

Easy-to-use PicoChip columns are pre-optimized for exact positioning from chip to chip-right out of the box.

Voltage

Factory installed, tested, and verified, each PicoChip contains a fresh voltage connection to ensure leak-free optimal liquid-junction-style voltage contact.

Tip Size

Each PicoChip has the integral high-performance, reliable PicoFri® column at its core, producing sharp peaks and optimal chromatography.

Flow Rate

Flow-rate control equals higher sensitivity. Need a specific flow rate? PicoChip columns can be ordered to your specification with column IDs ranging from 50-150 μm and supporting flow rates up to 3 $\mu\text{L}/\text{min}$.

nanoViper™ ready!



U.S. Headquarters
New Objective, Inc.
Two Constitution Way
Woburn, MA 01801-1023
Tel: 1 781 933 9560
www.newobjective.com

China Branch
Xing Wu Jie Instrument (Shanghai) Co., Ltd.
JuneYao Int'l Plaza, Room 649 6th floor
Zhaojiabanglu 789, Shanghai 200032
Tel: 021-61256849
www.newobjective.cn.com

Innovation in High-Sensitivity LC-MS

PROUD SPONSOR of CPSA SHANGHAI