



5TH ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions Through Analysis

CPSA

SHANGHAI

2014

**The New Era of Personalized Medicine:
Innovative Approaches for Drug Discovery and Development**

April 16 - 19, 2014
Renaissance Shanghai Pudong Hotel
Shanghai

*Where Technology and Solutions Meet
Where East Meets West*

因为专注，所以专业

AB SCIEX

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WELCOME

Inspiration to Application

Dear Colleague:

On behalf of the organizing committee and our sponsors, we welcome you to the 5th Annual Shanghai Symposium on Clinical & Pharmaceutical Solutions through Analysis (CPSA Shanghai 2014). 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 2014, 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 "The New Era of Personalized Medicine: Innovative Approaches for Drug Discovery and Development." 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.

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 2014 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., Founder CPSA



Jeff Zhang Ph.D., CPSA Shanghai 2014 Program Chair

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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.

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EXHIBITORS

Thank You!

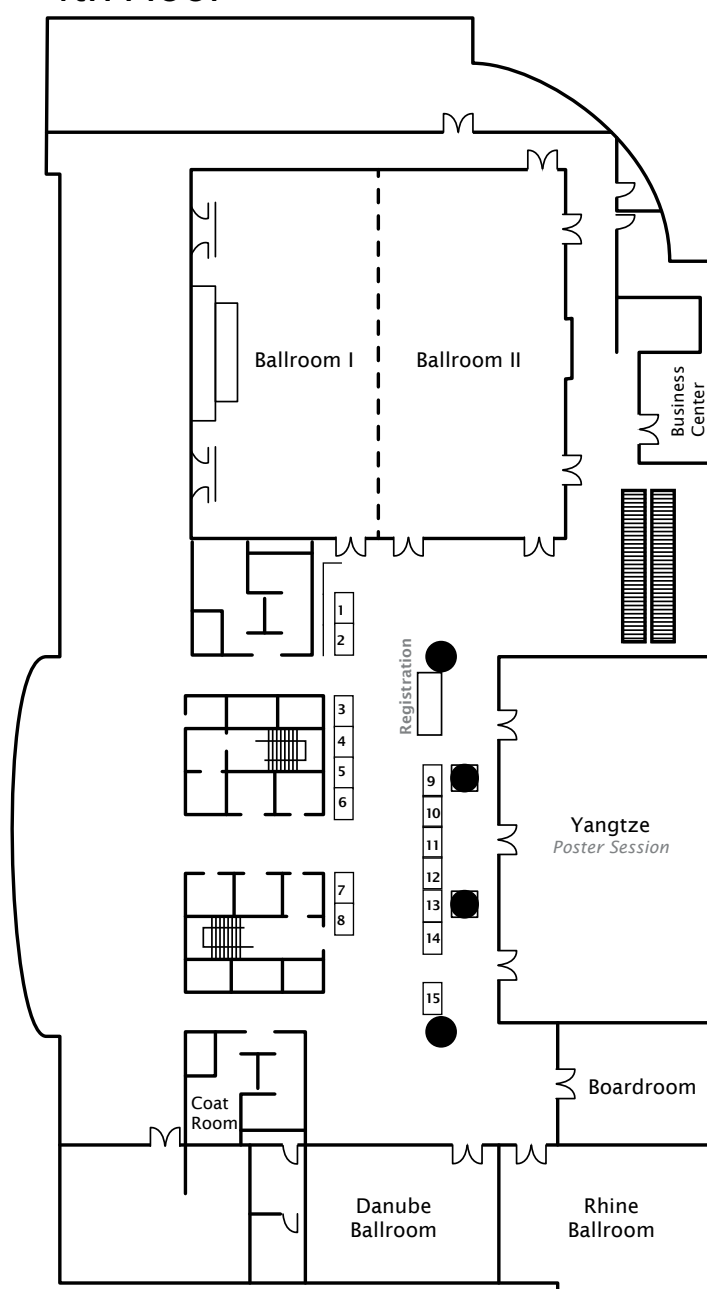
We would like to extend our sincere thanks to the exhibitors who made this year's annual CPSA Shanghai conference possible. It is with the support and commitment of these companies and people that technology can meet solutions! We hope to see you all in 2015!



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. Note that the joint meeting on Saturday with local area discussion groups will be held at the Shanghai Institute for Materia Medica.

4th Floor



EXPO HOURS

The CPSA Shanghai 2014 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
11	AB SCIEX
9	Agilent Technologies
1	Antpedia
15	Apricot Designs
7	Cambridge Isotope Labs
5	Covance
6	ES Industries
2	instrument.com.cn
12	McKinley Scientific
4	MS Parts
10	New Objective
14	NIKYANG Enterprise Ltd.
13	Thermo Scientific
3	Waters Corporation

FOR EXHIBITORS

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

WORKSHOPS

Wednesday April 16

10:00 AM

Registration Open

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

1:00 PM - 4:00 PM

WORKSHOP

Ballroom I & II

ADME Assays and Human Pharmacokinetic Projection

Metabolic Stability and Drug Interaction Assays

Chairs: Liangfu Chen, GlaxoSmithKline; Weiqing Chen, ChemPartner

Case Studies in Metabolite Identification by Triple-TOF

Kerong Zhang, AB SCIEX

Transporter Assays in Drug Discovery and Development

Liangfu Chen, GlaxoSmithKline

Human Pharmacokinetics (PK) and Dose Projection

Cheng Chang, Pfizer

5:00 PM - 6:00 PM

EXECUTIVE ROUNDTABLE

Ballroom I & II

Development of Personalized Medicine - Opportunities and Challenges

Moderator: Jeff Zhang, Novartis

Discussion Panel:

Patrick Bennett

Executive Director Biomarker Operations, PPD

Honggang Bi

General Manager, Covance China

Stephen Clarke

Head Drug Metabolism and Pharmacokinetics, GlaxoSmithKline

Cornelis Hop

Senior Director Drug Metabolism and Pharmacokinetics, Genentech

Hua-fen Liu

Director of Application Support, AB SCIEX

Bin Peng

*Executive Director and Global Head of Oncology Translational Medicine
China, Novartis*

Wei Tang

Vice President and Head of DMPK, ChemPartner

Personalized medicine aims to deliver the right drug to a right patient at the right time. It offers unique opportunities to integrate new technologies and concepts to disease prognosis, diagnosis and therapeutics. Over the past several years, there has been continuing interest in the research and development of personalized medicine in pharmaceutical industry. In this roundtable, we have invited executives from pharma, contract research organizations and instrument companies to lead a discussion on the current trends and strategy for personalized medicine R&D as well as the role they could play.

PROGRAM AGENDA

Wednesday April 16

6:00 PM - 9:00 PM

Lobby & Ballroom I & II

RECEPTION & SPONSOR'S DINNER

Hosted by Thermo Scientific

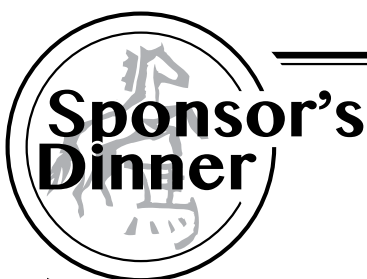
Program

Mass Spec Immunoassay Method for the High Sensitive Quantification and Qualification of Protein Drugs

Urban Kiernan, Business Development Manager, Thermo Fisher Scientific

The measurement of Insulin has been identified as a paramount metric for specific clinical research, and therapeutic development applications. Conventional insulin assays are plagued by the simple inability to differentiate endogenous from synthetic insulin analogs. While LC-MS has demonstrated the ability to overcome this shortcoming, these methods have lacked the sensitivity demanded by the field. Complicated by the presence of high plasma background, highly selective sample interface workflows are required for proper LC-MS detection/quantitation. In order to satisfy all the listed capabilities, a Mass Spectrometric Immunoassay (MSIA) method was developed for the high-throughput, highly sensitive quantification of insulin and its analogs from human plasma.

WEDNESDAY, APRIL 16



SPONSOR'S RECEPTION & DINNER

WEDNESDAY 6:00 PM

Celebrate the opening of this year's CPSA Shanghai at the gala Sponsor's Reception and Dinner!

A CPSA Shanghai Tradition!

Generously hosted once again by Thermo Scientific.

Enjoy dinner and cocktails while hearing about the latest advances in the quantification and qualification of protein drugs from Urban Kierman of Thermo Scientific

Welcome to CPSA Shanghai 2014!

Generously hosted by



PROGRAM AGENDA

Thursday April 17

7:30 AM	REGISTRATION OPEN
8:30 AM – 9:00 AM <i>Ballrooms I & II</i>	OPENING REMARKS Welcome <i>Mike Lee, Milestone Development Services</i> Objectives, Format, and Opening Remarks <i>Jeff Zhang, Novartis - Program Chair</i>
9:00 AM - 9:45 AM <i>Ballrooms I & II</i>	PLENARY LECTURE Human First Metabolism <i>Stephen Clarke</i> <i>Head of Drug Metabolism & Pharmacokinetics</i> <i>GlaxoSmithKline</i>
9:00 AM – 5:00 PM <i>Yangtze Ballroom</i>	POSTER HALL OPEN <i>Sponsored by Agilent Technologies</i> <i>Posters will be available all day today and Friday</i>
10:15 AM – 11:45 AM <i>Ballrooms I & II</i>	JOINT ADME/BA SYMPOSIUM & ROUNDTABLE The World of Antibody-Drug Conjugates: Bioanalytical and PK/PD Challenges <i>Chairs: Young Shin, Chungnam National University and Alicia Du, ChemPartner</i> ▶ Delineating ADC ADME: Challenges and Impact on ADC Development <i>Ben Shen, Genentech</i> ▶ Challenges and Solutions in Large Molecule Quantification using LC-MS/MS (LM by LCMS): "A Hot Topic in Regulated Preclinical and Clinical Bioanalysis" <i>Fabio Garofolo, Algorithme Pharma</i> ▶ Model Based Development of Antibody Drug Conjugates <i>Dhaval Shah, University of Buffalo</i>
11:00 AM - 2:00 PM <i>Lobby</i>	CPSA SHANGHAI EXPO - WHERE TECHNOLOGY AND SOLUTIONS MEET! <i>Chairs: Kelly Dong, GlaxoSmithKline; Shaolin Zhou, Novartis</i>
11:30 AM - 12:30 PM <i>Yangtze Ballroom</i>	POSTER SESSION / YOUNG SCIENTIST EXCELLENCE AWARD REVIEW <i>Sponsored by Waters Corporation</i> <i>Co-Chairs: Liangfu Chen, GlaxoSmithKline; Jenny Zheng, Janssen</i>

THURSDAY, APRIL 17

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- 自动MRM方法开发、专属肽碎片离子判断(B/Y离子), 多肽方法开发不再盲目

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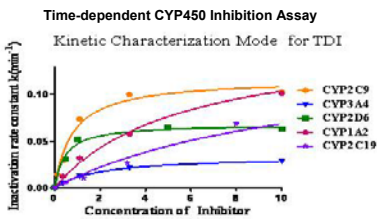


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ADME/PK-Toxicology Service at ChemPartner

In Vitro ADME Service

- Absorption (Caco-2, MDCK-MDR1)
- Protein binding (plasma and brain homogenate) and blood/plasma partition
- Metabolic stability/CYP Phenotyping
- DDI (CYP inhibition/induction)
- In vitro Met ID
- Solubility and Log D



Metabolic Stability (T_{1/2}) of reference compounds after incubation in liver microsomes

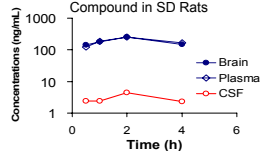
Compound	T _{1/2}				
	HLM	RLM	MLM	DLM	MnKLM
Testosterone	9.9 ± 3.4 (16)	<15	7.5 ± 2.2 (15)	17.29 (1)	13.78 (1)
Propranolol	24.8 ± 9.9 (3)	2.6 ± 1.0 (2)	6.1 ± 0.2 (2)	—	—
Verapamil	11.4 ± 6.4 (2)	3.4 (1)	15.1 ± 3.4 (2)	—	—
Ketanserin	38.7 (1)	13.2 ± 2.2 (2)	40.9 (1)	21.5 (1)	27.08 (1)

Mean ± SD (N)
N: number of independent experiment

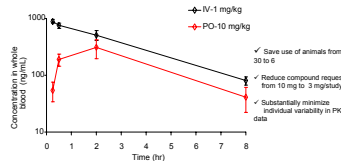
In vivo PK Studies

- Full course PK services including bioavailability, cassette dosing, IV infusion, PKPD and DMPK package including IND filing for SFDA and FDA
- Species: mouse (nude, SCID), rat, rabbit, mini-pig, dog (Marshall beagle) & monkey
- Special surgeries: CSF collection in rat, mouse and dogs, vein cannulation including portal vein, lung perfusion in mouse, etc.
- AAALAC Accreditation for small and large animal facilities
- Short turn-around time for most PK studies
- Discovery formulation support and screening

Brain Penetration and PK Profiling of A Model Compound in SD Rats



Mean whole blood concentration-time profile of Compound ABC after IV (1 mg/kg) and PO (10 mg/kg) administrations in male CD1 mice (N=3)



- ✓ Save use of animals from 30 to 6
- ✓ Reduce compound request from 10 mg to 5 mg only
- ✓ Substantially minimize individual variability in PK data

GLP and Non-GLP Bio-analytical Support

Instrumentation:

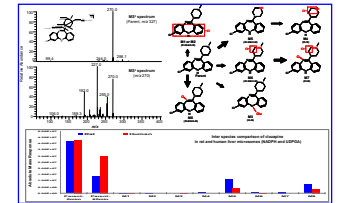
- API 4000 LC-MS/MS for GLP and validated software, IQ/OQ/PQ.
- Freezers (-20 and -70 °C) and Refrigerator (4 °C), IQ/OQ/PQ
- Temperature monitoring system, IQ/OQ/PQ include software, real-time temperature recording, out-of-range alarm system
- Balances/microbalance: IQ/OQ/PQ
- More than 10 LC/MS-MS for non-GLP BA support

Services:

Quantitative bioanalysis

- Parent, metabolite, and dosing solution bioanalysis; N in 1 bioanalysis supporting PK, PK/PD, In vitro ADME study;
- Matrices: biological fluids (plasma, serum, whole blood, bile, urine, CSF) and Tissues (brain, liver, lung, heart, muscle, kidney etc)
- Bioanalysis for challenged analytes (endogenous biomarker, polar analytes, prodrug, and poly-peptide etc.)

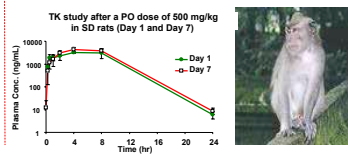
Qualitative work- Met.ID and Biotransformation



Toxicology

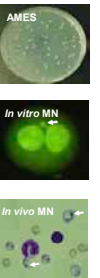
In vivo Study

- Rodent Toxicology Study
- Large Animal Toxicology facility
- Toxicokinetics
- Cardiovascular Safety in Guinea Pigs and Dogs



In vitro Study

- Genotox Assays
Ames test, MN test, Chromosome aberration
- Cardiac Toxicity
hERG Screening (QPatch-16)
- Cytotoxicity
ATP depletion, LDH and MTT assay
- Hepatotoxicity
Hepatocyte cell viability (LDH, ALT)
Mitochondria toxicity
Steatosis and phospholipidosis
- Molecular Toxicity



PROGRAM AGENDA

Thursday April 17

12:00 PM - 1:00 PM

LUNCH & LEARN WORKSHOPS

Ballroom I

Mass Spectrometry Technology Research and Innovation in Shanghai

Sponsored by McKinley Scientific

- ▶ The Structure and Performance of Some New Ion Trap Mass Analyzer
ChuanFan Ding, Fudan University
- ▶ Development of Fast Screening Ionization Source and Digital Ion Trap with the Perspectives in Personal Medicine
Wenjian Sun, Shimadzu

Ballroom II

Addressing Analytical Challenges in the Characterization & QC of Biologics, Biosimilars and Antibody Drug Conjugates

Sponsored by Agilent Technologies

Gurmil Gendeh, Agilent Technologies

1:30 PM - 3:00 PM

PARALLEL SYMPOSIA & ROUNDTABLES

<p>Traditional Chinese Medicine and Natural Product Research</p> <p><i>Ballroom I</i></p>	<p>Challenges and Opportunities of Bioanalysis in China <i>(Roundtable Discussion)</i></p> <p><i>Ballroom II</i></p>	<p>Moving Towards Next Generation Development</p> <p><i>Rhine Ballroom</i></p>
<p><i>Chairs: Chuan Li, Shanghai Institute of Materia Medica and Yang Sai, Hutchison MediPharma</i></p> <ul style="list-style-type: none"> ▶ Pharmacokinetics and Disposition of Tanshinol and Associated Herb-drug Interaction Potential <i>Chuan Li, Shanghai Institute of Materia Medica, CAS, Shanghai</i> ▶ In Vivo Metabolic Characteristics of Alkaloids in Natural Product <i>Yan Wang, Institute of Materia Medica, CAMS, Beijing</i> ▶ The Rationale of Herbal Combinations: How to Tackle the DDI's from ADMET Perspectives <i>Guoyu Pan, Shanghai Institute of Materia Medica</i> 	<p><i>Chairs: Alicia Du, ChemPartner and Philip Timmerman, Janssen Pharmaceuticals</i></p> <p><i>Panelists:</i> <i>Kelly Dong, GlaxoSmithKline</i> <i>Tee Zhang, Frontage Laboratories;</i> <i>Alicia Du, ChemPartner</i> <i>Philip Timmerman, Janssen</i> <i>Hisanori Hara, Novartis</i></p>	<p><i>Chairs: Todd Gillespie, Eli Lilly and Company and Chao-Pin Lee, GlaxoSmithKline</i></p> <ul style="list-style-type: none"> ▶ Translational Systems Medicine Enabling Patient Centric Drug Development <i>Thomas Keller, GlaxoSmithKline</i> ▶ Application of the Quality-by-Design Principals in Early Pharmaceutical Development <i>Qun Lu, Celgene</i> ▶ The Role and Advantages of Open Access LC/MS In Support of Recombinant Protein Drug Development <i>Gurmil Gendeh, Agilent Technologies</i>

THURSDAY, APRIL 17

PROGRAM AGENDA

Thursday April 17

3:30 PM - 5:00 PM

PARALLEL SYMPOSIA & ROUNDTABLES

<p>The Clinical and Regulatory Significance of In Vitro and Clinical Transporter Studies</p> <p><i>Ballroom I</i></p>	<p>Bioanalysis of Chinese Medicine</p> <p><i>Ballroom II</i></p>	<p>Technology Developments in the Application of Mass Spectrometry for Protein and Peptide Biomarker Discovery</p> <p><i>Rhine Ballroom</i></p>
<p><i>Chairs: Marcel Hop, Genentech and Liangfu Chen, GlaxoSmithKline</i></p> <ul style="list-style-type: none"> ▶ Drug Transporters, Drug Interactions and Drug Agency Review of Dolutegravir: A Case Study Review and Lessons Learned <i>Joe Polli, GlaxoSmithKline</i> ▶ Predicting Clinical Relevance of Drug Transporters in Drug Discovery <i>Marcel Hop, Genentech</i> ▶ Understanding Transporter DDI: Regulatory Stance and Industry Case Studies <i>Mingxiang Liao, Takeda</i> 	<p><i>Chairs: Dafang Zhong, Shanghai Institute of Materia Medica and Kate Yu, Waters</i></p> <ul style="list-style-type: none"> ▶ Simultaneous Determination of Five Active Components of Radix Isatidis in Rat Serum by LC-MS/MS <i>Haiyan Xu, Shenyang Pharmaceutical University</i> ▶ Simultaneous Determination of Butyl Phthalide and Four Metabolites in Human Plasma by LC-MS/MS <i>Xingxing Diao, Shanghai Institute of Materia Medica</i> ▶ Quantification of Two Major Bioactive Saponins of Lysimachia Capillipes in Rat Plasma by LC-MS/MS and its Application to a PK Study <i>Hongliang Jiang, Huazhong University of Science and Technology</i> ▶ Clinical Herb-Drug Interactions: Reassessing the Variability of Biological System Specific Properties <i>Ling Yang, Dalian Institute of Chemical Physics</i> 	<p><i>Chairs: Gary Valaskovic, New Objective and Shaolian Zhou, Novartis</i></p> <ul style="list-style-type: none"> ▶ Study of non-coding RNA's (miRNA and lncRNA)- Protein Interaction Based on Integrated Mass Spectrometry <i>Catherine CL Wong, National Center for Protein Science, Shanghai</i> ▶ Sensitivity and Throughput Using Nanospray Based LC-MS: Proteomics and Beyond <i>Gary Valaskovic, New Objective</i> ▶ Chemical Biology Technologies for Drug Target Identification <i>Qian Zhao, Novartis</i>

THURSDAY, APRIL 17

PROGRAM AGENDA

Thursday April 17

5:00 PM – 6:00 PM

Ballrooms I & II

CPSA SHANGHAI DISTINGUISHED LECTURE SERIES

Sponsored by AB SCIEX

Distinguished Lectures

- ▶ The Use of LC/MSMS for the Bioanalysis of Complex Antibody Drug Conjugates (ADC)

Suma Ramagiri

AB SCIEX Global Technical Marketing Manager

Quantitation and Metabolism

6:00 PM – 9:00 PM

EVENING SOCIAL *Offsite Hosted and Sponsored by AB SCIEX*

An Evening at ERA Shanghai: Intersection of Time

A must-see in Shanghai, ERA Shanghai a stunning acrobatic show combining traditional Chinese arts and modern technologies. The performers present Chinese acrobatics, martial arts and dance perfectly in harmony with music, sound, lighting, and other special effects, including a spectacular water screen.

The story of China's evolution from its ancient past to the future is told. Hence, the title 'Intersection of Time', as the viewpoint of the audience is set in the present between the past and the future.

For passes and event information, visit the AB SCIEX table.

THURSDAY, APRIL 17



DISTINGUISHED LECTURE SERIES

THURSDAY 5:00 PM

Distinguished Lecture Series *Ballrooms I & II*

The Use of LC/MSMS for the Bioanalysis of Complex Antibody Drug Conjugates (ADC)

Suma Ramagiri

AB SCIEX Global Technical Marketing Manager

Quantitation and Metabolism

Generously sponsored by



*Followed by CPSA Evening Social
Hosted by AB SCIEX*

More information is available at the AB SCIEX table

PROGRAM AGENDA

Friday April 18

7:30 AM

REGISTRATION OPEN

8:30 AM – 9:15 AM

PLENARY LECTURE

Ballrooms I & II

Exploring Diseases using Proteomics

John Yates

The Scripps Institute

9:00 AM – 5:00 PM

POSTER HALL OPEN

Yangtze Ballroom

Sponsored by Agilent Technologies

Posters will be available all day today

9:30 AM – 11:00 AM

JOINT ADME/BA SYMPOSIUM & ROUNDTABLE

Ballrooms I & II

Translational Biomarkers for Accelerating Drug Development: Bioanalytical and Emerging Applications

Chairs: Haojing Rong, Pfizer and Naidong Weng, Janssen Pharmaceuticals

▶ **Pk/Biomarker/Efficacy Relationship of Anti-GDF8 mAb for Efficacious Dose Projection in Humans**

Haojing Rong, Pfizer

▶ **Protein and SM Biomarker Quantification**

Naidong Weng, Janssen Pharmaceuticals

▶ **Small Molecule Biomarker Quantitation**

Xiaorong Liang, Genetech

11:00 AM - 2:00 PM

CPSA SHANGHAI EXPO - WHERE TECHNOLOGY AND SOLUTIONS MEET!

Lobby

Chairs: Kelly Dong, GlaxoSmithKline; Shaolin Zhou, Novartis

11:30 AM - 12:30 PM

POSTER SESSION / YOUNG SCIENTIST EXCELLENCE AWARD REVIEW

Yangtze Ballroom

Sponsored by Waters Corporation

Co-Chairs: Liangfu Chen, GlaxoSmithKline; Jenny Zheng, Janssen

PROGRAM AGENDA

Friday April 18

12:00 PM - 1:00 PM

LUNCH & LEARN WORKSHOPS

Ballroom I

Combining very high resolution accurate mass with customizable workflows:
A human metabolism case study

Sponsored by Thermo Scientific

Timothy Stratton, Thermo Scientific

Ballroom II

What's Your Spray DNA?™

Sponsored by New Objective

Gary Valaskovic, New Objective

1:30 PM - 3:00 PM

PARALLEL SYMPOSIA & ROUNDTABLES

<p>Pharmacokinetics in Chinese Populations: Ethnic Differences and Global Clinical Trial Strategies</p> <p><i>Ballroom I</i></p>	<p>New Technology</p> <p><i>Ballroom II</i></p>	<p>Applications of Protein and Peptide Biomarkers from Research to Development</p> <p><i>Rhine Ballroom</i></p>
<p><i>Chairs: Jenny Zheng, Janssen Pharmaceuticals and Jun Shi, Roche</i></p> <ul style="list-style-type: none"> ▶ Ethnic Sensitivity Assessment in Drug Development: Introduction of Roche-PUMCH Clinical Pharmacology Fellowship <i>Jun Shi, Roche</i> ▶ Dealing with Ethnic Differences in Clinical Development <i>Peiming Ma, GlaxoSmithKline</i> ▶ Population Pharmacokinetics of Mycophenoic Acid and Its Main Glucuronide Metabolite: Comparison Between Chinese and Caucasian Healthy Subjects Administrated with Mycophenolate Mofetil <i>Zheng Jiao, Fudan University</i> 	<p><i>Chairs: Shaolian Zhou, Novartis and Chad Briscoe, PRA International</i></p> <ul style="list-style-type: none"> ▶ Automation of Bioanalysis in PK Studies <i>Professor Yin Zheng, Nankai University</i> ▶ Opportunities and Challenges of Using HRMS in Regulated Bioanalysis <i>Mike Huang, Janssen Pharmaceuticals</i> ▶ Dried Blood Spots <i>Tee Zhang, Frontage Laboratories</i> 	<p><i>Chair: Catherine CL Wong, National Center for Protein Science</i></p> <ul style="list-style-type: none"> ▶ Quantification of Active and Inactive Biomarkers in Blood with Absolute Molecular Specificity <i>Nathan Yates, University of Pittsburgh</i> ▶ Discovery and Targeted Proteomics to Study Transplant Rejection <i>John Yates, The Scripps Research Institute</i> ▶ Technology Development of Proteomic Reactor and its Application in Biomarker Discovery <i>Hu Zhou, Shanghai Institute of Materia Medica</i>

FRIDAY, APRIL 18

PROGRAM AGENDA

Friday April 18

3:30 PM - 5:00 PM

SYMPOSIA & ROUNDTABLES

Working with CROs in China:
Opportunities, Challenges, and Lessons Learned

Ballroom I

Chairs: Rick Connell, Pfizer and Hongshi Yu, WuXi AppTec

- ▶ Introduction and Context to the Session
Rick Connell, Pfizer
- ▶ DMPK Outsourcing to China: A CRO's Perspective
Hongshi Yu, WuXi AppTec
- ▶ Sourcing for Success
Jonathan Connick, Merck
- ▶ Panel Discussion
Rick Connell, Pfizer; Hongshi Yu, WuXi AppTec; Jonathan Connick, Merck

MS and Bioanalysis:
Diagnostics and Hospitals

Ballroom II

Chairs: Patrick Bennett, PPD; Shuijun Li, Xuhui Hospital

- ▶ Application of LC-MS in Clinical Laboratory Testing
Sihe Wang, Cleveland Clinic
- ▶ Human Endogenous Steroids Analysis in Clinical Reference
Hua-Fen Liu, AB SCIEX
- ▶ 25-hydroxyvitamin D: Clinical Significance, Measurement, and Method Comparison
Shuijun Li, Xuhui Hospital

3:30 PM - 5:00 PM

INNOVATOR AWARD SESSION

Rhine Ballroom

Chairs: Kelly Dong, GlaxoSmithKline; Shaolian Zhou, Novartis

- | | |
|---|---|
| <ul style="list-style-type: none"> ▶ Outsourcing and Standardization of Global Studies
<i>Joseph Bower, Covance</i> ▶ Metabolite Analysis Using A Novel Relationship And Database Driven Software Platform Approach For Screening Metabolism
<i>Hui Wang, Waters</i> ▶ a LC/MS based-method combined with data analysis software was developed to evaluate the quality of Pu'er tea.
<i>Hui Wang, Waters</i> ▶ Prediction of Valsartan Pharmacokinetics in Different Pediatric Age Groups using Physiologically Based Pharmacokinetic (PBPK) Models
<i>Linda Lin, PharmGo</i> | <ul style="list-style-type: none"> ▶ Pharmacokinetics of Exendin-4-Fc fusion protein in Cynomolgus Monkey
<i>Hongzhen Li, Yan Xia, Joynn Laboratories</i> ▶ Quantification of 5 Steroid Hormones in Human Serum Using the ionKey MS system
<i>Hui Wang, Waters</i> ▶ Simultaneous Quantification of Human Insulin and Five Analogs in Human Plasma Using 2D UPLC MS System
<i>Hui Wang, Waters</i> |
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PROGRAM AGENDA

Friday April 18

5:00 PM – 7:30 PM

Ballrooms I & II

CPSA SHANGHAI CLOSING GALA

Dinner, Awards and Celebration

Sponsored by Agilent Technologies

Sponsor's Toast

Program Chair Recognition

Mike Lee, Milestone Development Services

CPSA Shanghai 2015 – Program Chair Announcement

Jeff Zhang, Novartis

Innovator Award Presentation

Kelly Dong, GlaxoSmithKline; Shaolian Zhou, Novartis

Young Scientist Excellence Award Presentation

Sponsored by Waters Corporation

Liangfu Chen, GlaxoSmithKline; Jenny Zheng, Janssen Pharmaceuticals

FRIDAY, APRIL 26



CPSA
2014

Program Chairs

Paul Corcoran
McKinley Scientific

Gary Valaskovic
New Objective

Plenary Speaker

Ann Weber
Merck

Keynote Speaker

Andy Hoofnagle
University of Washington

17th Annual Symposium on Clinical & Pharmaceutical Solutions through Analysis

Make plans now to attend CPSA 2014! This annual meeting began in 1998 and has evolved into the premier industry-led event dedicated to promoting awareness of issues and needs associated with research and development.

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

September 29 - October 2, 2014
Sheraton Bucks County Hotel
Langhorne, PA

Where Technology and Solutions Meet

PROGRAM AGENDA

Saturday April 19

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

- ▶ Interpretation of the Chinese Guideline of Non-Clinical Drug Metabolism and Pharmacokinetics Studies
Dafang Zhong, Shanghai Institute of Materia Medica
- ▶ Accelerating Drug Development with Quality Pharmacokinetics Data in China: Sanofi's Experience
George Liu, Sanofi
- ▶ Human Relevance:
The Implications from the Updated cFDA Nonclinical PK/DM Guideline
Yi Gu, Hutchinson China
- ▶ Hengrui's Focus on DMPK Studies in Novel Drug Development Process
Changyong Yang, Hengrui Pharmaceutical

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.

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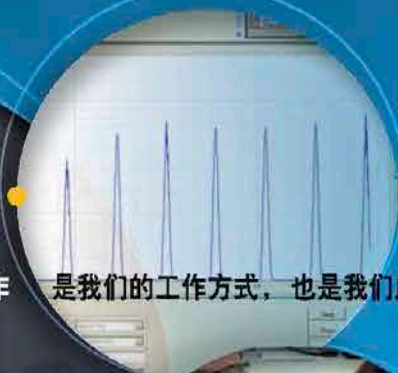
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携手发现

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