



8TH ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis

CPSA SHANGHAI 2017

Clinical and Pharmaceutical Success from
Discovery to Regulatory Approval:
Biomarkers, Modeling, and Analytical Technologies

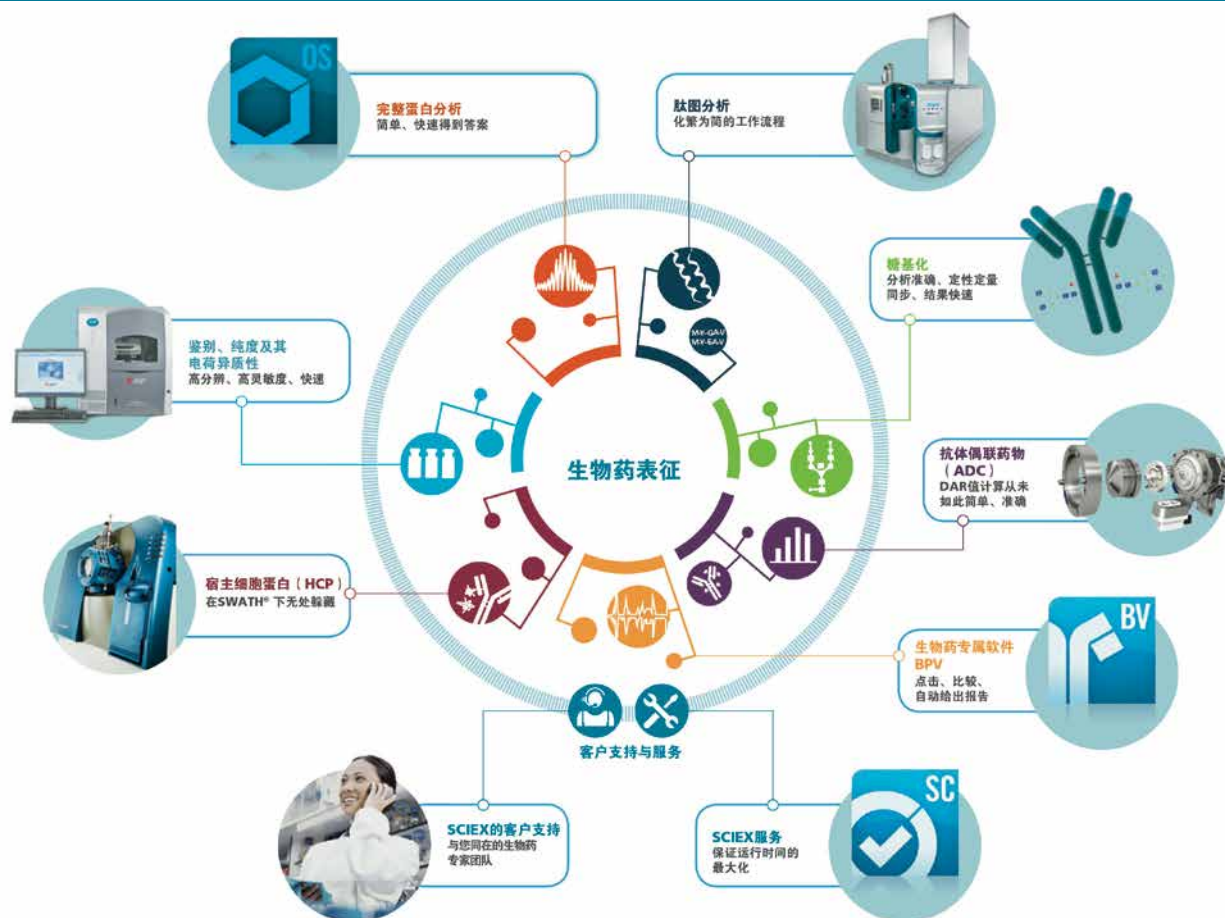
April 12 - 14, 2017
Renaissance Shanghai Pudong Hotel
Shanghai

MEETING PROGRAM

*Where Technology and Solutions Meet
Where East Meets West*

创新助力 化繁为简

SCIEX生物药物分析整体解决方案



- 高性能LC-MS/MS系统结合界面友好、智能的软件为生物药表征提供整体解决方案；
 - 实现从完整分子量、肽谱图、序列变异分析到宿主细胞蛋白 (HCP) 分析
 - SWATH 2.0数据非依赖采集技术，一次进样，可获得样品中高、低丰度在内的所有肽段谱图
- CESI 8000+将毛细管电泳CE的高效分离和超低流速的特性与电喷雾离子源ESI完美结合，显著提升灵敏度，且单次酶切，一次分析得到100%的序列覆盖度，翻译后修饰等信息；
- 毛细管电泳PA800+集定性定量分析、蛋白纯度和等电点亚型分布的自动化分析以及糖分析等多种功能于一体；
 - 结合最新推出的糖基化表征快速糖标记与分析试剂盒，可快速进行糖基定性和定量分析，比传统的HILIC方法快5倍
- SCIEX的生物药专家团队，是您在通向成功道路上值得信赖的合作伙伴。

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SCIEX



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WELCOME

Inspiration to Application

April 12, 2017

Dear Colleague:

On behalf of the organizing committee and our sponsors, we welcome you to the 8th Annual Shanghai Symposium on Clinical & Pharmaceutical Solutions through Analysis (CPSA Shanghai 2017). It is a pleasure to host this unique event once again 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 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 theme of this year's annual meeting "Clinical and Pharmaceutical Success from Discovery to Regulatory Approval: Biomarkers, Modeling, and Analytical Technologies" is reflected in the pre-conference events, symposia sessions and sponsored workshops. Our pre-conference Workshops and Executive Roundtable are once again sponsored by SCIEX. A traditional session on "Hot Topics in DMPK" will feature an inaugural session on "Guideline and Practice of Evaluation of Consistency of Quality and Efficacy of Generic Drugs" dedicated specifically to Chinese market and scientific interests.

Our Opening Reception is sponsored by WuXi AppTec and showcase another new event at CPSA Shanghai – Keynote Lecture Series – and feature Renuka Pillutla of Bristol-Myers Squibb who will deliver a lecture on "Getting More Drugs to Patients Faster: The Power of Technology Applications."

Plenary Lectures will be delivered by Cornelis Hop of Genentech on "Drug Discovery and Development: Looking for Needles in a Haystack" and Dafang Zhong of the Shanghai Institute of Materia Medica on "Non-clinical and Clinical ADME Studies of Several Innovative Drugs in China." CPSA traditions continue in Shanghai as the Symposia Sessions, Poster Sessions, CPSA EXPO, Innovator Award Session, and Young Scientist Session will help make our annual meeting a most unique event. We will 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 continues to foster our unique meeting tradition that encourages 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



Nathan A. Yates, Ph.D.
2017 Program Chair

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PROGRAM CHAIR

Nathan A. Yates
University of Pittsburgh USA

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Sylvia Zhao
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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



ACD/Labs



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moving your compound forward



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EXHIBITORS

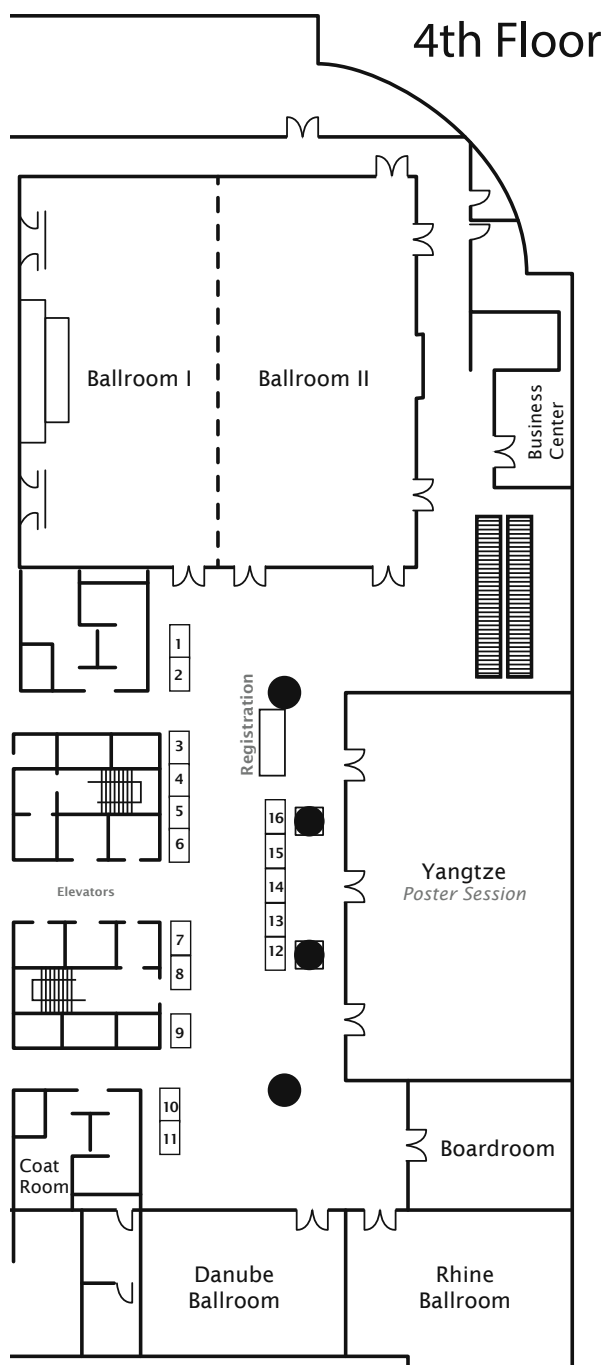
Thank You!

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 2018!



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 2017 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
13	ACD Labs
14	Agilent Technologies
8	Antpedia
16	BioCore
2	ChemPartner
15	Covance
7	CuraChem
10	ES Industries
12	Frontage Laboratories
9	Instrument.com.cn
5	McKinley Scientific
6	MOSIM
4	New Objective
11	Novilytic
3	SCIEX
1	Wuxi AppTec

FOR EXHIBITORS

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

WORKSHOPS

Wednesday APRIL 12

10:00 AM

Registration Open

Renaissance Shanghai Pudong 4th Floor Lobby

1:00 PM - 4:00 PM

PRE-CONFERENCE WORKSHOPS

Ballroom I

Guideline and Practice of Evaluation of Consistency of Quality and Efficacy of Generic Drugs

Sponsored by SCIEX

Workshop Leaders: Tianyi (Tee) Zhang, Frontage Laboratories; Jeff Zhang, Novartis

► **How to Conduct Clinical Bioequivalence Study and Related Bioanalysis**

如何开展生物等效性 (BE) 临床试验及生物样本分析

Tianyi (Tee) Zhang, Frontage Laboratories

张天谊, 方达医药 (中国)

► **Formulation Development Related to BE Study**

与生物等效性 (BE) 临床试验相关的制剂开发研究

Jun Fan, Overseas Pharmaceuticals

范军, 越洋医药

► **Regulatory Requirement and Inspection with BE Study**

生物等效性 (BE) 临床试验的监管要求和检查

Minji Wei, Institute of Clinical Pharmacology, Peking University First Hospital

魏敏吉, 北大药理研究所

Ballroom II

Hot Topics in DMPK

Sponsored by SCIEX

Workshop Leader: Naidong Weng, Janssen Research & Development

► **Fu Measurement of Highly Protein Bound Drugs**

Sophia Xu, Bristol-Myers Squibb

► **Bioanalytical Strategy for MIST Coverage: Human Unique Metabolites**

Shaolian Zhou, Roche

► **Microdosing/Microtracers in Clinical Development**

Shuguang Ma, Genentech

► **PBPK Application in Drug Development**

Jialin Mao and Yuan Chen, Genentech

► **Bioanalytical and Biotransformation of ADC Drugs**

Keyang Xu, Genentech

► **Fast and Sensitive Quantitation of Low Levels of Intracellular Substrates in Uptake Transporter Assays using Liquid Chromatography Mass Spectrometry**

Ming Yao, Bristol-Myers Squibb

PROGRAM AGENDA

Wednesday APRIL 12

4:00 PM - 6:00 PM

Ballroom I

EXECUTIVE ROUNDTABLE

The Paradigm Shifting for Global and China Bioanalysis Support

Chairs: Naidong Weng, Janssen Research & Development; Ajai Kumar Chaudhary, Merck

With the increasing globalization and merge of pharma companies, bioanalysis is rapidly evolving – more outsourcing in global setting, new platforms from both instrument technology and drug pipeline scaffolds, and more perhaps even more diversified regulations pertaining to bioanalysis. Traditional boundary between for example large and small molecules is being taken done to support newer drug pipelines such as ADC or PDC. The same can be said for bioanalysis and biotransformation, as newer instrument platform offered the possibilities of higher sensitivity, higher resolution, and information rich data acquisition. Even some of the traditional partnership such as toxicology and bioanalysis also sees new revolution – for example microsampling to drive 3R to reduce animal usages. On the other hand, delivery of high quality data with lower cost on time in an ever more complicating regulatory environment remains to be a major incentive for pharma to implement new strategy such as scientific validation and outsource bioanalytical work, particularly for GLP and clinical studies. A number of questions need to be answered to drive optimal bioanalytical support. Below are a few exemplary questions:

- How to do we bioanalytical scientists/managers adapt to the concept of scientific validation?
- Do we have the right bioanalytical infrastructures to support drug discovery/development?
- Do we fully explore the potential of new generation of instruments?
- How do we manage the regulatory environment globally and locally, for example, in China?
- Where do CROs, globally and locally, view their strategies to support global and local pharma in the future?

Discussion Panel:

Kelly Dong, GlaxoSmithKline

Xinping Fang, Wuxi AppTec

Jin Fan, Covance

Cornelis Hop, Genentech

James Munday, Covance

Renuka Pillutla, Bristol-Myers Squibb

Tianyi (Tee) Zhang, Frontage Laboratories

Shaolian Zhou, Roche

6:00 PM - 9:00 PM

Ballroom II

OPENING RECEPTION & HAPPY HOUR

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 2017!

Sponsored by Wuxi AppTec

Sponsor's Toast

Keynote Lecture

Getting More Drugs to Patients Faster - The Power of Technology Applications

Renuka Pillutla, Bristol-Myers Squibb

PROGRAM AGENDA

Thursday APRIL 13

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

Nathan A. Yates, University of Pittsburgh - Program Chair

9:00 AM - 9:45 AM

PLENARY LECTURE

Ballrooms I & II

Drug Discovery and Development: Looking for Needles in a Haystack

Cornelis Hop, Genentech

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

SYMPOSIUM SESSION

Ballrooms I & II

Innovative Approaches to Drug Development, Including SM, Biologics and Conjugates

Chairs: Shaolian Zhou, Roche; Sylvia Zhao, Novartis

▶ **Labelled Isotope Compounds in LC-MS Based Bioanalysis**

Naidong Weng, Janssen Research & Development

▶ **Clinical Pharmacology Impact on the Recommended Phase II dose Selection in Immuno-oncology**

Jian Xu, Novartis

▶ **Innovative LC-MS Applications in Characterization and Quantification of Biologics In Vivo: Challenges and Opportunities**

Keyang Xu, Genentech

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

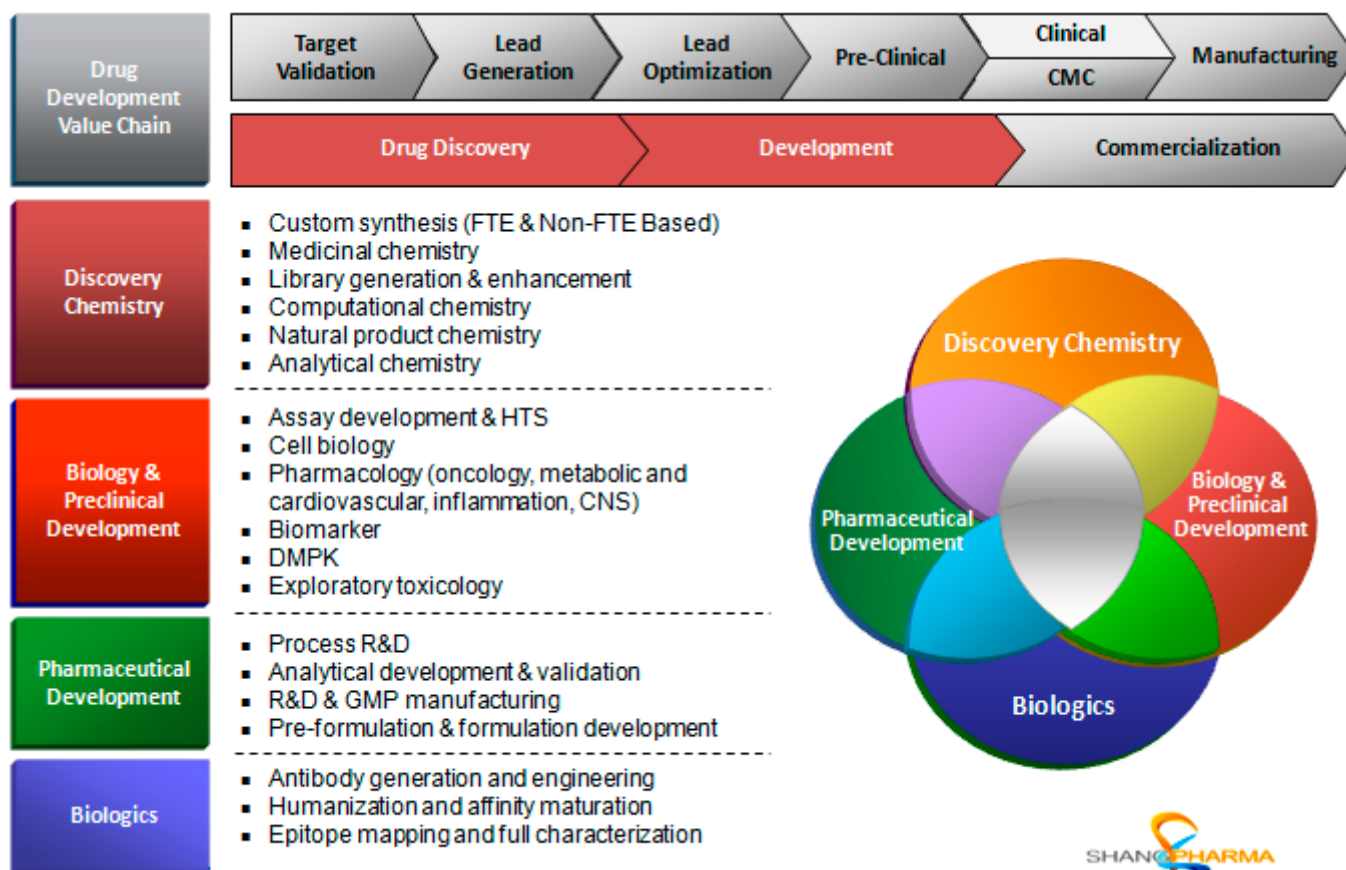
Yangtze Ballroom

Chairs: Min Liu, Merck; Jeff Zhang, Novartis; Naidong Weng, Janssen Research & Development; Young Scientist Excellence Committee Members: Luke Bi, Covance; Joseph Bower, Covance; Xiao Ding, Genentech; Kelly Dong, GlaxoSmithKline; Jonathan Josephs, Thermo Fisher Scientific; Fred Li, Hua Medicine; Qun Lu, Celgene; Hua Lv, Roche; Shuguang Ma, Genentech; Jasminder Sahi, Sanofi; Sihe Wang, Cleveland Clinic; Frances Wang, Janssen Research & Development; Yin Xiong, Wuxi AppTec; Sophia Xu, Bristol-Myers Squibb; Tianyi (Tee) Zhang, Frontage Laboratories; Sylvia Zhao, Novartis

Our Vision

Strives to become a global, science driven, technology based, quality contract research and manufacturing service provider for the biopharmaceutical industry

Well Established Drug Discovery and Development Platforms



INTEGRATED DMPK SERVICE

In vitro ADME

Discovery ADME

Metabolite ID

New Methods

Customer FIRST!

Customized Service

PK/PKPD

Study Directors

In Life
(small animals)

In Life
(large animals)

Pre-formulation

Bioanalysis

Discovery BA

Regulated BA

Biomarker

Peptide

Metabolomics

Toxicology

In vivo Assays

In vitro Assays



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- 体外试验
- 结构优化

临床前研究

- 代谢物鉴定/不同物种中的特点试验
- 探究性新药 (IND) / 新药 (NDA) 的体外吸收、分布、代谢和排泄试验

临床研究

- 安全性试验中的代谢物 (MIST) 试验
- 药物相互作用试验¹⁴C-吸收、分布、代谢和排泄试验

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60液相色谱-质谱联用仪/质谱仪

小分子

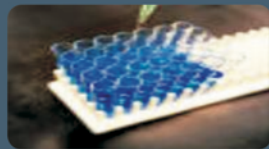
大部分工作是对专利产品的检测
200,000+个样品(年分析能力)

生物制品

80+个分析物
正在进行的定制的分析物和聚焦治疗领域

生物标记

小分子生物分析服务能力



方法开发、转移&验证



临床和非临床试验的样品分析



大量的已验证的生物分析方法



对有挑战的化合物的复杂分析拥有独特的技术能力

生物制品生物分析服务能力

分子类型

生物制品 单抗、抗体-药物偶联物、低聚核苷酸、肽、生物标记

分析方法

配体结合分析 ELISA&ECL

液相色谱-质谱联用仪 (LC-MS)/质谱仪 (MS)

技术

药动/毒代 - 药动分析

细胞相关分析 体外检测、毒性&生存力

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人才招聘

仪器及分析测试行业
专业人才招聘平台



PROGRAM AGENDA

Thursday APRIL 13

12:00 PM - 1:00 PM

LUNCH & LEARN WORKSHOPS

Ballroom I

WORKSHOP

Sponsored by McKinley Scientific

Ballroom II

WORKSHOP

Sponsored to be Announced

1:30 PM - 3:00 PM

PARALLEL SESSIONS TRACKS 1 - 4

<p>Track 1 Drug Metabolism Ballroom I</p>	<p>Track 2 Small Molecule Bioanalysis Ballroom II</p>
<p><i>Chairs: Shuguang Ma, Genentech; Jeff Zhang, Novartis</i></p> <ul style="list-style-type: none"> ▶ Integrated Workflow for Biotransformation Study of Therapeutic Proteins <i>Ji Ma, Amgen</i> ▶ Can We Select a Drug Candidate Which May Have Potential Auto-induction? <i>Frances Wang, Janssen Research & Development</i> ▶ Hydrolytic Metabolism of Cyanopyrrolidine DPP4 Inhibitors Mediated by Dipeptidyl Peptidases <i>Xiaoyuan Pang, Shanghai Institute of Materia Medica, Chinese Academy of Sciences</i> 	<p><i>Chair: Xiao Ding, Genentech; Jin Fan, Covance</i></p> <ul style="list-style-type: none"> ▶ Regulated Clinical Bioanalysis and Its Impact on the Clinical Study in China <i>Luke Bi, Covance</i> ▶ Development of a Multi-Matrix LC-MS/MS Method for Urea Quantitation and Its Application in Human Respiratory Disease Studies <i>Jonathan Wang, Genentech</i> ▶ Scientific and Regulatory Balance in Regulated Bioanalytical Studies Following FDA/EMA/CFDA BMV Guidance <i>Xinping Fang, WuXi AppTec</i> ▶ Incurred Sample Reanalysis - Investigation of Unexpected 5-Fluorouracil Results <i>Xiao Ding, Genentech</i>

THURSDAY, APRIL 13



2nd Annual Symposium on
Clinical & Pharmaceutical Solutions through Analysis

May 17-18, 2017 • Pittsburgh, PA USA

Program Chair
Nathan Yates
University of Pittsburgh

Plenary Speaker
Chris Johnson
Pittsburgh Pirates

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

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PROGRAM AGENDA

Thursday APRIL 13

1:30 PM - 3:00 PM

PARALLEL SESSIONS (CONTINUED)

<p>Track 3 Drug Developability <i>Rhine Ballroom</i></p> <p><i>Chairs: Qun Lu, Celgene; Sachin Lohan, Janssen Research & Development</i></p> <ul style="list-style-type: none"> ▶ Designing Drugs for Systemic vs Gut-restricted Exposure via Oral Route <i>Sachin Lohan, Janssen Research & Development</i> ▶ Rational Strategy for Solid Form Research in Discovery and Early Development <i>Yanfeng Zhang, CrystalPharmatech</i> ▶ Nanoformulation for Discovery, Preclinical and Clinical Studies <i>Sunny Panmai, WuXi AppTec</i> 	<p>Track 4 Biomarker Challenges <i>Danube Ballroom</i></p> <p><i>Chairs: Wenying Jian, Janssen Research & Development; Naidong Weng, Janssen Research & Development</i></p> <ul style="list-style-type: none"> ▶ Biomarker for Patient Selection <i>Yang Qiu, Janssen Research & Development</i> ▶ Clinical Application of LC-MS/MS Detection Method in Evaluation of Endogenous Vitamins, Amino Acids and Hormones <i>Li Li, iPhase Pharma Services</i> ▶ Complexities and Solutions for Biomarker Support of an Increasingly Complex Drug Development Portfolio <i>Daniel Sikkema, Frontage Laboratories</i>
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3:30 PM - 5:00 PM

PARALLEL SESSIONS TRACKS 5 - 8

<p>Track 5 Drug Discovery & Development <i>Ballroom I</i></p> <p><i>Chair: Min Liu, Merck</i></p> <ul style="list-style-type: none"> ▶ Forced Degradation Studies: Regulatory Expectations and Best Practices in Developing Stability-Indicating Methods and Elucidating Degradant Structures <i>Min Li, Huahai Pharmaceutical</i> ▶ Definitive Metabolite Identification Coupled With Automated Ligand Identification System (ALIS) Technology: A Novel Approach to Uncover Structure-Activity-Relationships and Guide Drug Design in a Factor IXa Inhibitor Program <i>Yong Liu, Merck & Co.</i> ▶ Strategy and Cases Shared for Resolving the Impact from Hemolysis of Plasma Samples During LC-MS/MS Bioanalysis <i>Biao Huang, Covance</i> 	<p>Track 6 Hot Topics of Bioanalysis I <i>Ballroom II</i></p> <p><i>Chairs: Sophia Xu, Bristol-Myers Squibb; Frances Wang, Janssen Research & Development</i></p> <ul style="list-style-type: none"> ▶ Key Considerations for the Regulated Immunogenicity Assessment in Support of Clinical Trials <i>Qikuan Huang, WuXi AppTec</i> ▶ Commonly Asked Bioanalytical Questions by FDA, EMA, Health Canada (TPD) and Japan PMDA <i>John Ling, Gilead Sciences, Inc.</i> ▶ Clinical BE Studies and Related Bioanalysis Requirements in China <i>Tianyi (Tee) Zhang, Frontage Laboratories</i>
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THURSDAY, APRIL 13

PROGRAM AGENDA

Thursday APRIL 13

3:30 PM - 5:00 PM

PARALLEL SESSIONS (CONTINUED)

<p>Track 7 In-vitro ADME <i>Rhine Ballroom</i></p>	<p>Track 8 Biosimilar Drug Development in China and Global Markets: From CMC to Filing <i>Danube Ballroom</i></p>
<p><i>Chairs: Hua Lv, Roche; Li Wang, Eli Lilly & Co.</i></p> <ul style="list-style-type: none"> ▶ Theoretical Approach based on a 3-Compartment Model for Estimating the Apparent Permeability Coefficient (Papp) in a Transcellular Transport Study <i>Kazuhisa Ozeki, Chugai Pharmaceutical Co., Ltd.</i> ▶ Quantitative Proteomics: A Promising Tool for the Prediction of Transporter-mediated Drug Disposition <i>Li Wang, Eli Lilly & Co.</i> ▶ Assessing the Reactivity of Acyl Glucuronides - A New Rapid in-vitro Assay for Drug Discovery <i>Giorgio Ottaviani, Roche Innovation Center Shanghai</i> ▶ Innovative DMPK Mechanistic Assays and Strategies to Support the Design of Liver Targeting Small Molecules <i>Hua Lv, Roche Innovation Center Shanghai</i> 	<p><i>Chairs: Xiao-Yan Cai, Wuxi AppTec; Yi Du, Huahai Pharmaceutical</i></p> <ul style="list-style-type: none"> ▶ Development of Insulin Analog Biosimilar: From China to U.S. <i>Heng Li, Gan & Lee</i> ▶ Quality Development for Biosimilars and Interchangeable Biologics <i>Yan Fang, Hengrui Medicine Co. Ltd</i> ▶ A Case Study of Immunogenicity Assessment in a Biosimilar Comparability Study: Impact of Target Interference and Solutions <i>Jing Shi, WuXi AppTec</i> ▶ Recent Industry (US) Recommendations for Immunogenicity Assay (ADA and NAb) Development and Validation to Support Comparability Studies for Biosimilar Drug Development <i>Xiao-Yan Cai, WuXi AppTec</i>

6:00 PM

CPSA SOCIAL

Yangtze Ballroom

Cocktails & Karaoke at CPSA

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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!

THURSDAY, APRIL 13

PROGRAM AGENDA

Friday APRIL 14

7:30 AM

Registration Open
Renaissance Shanghai Pudong 4th Floor Lobby

8:30 AM – 9:15 AM

PLENARY LECTURE

Ballrooms I & II

Non-clinical and Clinical ADME Studies of Several Innovative Drugs in China
Dafang Zhong, Shanghai Institute of Materia Medica

9:00 AM – 5:00 PM

Poster Hall Open

Yangtze Ballroom

Posters will be available all day today

9:30 AM – 11:00 AM

SYMPOSIUM SESSION

Ballrooms I & II

Combined DMPK/Bioanalysis
Chairs: Cornelis Hop, Genentech; Kelly Dong, GlaxoSmithKline

- ▶ Prediction of Human Pharmacokinetics Parameters Using Chimeric Mice with Humanized Liver
Maki Miyamoto, Takeda, Japan
- ▶ From Oral to Inhaled Drugs, Strategies for Successful Clinical PK Predictions
Ken Grime, AstraZeneca, Sweden
- ▶ In Vitro PK Study in A Long-Term Liver Model to Assess DDI Potentials and Major Clearance Pathways of a Drug Candidate in Healthy and Disease State
Nicole Kratochwil, Roche, Switzerland

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: Min Liu, Merck; Jeff Zhang, Novartis; Naidong Weng, Janssen Research & Development; Young Scientist Excellence Committee Members: Luke Bi, Covance; Joseph Bower, Covance; Xiao Ding, Genentech; Kelly Dong, GlaxoSmithKline; Jonathan Josephs, Thermo Fisher Scientific; Fred Li, Hua Medicine; Qun Lu, Celgene; Hua Lv, Roche; Shuguang Ma, Genentech; Jasminder Sahi, Sanofi; Sihe Wang, Cleveland Clinic; Frances Wang, Janssen Research & Development; Yin Xiong, Wuxi AppTec; Sophia Xu, Bristol-Myers Squibb; Tianyi (Tee) Zhang, Frontage Laboratories; Sylvia Zhao, Novartis

12:00 PM - 1:00 PM

LUNCH & LEARN WORKSHOPS

Ballroom I

WORKSHOP

Sponsored by BioCore

Preclinical and Clinical Development of Antibody-Drug Conjugates:
What Do We Need to Consider from Regulatory Perspectives?
Stephen Dueker, HeeJoo Le, and Sookie La, BioCore, Seoul, Korea

PROGRAM AGENDA

Friday APRIL 14

2:00 PM - 1:00 PM

LUNCH & LEARN WORKSHOPS (CONTINUED)

Ballroom II

WORKSHOP

Sponsored by New Objective

1:30 PM - 3:00 PM

PARALLEL SESSIONS TRACKS 9 - 11

<p>Track 9 Drug/Drug Interaction Prediction: Translation from In Vitro to In Vivo using the PBPK Approach</p> <p><i>Ballroom I</i></p>	<p>Track 10 Biomolecule and Oligonucleotides Bioanalysis</p> <p><i>Ballroom II</i></p>	<p>Track 11 Biomarkers: From Discovery to Patient Care</p> <p><i>Danube</i></p>
<p><i>Chair: Jialin Mao, Genentech</i></p> <ul style="list-style-type: none"> ▶ A Case Example of PBPK Application in a Discovery Project: How to Translate the Preclinical in vitro and in vivo Data to Assess Human CYP3A Induction Risk? <i>Jialin Mao, Genentech</i> ▶ Prediction of the Pharmacokinetic Interaction between Wuzhi Capsule (TCM) and Tacrolimus using PBPK Modeling <i>Xiaoqiang Xiang, Fudan University</i> ▶ Assessment of OATP Transporter Mediated DDI between GDC-0810 and Pravastatin using PBPK Modeling <i>Yuan Chen, Genentech</i> 	<p><i>Chairs: Qin Ji, Bristol-Myers Squibb; Naidong Weng, Janssen Research & Development</i></p> <ul style="list-style-type: none"> ▶ LC-HRMS Based Bioanalysis of Intact Proteins <i>Wenyong Jian, Janssen Research & Development</i> ▶ The Total Solution for DNA Damage Response Pathway Protein Biomarker Analysis <i>Hua-fen Liu, Sciex</i> ▶ LC/MS/MS for Large Molecule Bioanalysis <i>Song Zhao, Frontage Laboratories</i> 	<p><i>Chair: Sihe Wang, Cleveland Clinic</i></p> <ul style="list-style-type: none"> ▶ Targeted Biomarker Quantitation by LC-MS <i>Naidong Weng, Janssen Research & Development</i> ▶ FDA: A Brief Description of a Biomarker's Journey from Submission to Approval <i>Michael Leuther, Roche</i> ▶ Validation of Mass Spectrometry Assays for Clinical Use <i>Shuijun Li, Xuhui Central Hospital</i>

FRIDAY, APRIL 14



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PROGRAM AGENDA

Friday APRIL 14

3:30 PM - 5:00 PM

PARALLEL SESSIONS TRACKS 12 - 15

<p>Track 12 Technologies and Applications for Quantitation <i>Ballroom I</i></p> <p><i>Chairs: Erik Hansen, New Objective; Sihe Wang, Cleveland Clinic</i></p> <ul style="list-style-type: none"> ▶ Lessons and Pitfalls During PK/IMG/NAb Assay Transfer <i>Linlin Luo, Bristol-Myers Squibb</i> ▶ Quantification of Drugs and Metabolites to Support Pain Management <i>Sihe Wang, Cleveland Clinic</i> ▶ Challenges in Cross Validation and Transfer of Biomarker Assays: Evaluating Use of Data, Compliance, Technology, Geography and Laboratory Focus <i>Pat Bennett, PPD</i> 	<p>Track 13 Hot Topics of Bioanalysis II <i>Ballroom II</i></p> <p><i>Chairs: Tianyi (Tee) Zhang, Frontage Laboratories and John Ling, Gilead Sciences, Inc.</i></p> <ul style="list-style-type: none"> ▶ Challenges in Developing and Validating a Biomarker/Endogenous LBA following GLP Guidelines <i>Jing Tu, PPD</i> ▶ Bioanalytical Challenge of Measuring Highly Protein Bound Drugs <i>Sophia Xu, Bristol-Myers Squibb</i> ▶ Conducting Bioequivalence Studies in China: Challenges and Solutions <i>Min Meng, Consultant</i>
<p>Track 14 Innovator Award Session <i>Rhine Ballroom</i></p> <p><i>Innovator Award Committee Chairs: Kelly Dong, GlaxoSmithKline; Shaolian Zhou, Roche</i></p>	<p>Track 15 Scientific Validation and Related Topics <i>Danube Ballroom</i></p> <p><i>Chairs: Xinping Fang, WuXi AppTec and James Munday, Covance</i></p> <ul style="list-style-type: none"> ▶ Scientific Validation Approaches in Supporting Global and Domestic (China) Pre-IND to IND Projects <i>Yi Tao, WuXi AppTec</i> ▶ Scientific Validation Approaches in Early Biologic Drug Development <i>James Munday, Covance</i> ▶ Balance of Scientific Focus to Compliance from Early to Late Stage of Drug Development Projects: Roundtable Discussion <i>Naidong Weng, Janssen Research & Development</i>

FRIDAY, APRIL 14

PROGRAM AGENDA

Friday APRIL 14

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 2018 – Program Chair Announcement

Nathan A. Yates, University of Pittsburgh

Innovator Award Presentation

Innovator Award Committee Chairs: Kelly Dong, GlaxoSmithKline; Shaolian Zhou, Roche

Young Scientist Excellence Award Presentation

Young Scientist Excellence Committee Chairs: Min Liu, Merck and Jeff Zhang, Novartis

FRIDAY, APRIL 14

20th Annual Symposium Clinical & Pharmaceutical Solutions through Analysis



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Kyriakie Sarafoglou
University of Minnesota

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