



9TH ANNUAL SYMPOSIUM

Clinical & Pharmaceutical Solutions through Analysis

CPSA

SHANGHAI

2018

New Horizons in Drug Discovery and Development:
Bioanalysis, Biomarkers and ADME

April 18 - 20, 2018
Renaissance Shanghai Pudong Hotel
Shanghai

MEETING PROGRAM

*Where Technology and Solutions Meet
Where East Meets West*

OptiFlow定量解决方案

微流的灵敏度，分析流的易用性

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WELCOME

Inspiration to Application

April 18, 2018

Dear Colleague:

On behalf of the organizing committee and our sponsors, we welcome you to the 9th Annual Shanghai Symposium on Clinical & Pharmaceutical Solutions through Analysis (CPSA Shanghai 2018). 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 "New Horizons in Drug Discovery and Development: Bioanalysis, Biomarkers and ADME" 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. An annual pre-conference workshop held in Chinese on "Supporting Clinical Trials in China" will be lead by Jonathan Wang of Genentech. The Keynote Lecture Series, a new event at least year's meeting, features Zaiqi Wang of Roche, who will discuss "Future Prospect of Drug Innovation in China: Challenges and Opportunities."

Plenary Lectures will be delivered by Philip Timmerman of the EBF, and formerly of Janssen R&D, on "Regulated Bioanalysis: A Perspective on the Future Benefits and Challenges of Globalisation" and Lei Zhang of Silver Springs, MD, on "Transporters in Drug Development: Current Status and Contemporary Issues." CPSA traditions continue in Shanghai as the Symposia Sessions, Poster Sessions, CPSA EXPO, 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



Cornelis Hop, Ph.D.
2018 Program Chair

ORGANIZING COMMITTEE

PROGRAM CHAIR

Cornelis Hop
Genentech USA

ORGANIZING COMMITTEE

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Abbvie
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Philip Timmerman
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Belgium

Gary Valaskovic
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Jenny Zheng
Janssen Research & Development
China

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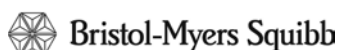
SPONSORS

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



Meeting Management

Media Sponsors

MICE PARTNERS



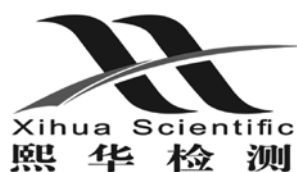
EXHIBITORS

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!

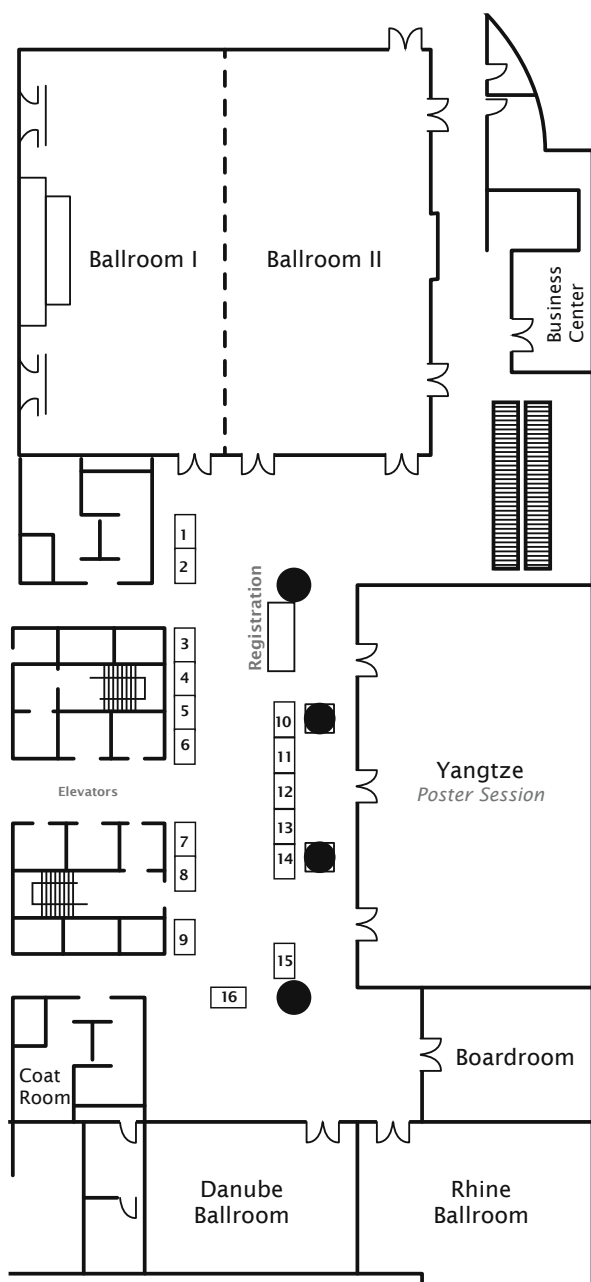


NEW OBJECTIVE



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 2018 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
2	Antpedia
6	ChemPartner
11	Covance
7	Frontage Laboratories
10	Instrument.com.cn
5	McKinley Scientific
4	New Objective
8	Phenomenex / Agela
3	SCIEX
12	Sciway Medical
13	Sinotherapeutics
1	Wuxi AppTec
14	Xihua Scientific

FOR EXHIBITORS

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

WORKSHOPS

Wednesday APRIL 18

10:00 AM

Registration Open

Renaissance Shanghai Pudong 4th Floor Lobby

1:00 PM - 3:30 PM

PRE-CONFERENCE WORKSHOPS

Ballroom I

Introduction to Drug Discovery

Workshop Leader: Cornelis Hop, Genentech

- ▶ **How to Succeed in Drug Discovery**
Cornelis Hop, Genentech
- ▶ **Bioanalysis & Metabolism**
Jeff Zhang, Novartis
- ▶ **Current Challenges in Clearance Assessments**
Zhengyin Yan, Genentech

Ballroom II

Supporting Clinical Trials in China

怎样在中国支持临床试验

Workshop Leader: Jonathan Wang, Genentech

- ▶ **Clinical DMPK Studies of Innovative Drugs in China**
中国新药 临床试验中的代谢和药动力学研究
Dafang Zhong, Shanghai Institute of Materia Medica
- ▶ **The Key Points and Common Issues for Clinical Sample Bioanalysis**
临床试验生物样品检测的主要关注点与常见问题
Hongliang Jiang, Huazhong University of Science and Technology
- ▶ **How Could Clinical Centers Get Better Experimental Results**
为获得好的分析测试结果，临床中心应该做查
Qing Wen, Jinan Central Hospital

PROGRAM

Wednesday April 18

4:00 PM - 4:45 PM

Ballroom II

KEYNOTE LECTURE

Future Prospect of Drug Innovation in China: Challenges and Opportunities
Zaiqi Wang, Roche

5:00 PM - 6:00 PM

Ballroom I

EXECUTIVE ROUNDTABLE

Outsourcing

Chair: Mira Hinman, Abbvie

► **Benchmarking Survey of Outsourcing Practices in the Pharmaceutical Industry**

Mira Hinman, Abbvie

Discussion Panel:

Ajai Chaudhary, Merck

Helen Yu, Novartis

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 2018!

Sponsored by New Objective

Sponsor's Toast

Given by Liping Bian, Antpedia

WEDNESDAY, APRIL 18



21st Annual Symposium on Clinical & Pharmaceutical Solutions through Analysis
**United to Beat Disease: Partners in Healthcare,
Partners in Science, Partners in Technology and Innovation**

October 15-18, 2018 • Philadelphia, PA USA

Program Chair

Alla Kloss
Sanofi

Plenary Speaker

Florian Eichler
Harvard Medical School

CPSA USA FEATURES

Short Courses • Symposia • Innovators Session • Roundtables Poster Session • Vendor Session • Exhibition • Workshops • Colloquium Series • Distinguished Analytical Scientist

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Where Technology and Solutions Meet

PROGRAM AGENDA

Thursday April 19

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

Cornelis Hop, Genentech - Program Chair

9:00 AM - 9:45 AM

PLENARY LECTURE

Ballrooms I & II

Regulated Bioanalysis:

A Perspective on the Future Benefits and Challenges of Globalisation

Philip Timmerman

EBF / Janssen Research & Development (ret)

9:00 AM – 5:00 PM

Poster Hall Open

Yangtze Ballroom

Posters will be available all day Thursday and Friday

10:00 AM – 11:45 AM

SYMPOSIUM SESSION

Ballrooms I & II

MIST and Drug Metabolism

Chairs: Susanna Tse, Pfizer; Jens Sydor, Abbvie

- ▶ **M.I.S.T.: Overall Strategy for Identification of Human Metabolite(s) and Estimation of Human and Toxicological Exposures**

Susanna Tse, Pfizer

- ▶ **How to Handle MIST Issues:**

The Use of the Mixed Matrix Method Illustrated with Clinical Examples

Cornelis Hop, Genentech

- ▶ **Case Studies of Disproportionate Human Metabolites – Ombitasvir and Venetoclax**

Jens Sydor, Abbvie

- ▶ **MIST Case Studies**

Hua Lv, Roche Shanghai

11:00 AM - 2:00 PM

CPSA SHANGHAI EXPO - WHERE TECHNOLOGY AND SOLUTIONS MEET!

4th Floor Lobby

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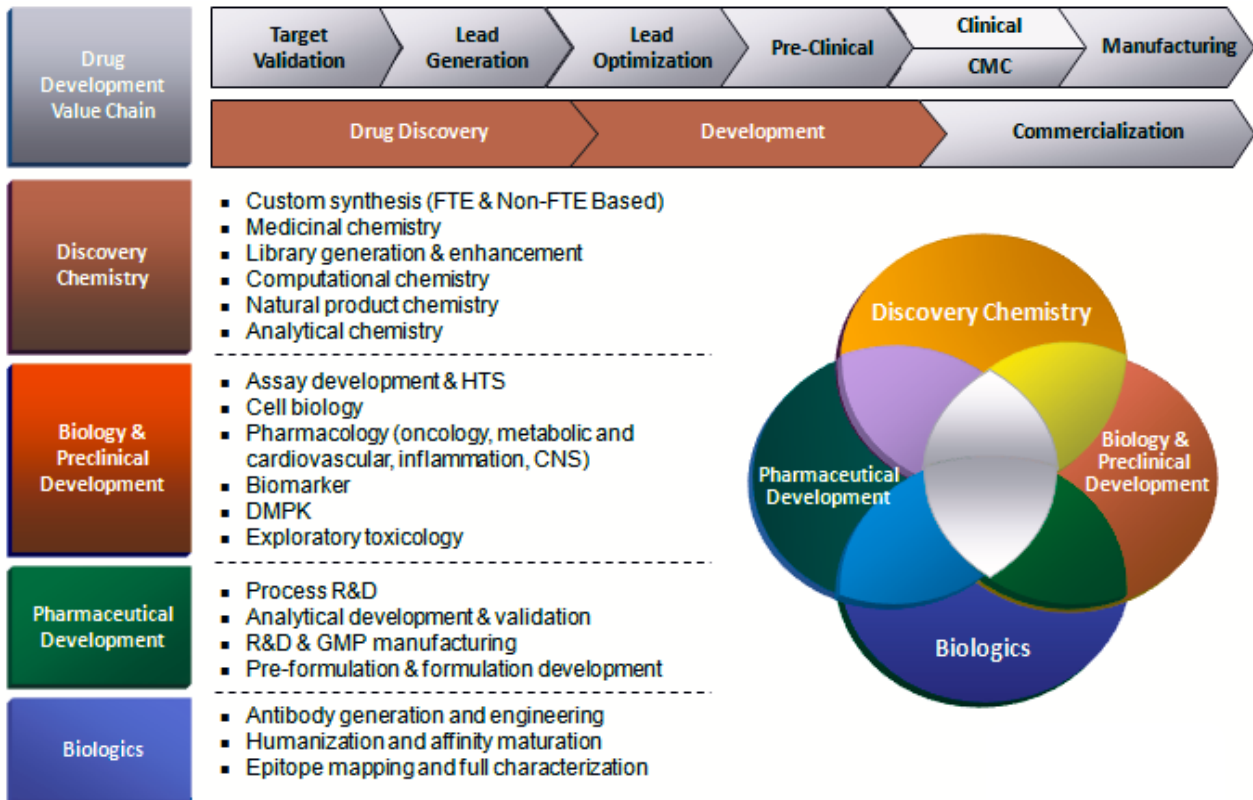
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Our Vision

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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PROGRAM AGENDA

Thursday April 19

11:30 AM - 1:30 PM

POSTER SESSION / YOUNG SCIENTIST EXCELLENCE REVIEW

Yangtze Ballroom

Review posters and speak with the next generation of up-and-coming scientists as they present their work and answer questions.

12:00 PM - 1:00 PM

LUNCH & LEARN WORKSHOPS

Ballroom I

WORKSHOP

Sponsored by SCIEX

Combining Selectivity and Sensitivity for Targeted Peptide Quantitation
Zhimin Long, SCIEX

1:30 PM - 3:00 PM

PARALLEL SESSIONS TRACKS 1 - 4

Track 1	Track 2
In Vitro ADME Challenges and Advances	<i>Small Molecule Bioanalysis</i>
<i>Ballroom I</i>	<i>Ballroom II</i>
<i>Chairs: Mandy Xu, Pharmaron; Zhengyin Yan, Genentech</i>	<i>Chairs: Luke Bi, Covance; Jonathan Wang, Genentech</i>
<ul style="list-style-type: none"> ▶ Improving Confidence in PPB Determinations for Highly Bound Drugs <i>Zhengyin Yan, Genentech</i> ▶ Novel Hepatic Spheroid Systems for Drug Discovery and Development <i>Volker Lauschke, Karolinska Institutet</i> ▶ Preclinical Evaluation of BBB Penetration of EGFR TKIs Using in vitro and in vivo Tools <i>Kan Chen, AstraZeneca Asia</i> ▶ In vitro Human-Based Experimental Systems for the Evaluation of Human Drug Properties <i>Albert Li, In Vitro ADMET Laboratories</i> 	<ul style="list-style-type: none"> ▶ The Determination of Antiretroviral Triphosphate Metabolite in Human Peripheral Blood Mononuclear Cells <i>Deqing Xiao, Gilead</i> ▶ Bioanalytical Challenges in the Development of Combination Therapies <i>Jonathan Wang, Genentech</i> ▶ LC-MS/MS Analysis of Drug in Hemolyzed Samples for Supporting BE Application: A Case Study <i>Minji Wei, Institute of Clinical Pharmacology, Peking University</i>

(PARALLEL SESSIONS CONTINUE)

THURSDAY, APRIL 19

PROGRAM AGENDA

Thursday April 19

1:30 PM - 3:00 PM

PARALLEL SESSIONS (CONTINUED)

<p>Track 3 Omics and Biomarker Challenges</p> <p><i>Rhine Ballroom</i></p> <p><i>Chairs: Yu Tian, Abbvie; Kelly Dong, UP Pharma</i></p> <ul style="list-style-type: none"> ▶ A Simple and High-Coverage Quantitative Metabolomics Platform Based on Chemical Isotope Labeling LC-MS <i>Liang Li, University of Alberta</i> ▶ Highly Sensitive Targeted Quantification of Proteins, Isoforms, and Modifications in Biofluids or Specific Cellular Pathways <i>Weijun Qian, Pacific Northwest National Laboratory</i> ▶ Critical Factors in Exploratory Biomarker Outsourcing in Clinical Studies <i>Helen Yu, Novartis</i> 	<p>Track 4 <i>Pharmaceutical Development: From Discovery to First-in-Human</i></p> <p><i>Danube Ballroom</i></p> <p><i>Chair: Qun Lu, Celgene</i></p> <ul style="list-style-type: none"> ▶ FIH Clinical Supply in China: Challenges and Changes <i>Larry Fang, Sinotherapeutics</i> ▶ Development, Characterization and Physical Stability of Amorphous Pharmaceutical Solids <i>Cai Ting, Chinese Pharmaceutical University</i> ▶ Roundtable Discussion
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3:30 PM - 5:00 PM

PARALLEL SESSIONS TRACKS 5 - 8

<p>Track 5 Challenges in Drug Discovery and Development</p> <p><i>Ballroom I</i></p> <p><i>Chairs: Lilly Xu, ChemPartner; Hua Lv, Roche</i></p> <ul style="list-style-type: none"> ▶ Implications of the New FDA Guidance for ADME Profiling <i>Stephen Fowler, Roche</i> ▶ The Application of in vitro Assays for in vivo DDI Prediction <i>Lilly Xu, ChemPartner</i> ▶ Safety Assessments of Preclinical Candidates – Some Considerations from DMPK Perspectives <i>Hong Wan, Shanghai Hengrui</i> 	<p>Track 6 <i>Issues in Regulated Bioanalysis</i></p> <p><i>Ballroom II</i></p> <p><i>Chairs: Naidong Weng, Janssen Research & Development; Tianyi Zhang, Frontage</i></p> <ul style="list-style-type: none"> ▶ Challenges of Immunogenicity Testing for Supporting Clinical Trials of Biotherapeutics <i>Weiping Shao, Regeneron</i> ▶ ADC PK Profiling Strategies on LC-MS Platforms: Top-Down, Bottom-Up, and Multiplexing <i>Song Zhao, Frontage</i> ▶ Advancement of High-Throughput Bioanalysis to Support Research and Development of Oligonucleotide Therapeutics and Biomarkers <i>Laixin Wang, Denali Medpharma</i>
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(PARALLEL SESSIONS CONTINUE)

PROGRAM AGENDA

Thursday April 19

3:30 PM - 5:00 PM

PARALLEL SESSIONS (CONTINUED)

<p>Track 7 MS Imaging <i>Rhine Ballroom</i></p> <p><i>Chair: Cornelis Hop, Genentech</i></p> <ul style="list-style-type: none"> ▶ MALDI-TOFMS Imaging for Environmental Toxicology <i>Chao Zhao, Hong Kong Baptist University</i> ▶ Imaging Mass Spectrometry: A Powerful Tool Enabling In Situ ADME Assessments <i>Cristine Quiason-Huynh, Genentech</i> ▶ Potential Usefulness of MS Imaging Technology with High Spatial Resolution in Pharmaceuticals <i>Miho Ayabe, Chugai</i> 	<p>Track 8 Non-Cytochrome P450 Metabolism <i>Danube Ballroom</i></p> <p><i>Chairs: Jeff Zhang, Novartis; Kelly Dong, UP Pharma</i></p> <ul style="list-style-type: none"> ▶ Aldehyde Oxidase and its Involvement in the Metabolism of a cMet Inhibitor <i>Jeff Zhang, Novartis</i> ▶ An Investigation into the Prediction of in vivo Clearance for a Range of Flavin-Containing Monooxygenase Substrates <i>Yu Wang, Pharmaron</i> ▶ Induction of Aldehyde Oxidase by Nimesulide and its Regulation Mechanism <i>Lei Zhong, Shanghai Institute of Materia Medica</i>
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6:00 PM

Yangtze Ballroom

CPSA SOCIAL

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!

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

See Martin at McKinley Scientific booth to request your song!



5th Annual Symposium on Clinical & Pharmaceutical Solutions through Analysis
Biopharmaceuticals and Biotechnology for Health:
B R A S I L New Trends, Opportunities, Diagnostics and Beyond

August 13-15, 2018 • São Paulo, Brazil

Program Co-Chair
Thiago Guia
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Symposia • Roundtables • Regulatory Compliance • Analysis Strategies
Technology Integration • Industrial Workflows • Expo • Social Events

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Where Technology and Solutions Meet. Where Together We Progress.

THURSDAY, APRIL 19

PROGRAM AGENDA

Friday April 20

7:30 AM

Registration Open
Renaissance Shanghai Pudong 4th Floor Lobby

8:30 AM – 9:15 AM

Ballrooms I & II

PLENARY LECTURE

Transporters in Drug Development: Current Status and Contemporary Issues
Lei Zhang, Silver Springs, MD

9:00 AM – 5:00 PM

Yangtze Ballroom

Poster Hall Open

Posters will be available all day today

9:30 AM – 11:30 AM

Ballrooms I & II

SYMPOSIUM SESSION

Drug Transporters

Chairs: Jasminder Sahi, Sanofi; Ikumi Tamai, Kanazawa University

- ▶ Drug-Drug and Drug-Food Interaction on Transporters
Ikumi Tamai, Kanazawa University
- ▶ Interactions Between Saponins and Hepatic Transporters
Chuan Li, Shanghai Institute of Materia Medica
- ▶ Prediction of Brain-to-Blood Unbound Concentration Ratios in CNS Drug Discovery
Employing in silico and in vitro Model Systems
Houfu Liu, GlaxoSmithKline
- ▶ Contribution of Xenobiotic Transporters to Drug Disposition:
Regulatory Case Studies
Jasminder Sahi, Sanofi

11:00 AM - 2:00 PM

4th Floor Lobby

CPSA SHANGHAI EXPO - WHERE TECHNOLOGY AND SOLUTIONS MEET!

Meet and mingle with vendors offering the latest in technology and services

12:00 PM - 1:00 PM

Ballroom I

LUNCH & LEARN WORKSHOPS

WORKSHOP

Sponsored by New Objective

PROGRAM AGENDA

Friday April 20

1:30 PM - 3:00 PM

PARALLEL SESSIONS TRACKS 1 - 4

<p>Track 1 PBPK Modeling <i>Ballroom I</i></p>	<p>Track 2 Large Molecule Bioanalysis <i>Ballroom II</i></p>
<p><i>Chairs: Tom Wilde, Janssen Research & Development; Avi Ghosh, Janssen Research & Development</i></p> <ul style="list-style-type: none"> ▶ The Important role of Virtual Chinese Population for PK/PD Prediction: Perspective View from an Academic Institution <i>Pei Hu, Peking Union Medical College Hospital</i> ▶ Beyond Small Intestine Absorption: Physiological Modeling and Interspecies Translation of Gut Tissue PK <i>Tom Wilde, Janssen Research & Development</i> ▶ Predicting Drug Concentrations in Renal Tubules Combining in vitro and in silico Methods <i>Kas Subramanian, Syngene</i> 	<p><i>Chairs: Wenyong Jian, Janssen Research & Development; Xiao-Yan Cai, Consultant</i></p> <ul style="list-style-type: none"> ▶ Total and Free Quantification of Therapeutic Antibodies by Liquid Chromatography-Tandem Mass Spectrometry <i>Ichio Onami, Chugai</i> ▶ Strength and Challenges of LBA on PK, ADA, NAb and Biomarker Bioanalysis: Case Studies <i>Xiao-Yan Cai, Consultant</i> ▶ Strategies for Drug Transporter Quantitation by LC-MS <i>Alan Deng, Genentech</i>
<p>Track 3 Radiolabeled Tools for Drug Development <i>Rhine Ballroom</i></p>	<p>Track 4 Biomarker Quantitation <i>Danube Ballroom</i></p>
<p><i>Chairs: Stephen Dueker, BioCore; Alicia Du, Calibra Diagnostics</i></p> <ul style="list-style-type: none"> ▶ Current Status and Requirement of Radio-ADME Studies in China <i>Zhe-ming Gu, Value Pharmaceutical Services</i> ▶ Human PK of 14C-Tagged Biologics <i>Wouter Vaes, TNO</i> ▶ A Benchtop CRDS Laser System for 14C Quantitation <i>Stephen Dueker, BioCore</i> 	<p><i>Chairs: Min Liu, Merck; Min Li, HuaHai Pharmaceutical</i></p> <ul style="list-style-type: none"> ▶ Translating MS Protein Assays and the Challenging Road Ahead: Post-Translationally Modified Proteins as Biomarker Targets for Clinical MS Protein Tests <i>Dobrin Nedelkov, Isoformix</i> ▶ The Importance of Bioanalytical Testing in Bioequivalence Evaluation of Generic Drugs <i>Xiaohang Shen, Xihua Scientific</i> ▶ Considerations for Fit for Purpose Biomarker Method Validation Activities <i>James Munday, Covance</i>

FRIDAY, APRIL 20

PROGRAM AGENDA

Friday April 20

3:30 PM - 5:00 PM

PARALLEL SESSIONS TRACKS 5 - 7

Track 5 PK/PD Modeling <i>Ballroom I</i>	Track 6 What's New? Recent Developments for ADCs <i>Ballroom II</i>	Track 7 Distinguished Scientist Lectures <i>Sponsored by Antpedia</i> <i>Rhine Ballroom</i>
<p><i>Chairs: Tom Wilde, Janssen Research & Development; Avi Ghosh, Janssen Research & Development</i></p> <ul style="list-style-type: none"> ▶ Modeling the Impact of Renal Tubular Drug Dynamics on Plasma Drug Concentration <i>Kas Subramanian, Syngene</i> ▶ Applications of Pharmacokinetic/ Pharmacodynamic Modeling in Biologics Development <i>Songmao (Ben) Zheng, Janssen Research & Development</i> ▶ PK/PD Analyses of Vfend (Voriconazole) Used for Pediatric License Renewal in China <i>Ping Lu, Pfizer</i> 	<p><i>Chairs: Keyang Xu, Genentech; Young Shin, Chungnam National University</i></p> <ul style="list-style-type: none"> ▶ Bioanalytical Assays for ADCs: New Developments and Case Studies <i>Mark Qian, Takeda Pharmaceuticals</i> ▶ Creating Next Generation ADCs with Industry Leading DAR Precision and Plasma Stability <i>Jeiwook Chae, LegoChemBio</i> ▶ Key Scientific and Regulatory Aspects of Nonclinical Development of an ADC Biosimilar <i>Yue Liu, 3S Bio</i> 	<p><i>Chairs: Liping Bian, Antpedia; Emily Ehrenfeld, New Objective</i></p> <ul style="list-style-type: none"> ▶ Early Identification of Potential DMPK Risks to Ensure Future Clinical Success <i>Kelly Dong, UP Pharma</i> ▶ Post-Translationally Modified Proteins as Biomarker Targets for Clinical Protein MS Tests <i>Dobrin Nedelkov, Isoformix, Inc.</i>

FRIDAY, APRIL 20

5:00 PM – 7:30 PM

Ballroom I & II

CPSA SHANGHAI CLOSING GALA

Dinner, Awards and Celebration
Sponsored by New Objective

Closing Toast

Given by Emily Ehrenfeld, New Objective

Program Chair Recognition

Mike Lee, Milestone Development Services

CPSA Shanghai 2019 – Program Chair Announcement

Cornelis Hop, Genentech

Young Scientist Excellence Award Presentation

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

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