CPSA
SHANGHAI
2011

PRELIMINARY PROGRAM AGENDA

Shanghai Symposium on Chemical and Pharmaceutical Structure Analysis

Revised Feb 011, 2011

Changing Paradigm in Drug Discovery and Development: East Meets West

Renaissance Shanghai Pudong Hotel
Shanghai, China
April 13-16, 2011

The CPSA Shanghai symposia and roundtables are highly interactive events where scientists share their experiences and visions in a collegial setting. The program will highlight speakers and sessions that provide real-world experiences with new technologies and critical insights into current issues and future needs. Education and specialized training are the foundation of all CPSA events.

Each session at CPSA Shanghai will address the current industrial landscape and the global need to bring products to market faster. The program chairs will promote discussion and exchange of experiences, ideas, and visions so that current processes that involve analytical measurement can be benchmarked and future strategies may be developed.

CPSA上海论坛与圆桌会议是为科学家们提供一个共同的平等交流的场所和平台，通过这一平台，科学家们可以高度互动，分享经验，共享愿景。所有安排的报告都是报告人的切身经历和经验，以及他们对最近和将来的新技术与新领域的深刻理解。 为青年科学家提供教育和培训的机会是所有CPSA 论坛的出发点。

CPSA上海论坛的每一场分会报告都将结合当前工业界的某一热点话题，以及将产品快速推向市场的全球化需要。大会与分会主席将会调动与会者积极的参与和热烈的讨论，资深科学家们将会现场回答问题，交流经验和提出建议，这些经验和建议将会为每一位参加者将来制定策略和规划提供非常有用的参考。

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PRELIMINARY AGENDA

Wednesday, April 13 – Workshops

Workshops

1:00 pm – 5:00 pm
Ballroom 1

Biotransformation: Lead Optimization and Clinical Candidate Selection Through in Vitro ADME Evaluation
Workshop Leader: Mingshe Zhu, Bristol-Myers Squibb

Common in Vitro ADME Assays: Methods and Data Interpretation
Weiqing Chen, ChemPartner

Assessment of Transporter-Mediated Drug-Drug Interactions: Current Strategy and Methodology
Cindy Xia, Millennium

Drug Metabolite Identification in Drug Discovery Using High-Resolution Mass Spectrometry
Jie Xing, University of Shandong, China

Design Proper in Vitro ADME Studies to Meet Needs in Drug Discovery
Mingshe Zhu, Bristol-Myers Squibb

1:00 pm – 5:00 pm
Ballroom 2

Bioanalysis: LC–MS/MS Bioanalysis from Drug Discovery to Development: Processes, Technologies and Regulations
Workshop Leader: Jian Wang, Bristol-Myers Squibb

Overview of LC-MS/MS Bioanalysis in Pharmaceutical Industry: Processes and Applications
Danlin Wu, Roche

Technical Fundamentals in LC-MS/MS Bioanlytical Method Development, Validation and Sample Analysis: Procedures, Issues and Solutions
Yuan-Qing Xia, Bristol-Myers Squibb

Performing Regulated Bioanalysis, Challenges and Case Studies from a CRO Perspective
Xiaohang Shen, WuXi AppTec

Discovery Bioanalysis
Jian Wang, Bristol-Myers Squibb

1:00 pm – 5:00 pm

Rhine Ballroom

Pharmaceutical Analysis
Workshop Leaders: Gang Xue, Pfizer; Yong-Guo "Fred" Li, Roche

High Speed and High Efficiency Method Development
Gang Xue, Pfizer

ICH Q-Series, Key Points Exploration
Yong-Guo "Fred" Li, Roche

Dissolution Design and Testing, Critical for Oral Drug
Mufeng Xie, Shanghai Institute for Food and Drug Control (SIFDC))

PRELIMINARY AGENDA

Evening	**Sponsor's Dinner**
	Hosted by Thermo Fisher Scientific
	Introduction and Welcome *Iain Mylchreest, Vice President and General Manager, Thermo Fisher Scientific*
	Applying Proven Proteomic Workflows and Tools for Quantitative Bioanalysis of Large Molecules *Jonathan McNally, Marketing Manager for Bioanalysis, Thermo Fisher Scientific*

Thursday, April 14 - Main Symposium

8:15 am – 8:30 am	Welcome *Mike Lee, Milestone Development Services* *Ballroom 1-2*
8:30 am – 8:45 am	Meeting Overview *Jing-Tao Wu, Millennium Pharmaceuticals* *Ballroom 1-2*
8:45 am – 9:30 am	**Plenary Lecture**
	Challenges and Future Direction of Oncology Drug Development *Pete Smith, Senior Vice President, Millennium Pharmaceuticals* *Ballroom 1-2*
10:15 am – 11:45 am	**Parallel Sessions**
Parallel Track I	**ADME I**
	Ballroom 1
10:15 am – 11:45 am	Comparison of Regulatory Requirements on DMPK Package *Chair: Jeff Zhang, Novartis*
	Overview of DMPK Package in China: Regulatory Requirement & Current Practice *Dafang Zhong, Shanghai Institute of Materia Medica*
	US/Europe Regulatory Requirements on Metabolites in Safety Testing *Mingshe Zhu, Bristol-Myers Squibb*
	US/Europe Regulatory Requirements on Drug/Drug Interactions *Mark Milton, Novartis*
Parallel Track II	**Pharmaceutical Sciences**
	Rhine Ballroom
10:15 am – 11:45 am	Emerging Trends and Technologies in Pharmaceutical Sciences *Chair: Jack Chen, DSM*
	PAT Applications in a Quality-by-Design (QbD) Environment *Kevin Bittorf, Vertex Pharmaceuticals*

PRELIMINARY AGENDA

Enhancing Product Performance Through Innovative Formulation and Manufacturing
Qun Lu, Merck

New Technology in Polymorph Studies
Beth Sarsfield, Bristol-Myers Squibb

Parallel Track III **Bioanalytical**

Ballroom 2

10:15 am – 11:45 am Dried Blood Spots and Other Emerging Bioanalytical Technologies
Chair: Naidong Weng, Johnson & Johnson

Applications of DBS for Clinical Bioanalysis Support
Tom Verhaeghe, Johnson & Johnson

Case Study of Dried Blood Spots Application in Toxicology Study
Luke Bi, Covance

High Resolution Accurate Mass Spectrometry in Quantitative Bioanalysis: Effect of Mass Resolution and Extraction Window on Selectivity
Yuan-Qing Xia, Bristol-Myers Squibb

High-Throughput Bioanalysis Using an Ultra-fast On-line Extraction System
Wenying Jian, Johnson & Johnson

11:45 am – 1:15 pm **Lunch & Roundtable Discussion**

11:45 pm – 1:15 pm **Sponsored Roundtable Workshops**

Hosted by AB Sciex – *Danube Ballroom*

High Resolution Quantitation for Bioanalysis using AB Sciex 5600 Triple Tof
Hesham Ghobarah, AB Sciex

Targeted Peptide Quantitation using MIDAS Workflow
Wenhai Jin, AB Sciex

Hosted by McKinley Scientific – *The Boardroom*

Topic to be announced

1:15 pm – 5:00 pm **Parallel Sessions**

Parallel Track I **ADME II**

Ballroom 1

1:15 pm – 2:45 pm Drug–Drug Interactions
Chairs: Cindy Xia, Millennium; Angela Wong, Merck Serono

DDI of Herbal Medicines
Chuan Li, Shanghai Institute of Materia Medica

PRELIMINARY AGENDA

Transporter-mediated DDI
Cindy Xia, Millennium Pharmaceuticals

Pharmacogenetics in Drug Discovery and Development
Renke Dai, South China University of Technology

3:00 pm – 5:00 pm

ADME Optimization to Advance CNS and Oncology Drug Discovery & Development: Industry Case Studies
Chairs: Zack Cheng, GlaxoSmithKline; Haojing Rong, Pfizer

Blood-Brain Barrier Transporters:
Friend or Enemy for CNS Drug Discovery and Development?
Zack Cheng, GlaxoSmithKline

Intranasal Administration for CNS Drug Delivery: Hope or Hype?
Haojing Rong, Pfizer

ADME Support of Oncology Programs:
Risk Management vs. Pursuit of Appropriate Drug-Like Properties
Hongjian Zhang, PharmaResources

Predictive Toxicology Approaches for Small Molecule Oncology Drugs
Vic Kadambi, Millennium Pharmaceuticals

Parallel Track II

Pharmaceutical Analysis Summit

Ballroom 2

1:15 pm – 2:45 pm

High-speed, High-Resolution Techniques for Pharmaceutical Analysis
Chairs: Anne-Françoise Aubry, Bristol-Myers Squibb; Xiaoyi Gong, Merck

Chromatographic Methodology and Technology for Developing TCM
Xinmiao Liang, Dalian Institute of Chemical Physics

Mass Spectrometry and Ion Mobility-Based Techniques for Rapid Pharmaceutical Analysis: No Sample Preparation?
Zhongli Zhang, Pfizer

Evaluation of Ionic Liquid Stationary Phases for GC-MS and GCxGC Analyses of Fatty Acids in Marine Biota
Qun Gu, Dalian Institute of Chemical Physics

3:00 pm – 5:00 pm

Analytical Approaches for the Determination of Low-Level Impurities to Comply with International Regulations
Chairs: Todd Gillespie, Eli Lilly and Company; Roman Szucs, Pfizer

Genotoxic Impurities in Drug Development
James An, Wilmington Pharmatech

Analytical Strategy for Quantifying Low-Level Genotoxic Impurities
Todd Gillespie, Eli Lilly and Company

Quantitation of API Impurities Near the Qualification Level
Tianmin Zhu, Hisun Pharmaceuticals

High-throughput Chiral Analyses
Xiaoyi Gong, Merck

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Parallel Track III — **Workshop**

Rhine Ballroom

1:15 pm – 5:00 pm — Absolute Quantification of Peptides and Proteins: From Sample Preparation and Chromatography to ESI-MS/MS
Leaders: Gary Valaskovic, New Objective; Nalini Sadagopan, Agilent Technologies

5:00 pm – 6:00 pm — **Poster Viewing** - Yangtze Ballroom

6:00 pm – 9:00 pm — **Dinner**
Ballroom 1-2

Welcome Toast - Agilent Technologies

Keynote Lectures

Stable and Reactive Metabolites in Drug Research
Scott Obach, Pfizer

Simultaneous Determination of the PK profile of Clozapine and its Metabolites in Rat Plasma Using a High-Resolution 6540 QTOF instrument
Lester C. Taylor, Shane Tichy, and Na Pi, Agilent Technologies

Friday, April 15

8:15 am – 9:00 am — **Plenary Lecture**
Ballroom 1-2

Multi-dimensional Chromatography-Mass Spectrometry for Protein Analysis
Xiangmin Zhang, Fudan University

9:30 am – 11:00 am — **Parallel Sessions**

Parallel Track I — **Novel Drug Delivery Technologies**

9:30 am – 11:00 am — *Chair: Mark Milton, Novartis*
Ballroom 1

Antibody Drug Conjugates - A General Review
Mark Milton, Novartis

Drug Targeting and Nanotechnology
Yiqiao Hu, Nanjing University

Novel Technologies for the Delivery of Biologics
Zhixuan Wang, Novartis

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Parallel Track II — **Biomarker Discovery**

9:30 am – 11:00 am — *Chairs: Scott Fountain, Pfizer; Nalini Sadagopan, Agilent*
Ballroom 2

Application of Target and Mechanism Biomarkers in Advancing Biotherapeutics and Pharmatherapeutics
Scott Fountain, Pfizer

Implementing Biomarkers into Clinical Trials on a Global Scale
Tom Turi and LiBin Ma, Covance

Proteomics Approaches to the Development of Plasma Markers for Predicting Pre-Term Birth
Kevin P. Rosenblatt, The Brown Foundation Institute of Molecular Medicine

Parallel Track III — **Comparison of Regulations for Pharmaceutical Sciences**

9:30 am – 11:00 am — *Chair: Gang Xue, Pfizer*
Rhine Ballroom

Reviews of CMC Requirements for Drug Development, Registration and Post Approval
Yanyun Chen, Pfizer

CMC Requirements for Analytical/QC
Wenfang Miao, Pharmaron

11:00 am – 12:00 pm — **Poster Session** – *Yangtze Ballroom*

12:00 pm – 1:30 pm — **Lunch / Roundtable Discussion**

12:30 pm – 1:30 pm — **Sponsored Roundtable Workshops**

Hosted by Thermo Fisher Scientific – *Danube Ballroom*
Identification and Screening for Drug Impurities, Leachables, and Extractables Using New Software and High Resolution Mass Spectrometery
Kate Comstock, Marketing Specialist for Drug Metabolism, Thermo Fisher Scientific

Hosted by New Objective – *Boardroom*
Topic to be announced
Gary Valaskovic, New Objective

1:30 pm – 5:00 pm — **Parallel Sessions**

Parallel Track I — **ADME III**

Ballroom 1

1:30 am – 3:30 pm — Development of Biologics as Therapeutics
Chair: Lawrence Gan, Biogen Idec; Haijing Rong, Pfizer

Introduction of Biologics
Jennifer Visich, Genentech

Biologics Drug Drug Interaction
Lewis Klunk, Biogen Idec

PK/PD of Biologics
Anup Zutshi, Pfizer

3:45 pm – 5:15 pm — PK/PD in Drug Discovery & Development
Chairs: Jenny Zheng, Pfizer; Zhuohan Hu, Research Institute for Liver Diseases

The Myths of PK/PD - Empirical? Mechanistic? Or System?
Jenny Zheng, Pfizer

A Mechanistic-Based PK/PD Modeling for Drug Metabolism by CYP3A in Rat
Wei Lu, Peking University, China

Case History – Use of PK/PD in Drug Candidate Selections
Lawrence Gan, Biogen Idec

Application of PBPK and In-Vitro Hepatocyte Models to Accurately Predict Human PK
Yurong Lai, Pfizer

Parallel Track II — **Regulated Bioanalysis Summit**

Ballroom 2

1:30 pm – 3:30 pm — Regulated Bioanalysis: State of the Art
Chair: Danlin Wu, Roche

Perspectives on Regional Differences in Bioanalytical Regulations
Mark Arnold, Bristol-Myers Squibb

Strategies to Avoid Pitfalls in Developing and Validating High-quality Quantitative Bioanalytical Methods to Support Regulated Studies
Eric Yang, GlaxoSmithKline

Importance of Reagent Quality for Ligand Binding Assay Development
Roland Staak, Roche

Validation and Application of Ligand Binding Assays for Protein Therapeutics Quantitation and Immunogenicity Testing: A GLP Bioanalytical Lab Perspective
Eginhard Schick, Roche

3:45 pm – 5:15 pm — Regulated Bioanalysis: Current Challenges
Chair: Anne Françoise-Aubry, Bristol-Myers Squibb

Unexpected Event Investigations in the Bioanalytical Laboratory
Anne Françoise-Aubry, Bristol-Myers Squibb

Bioanalytical Method Transfer: Challenges & Opportunities
Naidong Weng, Johnson & Johnson

Harmonization of Regulated Bioanalytical Operation at both U.S. and China Sites
XinPing Fang, XenoBiotic Laboratories

Parallel Track III — **Workshop**

Rhine Ballroom

1:30 pm – 5:15 pm — Pharmacokinetic Applications in Drug Discovery and Development: Human PK and Efficacious Dose Prediction
Workshop Leaders: Frances Wang, Astra Zeneca; Xingmei Han, Novartis

6:00 pm – 9:30 pm	**CPSA Shanghai Gala Dinner**
	Ballroom 1-2 *Held in conjunction with local bioanalytical and metabolism discussion groups*
6:00 pm – 7:00 pm	Dinner Gala
7:00 pm – 7:30 pm	Awards and Announcements
7:30 pm – 9:30 pm	Point/Counterpoint Discussions
	Future Direction of Pharmaceutical R&D in China *Moderator: Jeff Zhang, Novartis*

Saturday, April 16

Morning	**Joint session with local bioanalytical and metabolism discussion groups**
	Application of PK/PD in Drug Discovery and Development *Li Yu, Hoffmann-La Roche*
	Application of In-Vitro Data to Predict Clinical PK and Drug-Drug Interaction by Simcyp *Jing Lin, Pfizer*
	Application of Radioisotopes in Drug Absorption, Distribution, Metabolism, and Excretion Studies *Zhe-ming Gu, XBL-China*