CPSA
SHANGHAI

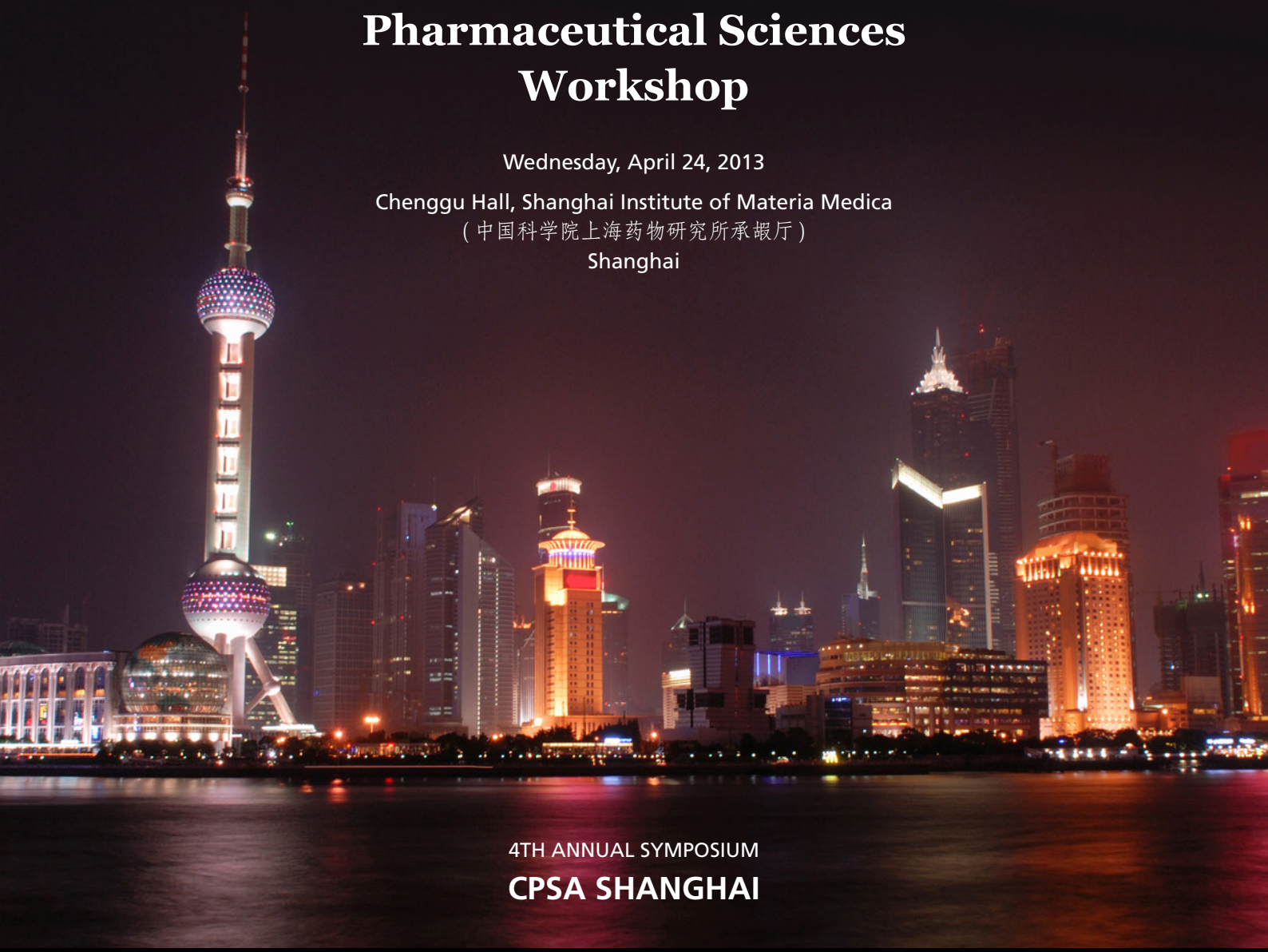
PRE-CONFERENCE WORKSHOP

Held in conjunction with CPSA SHANGHAI 2013

Pharmaceutical Sciences Workshop

Wednesday, April 24, 2013

Chenggu Hall, Shanghai Institute of Materia Medica
(中国科学院上海药物研究所承蝦厅)
Shanghai



4TH ANNUAL SYMPOSIUM

CPSA SHANGHAI

Where Technology and Solutions Meet
Where East Meets West

Milestone Development Services

CPSA SHANGHAI 2013

WORKSHOP REGISTRATION

Early Registration $75.00
(before April 6, 2013)

Regular Registration: $100.00
(after April 6, 2013)

Complimentary Workshop Registration for Students with ID (学生凭学生证免费入场)

Visit the CPSA Shanghai website for more information as well as to register:

www.cpsa-shanghai.com

Directions to The Shanghai Institute of Materia Medica

From the Renaissance Hotel, travel to the SIMM is an easy 15 RMB (~US$4.00) taxi ride.

To take public transportation from the Renaissance Hotel, 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.

Shanghai Institute
of Materia Medica, CAS
(中国科学院上海药物研究所)

WORKSHOP

Analytical & Quality Consideration in Pharmaceutical Science

主题：药物研发中的质量研究

Wednesday, April 24, 2013
9:00 AM - 4:00 PM

Shanghai Institute of Materia Medica, ACS (中国科学院上海药物研究所)
Chenggu Hall
555 Zu-Chong-Zhi Road (上海市浦东张江祖冲之路555号)
Pudong New District, Shanghai

Organized by (组织方):
Clinical & Pharmaceutical Solutions through Analysis (CPSA Shanghai 2013)
Pharma-Valley Analytical Discussion Group (PVADG, 药谷分析讨论组)

Hosted by (承办):
Pharmaceutical Analysis & Solid-State Chemistry Research Center
Shanghai Institute of Materia Medica, ACS
(中科院上海药物研究所 药物质量控制与固体化学研究中心)

Morning Session 9:00 AM -12:00 PM

Chairs:
Dr. Yong-Guo "Fred" Li, Hua Medicine（李永国 博士， 华领医药）
Prof. Xuefeng Mei, Shanghai Institute of Materia Medica（梅雪峰 博士，中科院上海药物所）

Welcome & Introduction

Todd Gillespie, Ph.D. *Eli Lilly & Co.* (Todd Gillespie 博士， 礼来制药)
Yong-Guo "Fred" Li, Ph.D. *Hua Medicine, Ltd.* （李永国 博士， 华领医药）

Solid State Characterization & Profiling in Pharmaceutical Development (药物固态化学研究策略)

- Solid state chemistry and QbD
- Solid state characterization Tools (药物的固体表征)
- Salt and polymorph Profiling （成盐与晶型筛选)
- Solid state studies required by health authorities (药监部门的要求)

Prof. Xuefeng Mei, Director, Pharmaceutical Analysis & Solid-State Chemistry Research Center, Shanghai Institute of Materia Medica

Prof. Mei has experience in pharmaceutical industry and academy, 10+ years in preformulation and analytical, research focus on salt/polymorph/co-crystal screening and amorphous characterization (梅雪峰 博士，中科院上海药物研究所 药物质量控制与固体化学研究中心主任，同时具有制药企业与研究机构工作经验，主要研究领域为配方前物化性能优化与质量研究，包括成盐、晶型、共结晶筛选和无定形药物制备与表征等)

Stability Consideration in Drug Discovery & Development (药物稳定性研究)

- Overview of stability study （稳定性研究概览)
- From protocol to report （从稳定性研究方案到研究报告)
- Key points of stability （稳定性研究的注意点)

Ms. Lan Lin, Associate director, WuxiApptec

Ms. Lan has hands-on experience in stability and analytical development near 10 years, and as one young talent and future leader in Wuxi ADS department. Wuxi ADS has the state-in-art facilities and capacities in stability. (林岚 女士 上海药明康德新药研究有限公司 分析服务部 副总监，长期从事稳定性研究和分析开发等工作。)

Specification as a Key in Pharmaceutical Science (药物的质量标准)

- The role of specification （质量标准的作用）
- Development and establishment of Specification (质量标准的制定)
- Key points of specification （几个注意点)

Dr. David Chen, Vice President of Quality & Compliance, Desano Pharma （陈志红 博士，迪赛诺质量部 副总裁， 30多年的药物分析和质量管理经验，曾任罗氏研发（中国）有限公司 质量管理部 总监等。)

CPSA
SHANGHAI
2013

What is CPSA?

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.

Goals

The goal of CPSA Shanghai is to provide in-depth review of innovative technology and industry practices through open discussion of industry-related issues and needs. 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.

Visir the CPSA Shanghai website fro more information

www.cpsa-shanghai.com

ShortCoursesFeVisittheCPSAShanghaiwebsite

WORKSHOP

Analytical & Quality Consideration in Pharmaceutical Science

主题：药物研发中的质量研究

Afternoon Session 1:00 PM - 4:00 PM

Chairs:
Dr. Marc Cao, *Eli Liily R&D (China)* (曹化川 博士， 礼来（中国）研发中心)
Dr. Baiming Xiao, *Jiangsu Simcere Pharmaceutical Group, Ltd.* (肖柏明 博士，江苏先声药业有限公司)

Challenges for Generic Drug Impurity Studies
(仿制药开发的巨大挑战--仿制药杂质的研究方法)

- Great challenges in generic drug development (仿制药开发的巨大挑战)
- Impurity profiling and technical difficulties (仿制药中的杂质研究)
- Cases for impurity studies (案例分析)

Dr. Baiming Xiao, *Executive Director of Pharmaceutical R&D, Simcere Pharmaceutical Group, Ltd.*

Dr. Xiao received his Ph.D. in Chemistry from Seton Hall University, and worked at Johnson & Johnson (J&J) and Bristol-Myers Squibb (BMS) prior to join in Simcere as Executive Director. He has 25 plus years pharmaceutical experiences from IND to NDA in both innovative and generic drug development, especially in ARD fields, in Sino and Western. (肖柏明 博士，执行总监， 江苏先声药业，Seton Hall University 博士，在Johnson & Johnson (J&J) 和 Bristol-Myers Squibb (BMS)等制药企业有25年的工作经验， 先后参与多项从IND到NDA的创新药和仿制药的研发。)

Integrating Analytical Science & Technologies to Support Drug Discovery and Development (整合现代分析技术用于支持药物研发)

- Integrated Analytical & Purification Platform (分析纯化平台介绍)
- Functions and Capacities (平台功能)
- Case studies (案例分析)

Dr. Penny Ding, *Group Leader in Roche R&D Center*

Dr. Ding has strong background with the expertise in structural ID through MS and NMR in my analytical team in Roche.) (丁佩兰 博士，复旦大学获博士学位后， 加入罗氏研发（中国）有限公司，长期从事高通量药物分析，纯度分析，和杂质分析等。)

Panel Discussion: Key Points of Analytics in Drug Development
(专题讨论与问答：质量研究的一些关键问题)

- Analytical roles in Drug Discovery & Development (分析如何发挥作用)
- Phase appropriate analytical (基于不同研发阶段的质量研究)
- Analytical & quality research in IND/NDA filing (质量研究与报批资料)
- Q&A (问答)

Moderator: Dr. Yong-Guo "Fred" Li, *Hua Medicine* (李永国 博士， 华领医药)

Panelists :

Dr. Todd Gillespie, *Eli Lilly & Co.* (Todd Gillespie 博士， 礼来制药)
Dr. Bo Zhang, *GlaxoSmithKline (China)* (张博 博士，GSK (中国）研发中心)
Dr. Marc Cao, *Eli Liily R&D (China)* (曹化川 博士， 礼来（中国）研发中心)
Dr. Baiming Xiao, *Jiangsu Simcere Pharmaceutical Group, Ltd.* (肖柏明 博士，江苏先声药业)