



CHINA PRETRIALS 2010

GLOBAL PRECLINICAL
DEVELOPMENT SUMMIT

October 17-19, 2010 | Beijing, China

PROGRAM AGENDA

SUNDAY — OCTOBER 17, 2010

3:00pm-7:00pm

PRE-CONFERENCE WORKSHOP

All About Compliance: A Detailed Look at the Current Status of GLP in China

Workshop Moderators:

Jianfei Wang, Ph.D., *Director, Laboratory Animal Science*

GLAXOSMITHKLINE R&D CHINA

Zuoxiang Yu, Ph.D., *Alliance GLP Management Support Director*

ASTRAZENECA CHINA

Workshop Presentations:

■ **Training for GLP Compliance in China**

Zuoxiang Yu, Ph.D., *Alliance GLP Management Support Director*

ASTRAZENECA CHINA

■ **A Look at Sample FDA Warning Letters Based on GLP Regulations**

Steven Kuwahara, Ph.D., *Principal Consultant*

GXP BIOTECHNOLOGY

■ **Animal Welfare According to US FDA Standards vs. China SFDA**

Kathryn Bayne, M.S. Ph.D., *Global Director*

AAALAC INTERNATIONAL

Jianfei Wang, Ph.D., *Director, Laboratory Animal Science*

GLAXOSMITHKLINE R&D CHINA

■ **LIME System: Digital Data Collection to Improve Study Efficiency & GLP Implementation**

York Xia, *Chief Executive Officer*

SHANGHAI GENIUS INFORMATION TECH

■ **Electronic Data Capture System Validation**

Alice Lu, Ph.D., *Senior Director of Operation*

PHARMARON

■ **The Use of Digital Pathology As a Solution for the Shortage of Pathologists in China?**

Ole Eichhorn, *Chief Technology Officer & Vice President, Development*

APERIO

7:00pm-8:30pm

CRO Meet & Greet Welcome Reception

Business development representatives from all the major CROs in China will be on hand for a meet and greet session. If you are a small or emerging biotech company, this is your opportunity to meet and schedule meetings and off-site visits for the coming week with potential local partners. Cocktails will be served and your peers from global big pharma are also invited!



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MONDAY — OCTOBER 18, 2010

7:00am-8:00am

Registration & Breakfast

8:00am-8:10am

Chairperson's Opening Remarks

8:10am-9:10am

OPENING KEYNOTE ADDRESS

Expansion into Asia Pacific in the Preclinical Arena: The Awes & Disappointments, The Hopes & Challenges, and What Are the Next Steps?

The past few years have marked increased investment by big pharma in building up their Asia Pacific R&D to include preclinical capabilities. What are the reasons behind this? What are some of the expectations of big pharma by setting up R&D centers in Asia? What are the challenges they are facing and what lessons have been learned so far?

Helen Han Hsu, DVM, Ph.D., *Vice President, Head of Preclinical Development, Asia Pacific*
JOHNSON & JOHNSON, PHARMACEUTICAL RESEARCH & DEVELOPMENT

9:10am-10:10am

KEYNOTE PANEL DISCUSSION

A Look at the Different Preclinical Development Strategies Being Employed By Big Pharma in China

Big pharma has taken a variety of approaches with their preclinical development strategies in China. This panel discussion will take a look at the 3 main different strategies being employed, 1. setting up full R&D centers in China, 2. virtual management from the West, and 3. hybrid approach with some staff in located in China. What can be learned by these 3 different approaches? And what led each company to choose their particular strategy?

Moderator:

Helen Han Hsu, DVM, Ph.D., *Vice President, Head of Preclinical Development, Asia Pacific*
JOHNSON & JOHNSON, PHARMACEUTICAL RESEARCH & DEVELOPMENT

Panelists:

Jing-Shan (Jennifer) Hu, Ph.D., *Director, Licensing & External Research*
MERCK & CO.

Steve Yang, Ph.D., *Vice President, Head of R&D, Asia*
PFIZER GLOBAL R&D CENTER

Yi Yang, M.D., Ph.D., *Head of Preclinical Safety, China R&D*
SANOFI-AVENTIS CHINA

10:10am-10:40am

Mid-Morning Refreshment Break



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10:40am-11:10am KEYNOTE ADDRESS #2

A Comparison of US FDA vs. SFDA Regulatory Guidelines for Preclinical Studies

With the rapid growth of healthcare market in China, more multinational global biopharmaceutical companies are interested in developing and registering new therapeutics in China. Understanding the US and Chinese regulatory requirements for preclinical studies would be helpful. US FDA has extensive experience in regulating new drug (NME) development, and is actively involved in the development and implementation of ICH guidelines and standards. SFDA has reviewed and approved a large number of generic drugs, but only a small number of NMEs. However, new drug applications are increasing recently. SFDA has made significant improvement in the last few years --- communicating regularly with US and EU regulatory authorities, adopting more and more ICH guidelines, and drafting and modifying many SFDA new regulations. In the next few years, more harmonization in regulatory requirements are expected in the preclinical new drug development.

John Gong, Ph.D., M.D., *Vice President & CTO*

JOINN LABORATORIES

11:10am-12:00pm PANEL DISCUSSION

Taking Stock: China Preclinical CRO Progress & Challenges

Moderator:

Kewen Jin, *General Manager*

CHARLES RIVER LABORATORIES CHINA

Panelists:

Charlene Chen, *Director, Center of Toxicology & Preclinical Sciences*

DEVELOPMENT CENTER FOR BIOTECHNOLOGY

Edward Hu, Ph.D., *Chief Operating Officer*

WUXI APPTec

Tina Huang, Ph.D., *Senior Vice President, Operation, Preclinical Services*

PHARMARON

Li Tian, Ph.D., *Chief Operating Officer*

FRONTIER BIOSCIENCES

James Yan, M.D., Ph.D., DABT, *Executive Director./Head of Drug Safety Evaluation*

HUTCHISON MEDIPHARMA

Zuoxiang Yu, Ph.D., *Alliance GLP Management Support Director*

ASTRAZENECA CHINA



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12:00pm-1:00pm

Networking Expert Luncheon

Join a table discussion led by our speakers and other experts in the China preclinical development field. Each table at lunch will have a specific theme for discussion, covering all aspects of the preclinical development industry in China. This lunch will give you the opportunity to more personally interact with our speakers and experts on topics directly of interest to you.

1:00pm-1:30pm

Trends in Animal Care and Use Programs in China and the Broader Pacific Rim Observed by AAALAC International

AAALAC International accreditation provides an international bench-marking of an organization's animal care and use program and is key to ensuring a high level of animal care, as well as high quality research data. The process and benefits of achieving accreditation at an international standard, as well as trends observed in the Pacific Rim region will be described.

Kathryn Bayne, M.S. Ph.D., *Global Director*

AAALAC INTERNATIONAL

DEVELOPING THE BEST PRECLINICAL OUTSOURCING STRATEGIES TO CHINA

1:30pm-2:00pm

What To Look For When Selecting A China-Based Preclinical CRO

There are many choices of Preclinical CROs in China nowadays. In short, there are fully integrated and specialized service laboratories. In addition, there are western and domestic providers. What are the Pros and Cons of these different types of CRO? Are there differences in decisions for large vs. smaller companies when selecting certain kinds of CRO? Does higher cost translate to better quality in China? Will you sacrifice quality by outsourcing to China or to a lower cost CRO if you do decide to collaborate with a China-based CRO? In addition to the aforementioned key questions, this talk will point out technical issues that one should pay attention to when selecting a China-based CRO.

Gene Hsu, Ph.D., DABT, *Deputy Director*

NATIONAL SHANGHAI CENTER FOR NEW DRUG SAFETY & EVALUATION & RESEARCH

2:00pm-2:45pm

PANEL DISCUSSION

Full Service CROs vs. Specialized: Can Full-Service CROs Maintain Quality Doing So Many Different Things?

Moderator:

Gene Hsu, Ph.D., DABT, *Deputy Director*

NATIONAL SHANGHAI CENTER FOR NEW DRUG SAFETY & EVALUATION & RESEARCH

Panelists:

Honggang Bi, Ph.D., *Corporate VP & General Manager*

COVANCE CHINA

Edward Hu, Ph.D., *Chief Operating Officer*

WUXI APPTec



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Darren Ji, Ph.D., *Chief Executive Officer*
PHARMALEGACY

Yi Yang, M.D., Ph.D., *Head of Preclinical Safety, China R&D*
SANOFI-AVENTIS CHINA

Michael Zhou, Ph.D., *Director, Bioanalytical Chemistry/DMPK*
SYNTA PHARMACEUTICALS

2:45pm-3:15pm

Understanding China's Capabilities in Formulation and CMC

Deepak Hegde, Ph.D., *VP, Formulation Development*
WUXI APTEC

3:15pm-3:40pm

Mid-Afternoon Refreshment Break

3:40pm-4:05pm

Bridging East-West Preclinical Trials Under Regulated Compliance

Michael Zhou, Ph.D., *Director, Bioanalytical Chemistry/DMPK*
SYNTA PHARMACEUTICALS

4:05pm-5:00pm

PANEL DISCUSSION

From Drug Discovery to Development to Licensing: China vs. Global

The greater majority of small to mid-sized drug developers favor a strategy of out-licensing their drug candidates as opposed to bringing them all the way to market. In order to build value for the drugs in development, these drug developers should start the value-add process in the preclinical development stage. This panel session will explore the steps small to mid-sized drug developers should take to best position themselves for out-licensing and specific discussion will also focus on the emerging opportunities for licensing in China and the rest of Asia.

Moderator:

Ada H.C. Kung, Ph.D., *Senior Vice President, Preclinical Development*
TAIGEN BIOTECHNOLOGY

Panelists:

Ming Guo, Ph.D., *Co-Founder & Chief Operating Officer*
ASCENTAGE PHARMA GROUP

Jing-Shan (Jennifer) Hu, Ph.D., *Director, Licensing & External Research*
MERCK & CO.

John Jin, Ph.D., *Vice President, Business Development*
TAIGEN BIOTECHNOLOGY

Stella Xu, Ph.D., *Executive Director*
ROCHE



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5:00pm

End of Day One

TUESDAY — OCTOBER 19, 2010

GLP COMPLIANCE FOR PRECLINICAL STUDIES IN CHINA

7:40am-8:40am

Breakfast, Networking & Exhibits

8:40am-8:50am

Chairperson's Recap of Day One

James Yan, M.D., Ph.D., DABT, Executive Director./Head of Drug Safety Evaluation
HUTCHISON MEDIPHARMA

8:40am-9:10am

Inspections in China Preclinical Labs from the Perspective of an OECD GLP Monitorate: Experiences, Current Challenges and Proposed Way Forward

Acceptance of outcome of GLP Inspections abroad of OECD countries are not foreseen by the OECD Council Decision on Mutual Acceptance of Data in the Assessment of Chemicals. Some countries have signed the Council Decision on Adherence of Non-Member Countries to the Council Acts related to the Mutual Acceptance of Data, to overcome this problem. As long as China has not signed the MAD, sponsors of studies by test facilities in China should contact before all different receiving authorities where they intend to introduce their dossier. The Belgian GLP monitorate can than schedule study audits on demand of this authorities. At that time a full GLP verification of the test facility can be foreseen which can result in a certificate of GLP compliance for a maximum of 3 year.

Guido Jacobs, Coordinator
BELGIUM GLP MONITORATE

9:10am-9:35am

Access to High-Quality Animals in China

- Availability of Non-Human Primates for Large Molecule Preclinical Studies
- Required dietary and bedding materials
- Quality control & monitoring systems

Jianfei Wang, Ph.D., Director, Laboratory Animal Science
GLAXOSMITHKLINE R&D CHINA



PROGRAM AGENDA

9:35am-10:00am

How Can the GLP Industry in China Survive Increasing Globalization?

GLP service is a relatively new but rapidly evolving industry in China. With more and more major pharmaceutical companies expanding their R&D activities into China, multinational nonclinical CROs, such as Charles River and Covance, have also started building/offering their GLP services in China. Therefore, the emerging GLP industry in China is facing increased opportunities and challenges as a result of the globalization of pharmaceutical R&D and services. This presentation will provide an overview of the GLP industry in China and challenges that it is facing. In addition, suggestions on how to deal with the challenges will be discussed.

Joe Zhang, M.D., Ph.D., *Head of DMPKS*

ROCHE R&D CENTER CHINA

IMPROVING IND-ENABLING CAPABILITIES IN CHINA

10:00am-10:25am

Clinical Development of a Novel HDACi – Chidamide: “Made in China” & SFDA/FDA Regulatory Path

Chidamide is a novel benzamide HDAC inhibitor discovered by Chipscreen scientists and currently under NDA-directed clinic development for oncology indication in China. It has also successfully entered phase I study in the US with the support of Chinese IND data. The presentation will focus on the clinic profile up-to-date, and the regulatory path along the development of Chidamide both in China and the US will be discussed.

Xian-Ping Lu, Ph.D., *Chief Executive Officer & Chief Scientific Officer*

CHIPSCREEN BIOSCIENCES

10:25am-10:50am

Mid-Morning Networking Break

10:50am-11:15am

Bridging Research & Development: Faster to Proof of Concept

Nick Zhang, Ph.D., *Head of CPP/PHAD China*

NOVARTIS CHINA

11:15am-11:40am

China IND Process & Experiences: Promoting Innovative Drug R&D From Our Homeland for Global Applications

Xun Zhang, Ph.D., *SVP, Non Clinical Development & Project Operations*

HUTCHISON MEDIPHARMA



PROGRAM AGENDA

11:40pm-12:05pm

Safety Pharmacology: Telemetry Technology Application in China

Safety pharmacology is an important part of the IND-enabling preclinical safety study package but its application is also widely extended to early candidate profiling and screening. Telemetry technology offers an innovative approach to collecting physiological data from conscious animals in a similar quality with that from the clinical setting and, at the same time, it also improves animal welfare. This new technology was introduced to China preclinical arena a few years ago but its application for production and related validation are still a challenge.

Yi Yang, M.D., Ph.D., *Head of Preclinical Safety, China R&D*

SANOFI-AVENTIS CHINA

11:40pm-12:05pm

Broadening the Future and Impact of DMPK in Drug Discovery and Development through the Power of Collaboration in China

The science of DMPK needs to evolve constantly to support the invention of new class of molecules and the development of personalized medicines. An overview of current and future strategic opportunities, for Pfizer PDM and Scientists in China to collaborate from basic research to integrated drug development and patient characterisation.

Christelle Perros-Huguet, Ph.D., *Vice President, Head of PK, PD & Metabolism, PDM NCE*

PFIZER GLOBAL RESEARCH & DEVELOPMENT

12:40pm-1:40pm

Networking Lunch

1:40pm-2:10pm

Selecting the Right Compounds and Improving Developability: The Role of DMPK

Hequn Yin, Ph.D., *Head, DMPKS*

NOVARTIS CHINA

2:10pm-2:40pm

Utility of Pharmacokinetics & Pharmacodynamics in Facilitating IND-Enabling Studies

Mingxin Qian, M.D., Ph.D., *Vice President, DMPK/Preclinical Service*

SHANGHAI CHEMPARTNER

2:40pm-3:10pm

Closing Remarks: What Have We Learned and Where Does the Industry Head Next?

Helen Han Hsu, DVM, Ph.D., *Vice President, Head of Preclinical Development, Asia Pacific*

JOHNSON & JOHNSON, PHARMACEUTICAL RESEARCH & DEVELOPMENT

3:10pm

Conference Concludes