3rd DIA China Annual Meeting
Quality & Standards — Elevating China Pharmaceutical Development

Pre-conference Workshops: May 15, 2011
Conference & Exhibition: May 16-18, 2011
Crowne Plaza Sun Palace Beijing
Beijing, CHINA

Co-sponsored by
China Center for Pharmaceutical International Exchange of the SFDA
As a global neutral platform, DIA invites you to attend the 3rd DIA China Annual Meeting, which will explore the latest developments within the China pharmaceutical industry, explore ideas that will impact global health, and feature open debate by senior professionals, top academics and high-level officials from pharma, R&D, and regulatory affairs.

As China unveils its 12th Five-Year Plan, the Chinese biopharmaceutical industry once again draws global attention as one of the investment heavyweights. Billions of special funds are pouring in. Yet, new policies and industry reorganization have placed China’s pharma industry at a critical stage. Future elevation and sustainable development of the industry require revisiting quality and standards.

China’s new medical reform has both rationalized the health care system and spiked enthusiasm to engage in new drug research. With quality throughout the whole manufacturing process, and world-class normative clinical research, the future of China’s drug innovation is golden.

**KEY SESSIONS AND TOPICS**

- Drug Standards and Quality
- Clinical Research and Drug Safety
- Regulations and Implementation
- Data Management and Statistics
- Medical and Scientific Affairs
- Clinical Development and Capacity Building
- QA/QC in Clinical Development

**WHO SHOULD ATTEND**

This program will benefit those who work in relevant areas of drug development and medical marketing and who are practicing physicians treating patients and conducting clinical trials in health care institutions, including, but not limited to:

- Clinical trial investigators
- Clinical research and development
- Clinical research operations
- Drug safety and pharmacovigilance
- Regulatory affairs
- Biostatistics and data management
- Medical writing
- Medical practicing

Simultaneous translation will be available on May 16-18.

**CONTACT INFORMATION**

Conference: For general inquiries and registration, contact  
Mr. Fei XIE: fei.xie@diachina.org

Exhibits: Contact Ms. RunShan CHEN: ting.chen@diachina.org
PROGRAM CO-CHAIRPERSONS

James CAI, MD
President, Pangu Biopharma Ltd.

ZHAO Yajun
Director-General, China Center for Pharmaceutical International Exchange, SFDA

PROGRAM VICE CHAIRPERSON

John HU, PhD
Vice President, International General Manager, USP-China

PROGRAM COMMITTEE MEMBERS

Paul DAI, MD
Senior Director, Regional Head of ICRO AMAC & Greater China Region, Beijing Novartis Pharma Co., Ltd., China

GUI Min, PhD
Director, CMC AP and China CMC & Operation, Global Regulatory Science, Bristol-Myers Squibb

GUO Xiaojun, PhD
Safety Manager, Patient Safety, AstraZeneca China

GU Zheng, MD
Senior Medical Director, sanofi-aventis, China

Laurence HUANG
Executive Director-Regulatory Affairs AstraZeneca China

JIAO Qingan, MD
Head of Clinical Operations, Roche Product Development in Asia Pacific

LI Haiyan, MD, Professor
Director, Drug Clinical Trial Center, Peking University Third Hospital, China

LI Ning, PhD
Senior Group Director, Medical Policy, sanofi-aventis, China

Daniel LIU, PhD
Director, China Development, Medidata Solutions Worldwide

Hannah CHEN, MD
Clinical QA Regional Manager, AP, GlaxoSmithKline
PRE-CONFERENCE WORKSHOPS | SUNDAY, MAY 15

8:30 – 17:30 WORKSHOP 1

HOW TO PREPARE FOR SUCCESSFUL COMPLIANCE AUDIT AND INSPECTIONS

ABOUT THE WORKSHOP
This is a brief training workshop on how to prepare and implement a regulatory inspection per GCP perspectives. The experienced global inspection experts and FDA authority will give trainees the fundamental knowledge and understanding of regulatory inspection practices and expectations in a global GCP environment. The trainees will also learn how to plan and conduct a regulatory process and how to explain an FDA regulatory report. Moreover, the training workshop will illustrate strategic techniques of e-clinical validation from the standpoint of regulatory inspection views.

LEARNING OBJECTIVES
At the conclusion of this workshop, you should be able to:
• Know what is involved when conducting an effective internal and external quality audit, and how to plan for its successful implementation
• Understand the types of QA audits conducted, why they are necessary, and the value they provide
• Learn how to prepare for an audit, achieve closure, and get the best out of your quality audit system
• Prepare for a clinical data system inspection and assess risk areas that need prioritization
• Review the system for regulatory vulnerabilities and to develop an action plan intended to close those gaps

WHO SHOULD ATTEND
• Clinical study professionals
• Clinical project management
• Auditor and inspector
• Regulatory affairs
• Data management
• Clinical information professionals
• Clinical monitors
• Quality assurance and quality control professionals
• Clinical researchers and study coordinators

SPEAKERS
Earl HULIHAN
Senior Vice President, Regulatory Affairs Medidata Solutions

Daniel LIU, PhD
Director, China Development, Medidata Solutions Worldwide

Byungja MARCIANTE
Senior Assistant Director, US FDA Shanghai Office, China

Kim NITAHARA
Principal Consultant and CEO, META Solutions, Inc.

8:30 – 17:30 WORKSHOP 2

BIO-ANALYTICAL METHOD DEVELOPMENT AND VALIDATION CHALLENGES AND PRACTICAL SOLUTIONS

The bio-analytical workshop will review the significance of bio-analytical analysis and regulatory requirements for bio-analytical method development and validation, discuss general practice in bio-analytical method development and validation, share perspective and provide solutions on overcoming challenging issues in bio-analytical method development including chemical stability, metric stability, specific and non-specific binding, etc. The instructors are senior scientists and managers from major pharmaceutical companies and contract research bio-analytical organization.

LEARNING OBJECTIVES
At the conclusion of this workshop, you should be able to:
• Understand technical and regulatory compliance requirements in developing robust and sensitive bio-analytical methods
• Validate bio-analytical methods that are sensitive, selective, reproducible, and cost effective
• Explain strategies and skills in problem solving to ensure data integrity

WHO SHOULD ATTEND
• Bio-analytical scientists
• PK/TK scientists
• Lab management
• Bio-analytical QA

SPEAKERS
ZHANG Fa, PhD
Senior Research Fellow, Johnson & Johnson, USA
VACCINE CLINICAL DEVELOPMENT AND REGULATION

Developing a vaccine with a high quality efficacy and safety profile is essential to public health. China has developed nicely in vaccine production and took the lead to market N1H1 vaccine products in 2009, which indicates the region's established capability and capacity to develop vaccines. However, vaccine development and regulation should be improved match ICH GMP and ICH GCP standards so that vaccine products developed and manufactured in China are accepted internationally.

Global vaccine companies are shifting their strategy to adapt to the local regulation in order to market their products in China as early as possible. Their efforts include setting up their own manufacturing plants or acquiring a local company with manufacturing capacity. Because the investment burden on global vaccine companies is so large, companies would like to harmonize Chinese vaccine regulation with ICH GCH.

TOPICS
• China vaccine development landscape
• Vaccine clinical development program under FDA regulation-best practice from real case
• Vaccine clinical development-statistical consideration
• Discussion-operational consideration

WHO SHOULD ATTEND
• Vaccine development professionals in Chinese companies
• Regulatory affairs professionals

LEARNING OBJECTIVES
At the conclusion of this workshop, you should be able to:
• Clinical project management in global and Chinese companies
• QC/QA professionals
• Clinical research coordinators and site monitors

SPEAKERS
Mike CORRADO, Professor
CSO, INC Research
Professor, University of Pennsylvania, USA
Jessica LIU, MD
Senior Director, Clinical Operations, Head of Asia-Pacific, Global Clinical Operations, INC (Beijing) Medical Technology Co., Ltd.
William WANG, PhD
Head, Asia Pacific Hub, Biostatistics and Research Decision Sciences (BARDs), Merck Research Laboratory, Merck & Co., Inc
ZHAO Yuliang, MD
Director, Hebei CDC
ZHENG Haifa
General Manager, Beijing MingHai Biotechnology Co., Ltd.

ETHICAL MEDICAL WRITING PRACTICES – EVERY DOCUMENT, EVERY TIME, EVERY COUNTRY!

Medical writers in China are making increasingly important contributions to documents designed to reach international audiences. Writers are being asked to prepare many types of documents, including publications in international peer-reviewed journals, presentation materials for international conferences, protocols for international clinical trials, and clinical study reports for international regulatory submissions. Although each document has specific requirements, EVERY document must be prepared in an ethical manner. Thus, medical writers in China (and throughout the world) must be aware of and adhere to ethical medical writing practices. Failure to do so could endanger patient care and damage the reputations of the writer, the sponsor, the institution, and the country involved.

TOPICS
• Real-life examples to reinforce why ethical practices are critical
• Important international guidelines
• Critical ethical practices writers should follow when preparing different types of documents (e.g., protocols, clinical study reports, abstracts, slides, posters, manuscripts)
• Solving ethical medical writing challenges

LEARNING OBJECTIVES
At the conclusion of this workshop, you should be able to:
• Explain why medical writers should follow internationally recognized ethical medical writing practices
• Identify important international guidelines that describe ethical medical writing practices
• Outline ethical medical writing practices when preparing different types of documents

WHO SHOULD ATTEND
• Medical writers
• Investigators
• Clinical researchers
• Regulatory affairs staff

SPEAKER
Karen WOOLLEY, PhD
ProScribe Medical Communications, Australia
NEW CDISC GLOBAL APPROACH

The existing typical process for biomedical research is antiquated and crying out for real technological transformation. Glaring inefficiencies remain to which solutions will require the adoption and implementation of key enablers; these enablers include workflow integration, eSource and efficient exchange of information from site to study sponsor to reviewer (whether this be a regulatory authority, an IRB or DSMB, an academic institution, a clinician investigator or scientist, or another reviewer of research information). In addition, addressing unnecessary data quality issues hinders workflow speed and uses excessive and expensive resources.

The Clinical Data Interchange Standards Consortium (CDISC) has collaborated with numerous organizations on a global basis to analyze research regulations and processes through which a set of enablers that can recognizably accelerate the medical research process, from protocol through analysis and reporting has emerged.

LEARNING OBJECTIVES
At the conclusion of this workshop, you should be able to:
• Explain how to improve data quality and streamline workflow at investigative research sites and sponsoring organizations

WHO SHOULD ATTEND
• Medical Researchers

SPEAKERS
Rebecca D. KUSH, PhD
President and CEO, CDISC

Claire TAN
Senior Director, Biostatistics, Quintiles Medical Development (Shanghai) Co., Ltd. Beijing Branch
CONFERENCE DAY 1 | MONDAY, MAY 16

13:30 - 15:00  OPENING CEREMONY (PLENARY SESSION)
YN GRAND BALLROOM A+B+C (Level 3)

INTRODUCTION
Jane CAI, PhD
Director, DIA China

OPENING REMARKS
James CAI, MD
President, Pangu Biopharma Ltd.

ZHAO Yajun
Director-General, China Center for Pharmaceutical International Exchange, SFDA, China

WELCOME
Richard O. DAY, AM, MB, BS, MD, FRACP
President, DIA
Professor of Clinical Pharmacology
St. Vincent’s Hospital, Australia

Paul POMERantz
Worldwide Executive Director
DIA, USA

AWARD & RECOGNITION

KEYNOTE SPEECH

KEYNOTE SPEAKER
SFDA (Speaker Invited)

15:15 – 15:45  PRESENTATION 1
MODERATOR
CCPIE (Moderator Invited)
China Drives to “Indigenous Innovation”
Michael ZIELENZIGER
Visiting Scholar, University of California, Berkeley, USA

15:45 – 16:15  PRESENTATION 2
China New GMP
SFDA (Speaker Invited)

16:15 – 17:45  OPENING DEBATE
Forum: Positioning China - The Strengths and Challenges in Innovative Drug Development
MODERATOR
SU Ling, PhD
Senior Vice President, Head of Development Greater China, Beijing Novartis Pharma Co., Ltd., China

PARTICIPANTS:
DONG Ruiping, MD, PhD
Senior Vice President, Head of Emerging Markets R&D, Merck Research Laboratories, USA
LI Ning, PhD
Senior Group Director, Medical Policy, sanofi-aventis, China
SFDA (Speaker Invited)

Center for Drug Evaluation, SFDA (Speaker Invited)
Ministry of Science and Technology (Speaker Invited)
LU Xianping, PhD
President and Chief Scientific Officer, Chipscreen Biosciences, Ltd., Shenzhen

Additional Panelists invited

18:00 – 19:30  RECEPTION
Function Hall (Level 2)
CONFERENCE DAY 2 | TUESDAY, MAY 17

8:30 – 10:00    SFDA TOWN HALL MEETING

8:30 – 10:00    SFDA Town Hall Meeting
YN GRAND BALLROOM A+B+C (Level 3)

2011 is the first year of the 12th 5-year-plan in China. Aligning with continuous effort of health care system reform, SFDA will share the major achievements in 2010 and the agency strategy for 2011.

MODERATOR
SFDA (Moderator Invited)

SFDA (Panelists Invited)

10:00 – 10:30    REFRESHMENT BREAK

Receive Deep Discounts on ALL DIA Educational Offerings!

For RMB 880 you can take advantage of all the benefits of membership.

- Subscription to the Drug Information Journal, DIA’s peer-reviewed, scholarly journal
- Subscription to the Global Forum
- Subscription to ePublications, including timely FDA and regulatory updates delivered to your inbox
- Subscription to the Contract Service Organization Directory
- Member registration discounts on all conferences and Annual Meetings, training courses, and webinars
- Access to our comprehensive online career center
- Career development and networking opportunities through DIA Connex and as a member of Special Interest Area Communities (SIACs)
- Members-only searchable index of DIA articles
- Opportunities to join committees and to volunteer as a speaker, session chair, or author
- Discounts on industry products and services

For more information, visit www.diahome.org and click on Membership.
## TRACK 1
### Clinical Research and Drug Safety

### Session T 1-1
**Quality – Core in Clinical Research and Drug Safety**

**Co-Chairpersons**
- **Hannah CHEN, MD**
  Clinical QA Regional Manager, AP, Glaxo-SmithKline
- **GUO Xiaojun, PhD**
  Safety Manager, Patient Safety, AstraZeneca China

**Inspection Findings Around Source Document In Clinical Trials**
- **Byungja MARCIANTE**
  Senior Assistant Director, US FDA Shanghai Office, China

**Serious Adverse Event Reporting in Clinical Trials - Great Expectations**
- **ZHANG Lin**
  Medical Director, Patient Safety AstraZeneca USA

**Panel Discussion:**
- Challenges in conducting clinical trials in China
- Source of documents and data quality
- Safety information reconciliation between clinical and safety databases

**Panelists**
- **Lois HONG, MD**
  GCP QA Auditor, R&D Beijing Hub, Merck Serono China
- **ZHANG Wen, MD**
  Internal Medicine, Cancer Hospital, CAMS & PUMC
- **WANG Yuhong, MD**
  Drug Safety Manager, Safety Operation, Roche Product Development in Asia Pacific
- **Michelle YANG**
  Senior Clinical Research Associate, AstraZeneca China
- **CHEN Rui, MD**
  Senior Clinical Research Associate, Pfizer Pharmaceutical

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## TRACK 2
### Regulation, Development & Practices

### Session T 2-1

**Chairperson**
- **LI Ning, PhD**
  Senior Group Director, Medical Policy, sanofi-aventis, China

**SFDA (Speaker Invited)**

**PFDA (Speaker Invited)**

**Center for Certificate of Drugs, SFDA (Speaker Invited)**

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## TRACK 3
### Data Management and Statistics

### Session T 3-1
**Regulatory Guidelines and International Data Standards with Regard to Computerized Systems**

**Chairperson**
- **Daniel LIU, PhD**
  Director, China Development, Medidata Solutions Worldwide

**A Newly Published GCP Guideline: Computerized Systems in Clinical Research**
- **Earl HULIHAN**
  Senior Vice President, Regulatory Affairs, Medidata Solutions, Inc.

**Foundation And Strategy Of E-Clinical Practice: Computerized Systems Validation In The E-System’s Life-Cycle**
- **Kim NITAHARA**
  Principal Consultant and CEO, META Solutions, Inc.

**Data Management in Clinical Studies – Regulatory Perspective**

**Center for Certificate of Drugs, SFDA (Speaker Invited)**

**Panel Discussion**
## Conference Agenda

### CONFERENCE DAY 2 | TUESDAY, MAY 17

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<td>Capability &amp; Capacity Building, Clinical Development</td>
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### TRACK 4

**Session T 4-1**

**Quality and CMC Vendor Qualification**

**Chairperson**

John HU, PhD  
Vice President, International General Manager, USP-China

**Pharmaceutical Reference Standards: Overview and Role in Global Harmonization**

Matthew BORER, PhD  
Advisor, Eli Lilly and Company, USA

**Evaluation and Qualification of Contract Research Organizations (CRO) – an Analytical Perspective**

Joan RUAN, PhD  
Associate Director, Analytical Development, Bristol-Myers Squibb, USA

**Building a Quality Mindset with Your Partner to Manufacture Safe Clinical Materials**

Hung Chih CHANG, PhD  
Director, Pharmaceutical Science R&D, Lilly Research Laboratories, Eli Lilly and Company, USA

### TRACK 5

**Session T 5-1**

**Phase I Capability, Crossing the Chasm - Reshape Your Clinical Development Strategy in China**

**Chairperson**

Frank JIANG, MD, PhD  
Vice President, Global R&D and Head Asia Pacific R&D, sanofi-aventis, China

**Building A Quality Phase I Study Site In China**

Jack XU  
Senior VP, Shanghai Clinical Research Center

**Capability And Capacity For Early Phase Development - CRO Perspective**

ZHANG Dan, MD, MPH  
Chairman & CEO, Fountain Medical Development Ltd.

### TRACK 6

**Session T 6-1**

**What is MA/SA, its Role & Responsibility in Biopharmaceutical Value Chains and Transferring Scientific Data into Patient Centric Medical Practices**  
**Co-Chairpersons**

GU Zheng, MD  
Senior Medical Director, sanofi-aventis, China

Min IRWIN, MD, PhD  
Medical Director, Bayer China

**Overview of Medical & Scientific Affairs in Life Cycle Management & Medical Marketing**

Avery Basil INCE  
Medical Director, Merck, China

Richard NIEMAN, MD  
Head of Global Medical Affairs Asia, Bayer Healthcare Global R&D Center

**Regulation Update and Trends**

- SOX  
- Legal and Compliance

**Katherine WANG**

China Strategic Advisor, Sidley Austin LLP

**Clinical Diagnosis Path**

JIAO Yahui  
Director, Medical Management Division, Ministry of Health, China
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<td>Regulation, Development &amp; Practices</td>
<td>Data Management and Statistics</td>
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**Session T 1-2**

**Case Study: How to Improve Source Documents to Meet GCP Requirements?**

**Co-Chairpersons**
- Hannah CHEN, MD  
  CQA Regional Manager, AP, GlaxoSmithKline
- GUO Xiaojun, PhD  
  Safety Manager-Patient Safety  
  AstraZeneca China

**Panel Discussion**

- Verification of subject eligibility according to protocol requirements - what source document we must have
- Clear Definition of SAE (Death as outcome, disease progression)
- Clear instruction of SAE management

**Panelists:**
- Lois HONG, MD  
  GCP QA Auditor, R&D Beijing Hub, Merck Serono China
- Wen ZHANG, MD  
  Cancer Hospital, CAMS & PUMC
- WANG Yuhong, MD  
  Drug Safety Manager, Safety Operation, Roche Product Development in Asia Pacific
- Michelle YANG  
  Senior Clinical Research Associate, AstraZeneca
- ZHANG Lin  
  Medical Director, Patient Safety AstraZeneca USA
- CHEN Rui, MD  
  Senior Clinical Research Associate, Pfizer Pharmaceutical

**Session T 2-2**

**The Progress of New Drug R&D Technical Guidelines Development in China**

**Chairperson**
- Janet LV  
  Head of Regulatory in Asia Pacific, Product Development in Asia Pacific, Shanghai Roche Pharmaceuticals Ltd.

**SFDA (Speaker Invited)**

**Center for Drug Evaluation, SFDA (Speaker Invited)**

**Maggie CHANG**  
Director, Drug Regulatory & Medical Affairs, China Association of Enterprises with Foreign Investment

**Session T 3-2**

**Implementing Data Quality Measures That Integrate People, Process and Technology**

**Chairperson**
- Joanne LIU  
  Regional Director, Asia Pacific Data Management Center, Global Data Management & Standards, Merck & Co. Inc., China

**Panel Discussion and Q&A**

**A Winning Strategy on Data Quality - Putting the Right Pieces Together**

**Jessie CHEN**  
Head of Global Clinical Data Services, Pfizer (China) Research & Development Co., Ltd.

**Data Manager’s Role in Data Quality and KPI for Data Management Process**

**Joyce LAI**  
Manager, Global Data Operations Asia Pacific, Merck Sharp & Dohme (Shanghai) Pharmaceutical Consultancy Co., Ltd.

**Enhancing the CRO-Sponsor Collaboration to Ensure High Quality of Clinical Data**

**Charles YAN**  
Senior Director, Clinical Data Management, Shanghai Clinical Research Center (SCRC)

**Panel Discussion and Q&A**

**15:00 – 15:30 REFRESHMENT BREAK**
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<td>Standards and Pharmacopeia</td>
<td>Has China Delivered Its Promises For Global Pivotal Studies? Strategy, Gap Analysis and Recommendations</td>
<td>Establish Practical and Effective Medical/Scientific Affairs Strategy</td>
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<td><strong>Chairperson</strong></td>
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<td>John HU, PhD</td>
<td>TAN Lingshi, PhD</td>
<td>GU Zheng, MD</td>
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<tr>
<td>Vice President, International General Manager, USP-China</td>
<td>General Manager Pfizer(China) R&amp;D Co., Ltd. China</td>
<td>Senior Medical Director, sanofi-aventis china</td>
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<tr>
<td><strong>How To Strengthen The Interactions Between Standard-Setting Organizations And Stakeholders</strong></td>
<td><strong>Growing market potential and abundance in patients needing medical breakthroughs in China have driven the number of international multi-centered trials in China to triple in 2009 over 2008. Numbers aside, what has kept the country from becoming a dominant player for first-in-kind pivotal trials? Where are the limiting factors and how are the problems addressed?</strong></td>
<td><strong>Plavix® Life Cycle Management: A Long Road To Success</strong></td>
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<tr>
<td>Chinese Pharmacopoeia Commission, SFDA (Speaker Invited)</td>
<td>The Session Under Development</td>
<td><strong>Closing The Gap Between Clinical Practice And Guideline- Learning From Cpcs</strong></td>
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<td>EDQM (Speaker Invited)</td>
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<td><strong>Dominique ROOME, MD</strong></td>
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<td>USP and Its Standard Setting Activities</td>
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<td>Associate Vice President, Strategic Mature Products/PCS - Global Operations, sanofi-aventis, France</td>
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<tr>
<td>John HU, PhD</td>
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<td><strong>GAO Runlin, MD, Professor</strong></td>
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<tr>
<td>USP-China</td>
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<td>Senior Medical Director, Fuwai Cardiovascular Hospital, Chinese Academy of Medical Sciences</td>
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<td><strong>WHO Activities for Manufacture and Regulation of Medicines in China</strong></td>
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<td><strong>Working with Marketing and Clinicians on Evidence-based Medical-Marketing Communication: Post Marketing Study and Data Assembling</strong></td>
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<td>Milan SMID, MD, PhD</td>
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<td><strong>LI Huafei</strong></td>
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<tr>
<td>Technical Officer, Quality Assurance &amp; Safety of Medicines, World Health Organization</td>
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<td>Medical Liaison Manager, AstraZeneca China</td>
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## TRACK 1
### Clinical Research and Drug Safety

**Session T 1-3**

**Operational Excellence**
- Operational Excellence to Improve Trial Conduction Efficiency
- The Fundamental Elements of Clinical Safety Operational Excellence – A Good Safety System (Including Database and Workflow Management, Etc.).
- Efficient Collaboration Among Sponsors, CROS and Investigators/Sites

**Chairperson**
Jessica LIU, MD
Senior Director, Clinical Operations, Head of Asia-Pacific, Global Clinical Operations, INC (Beijing) Medical Technology Co., Ltd.

**TOPIC (TBD)**
CAI Yan, MD, PhD
Director, Clinical Operations, Novo Nordisk International Operation Clinical Development Center

**TOPIC (TBD)**
Conny MO, MD
Head of US Drug Safety Unit, Safety Evaluation and Reporting, Worldwide Safety & Regulatory Operations, Pfizer (China) Research & Development Co., Ltd.

**DEBATE**
- **DEBATE FACILITATOR:**
  XU Ning, MD, MBA
  Executive Director, Head of Clinical Development Service, Covance
- **TEAM 1 LEADER:**
  Jessica LIU, MD
  INC (Beijing) Medical Technology Co., Ltd.
- **TEAM 2 LEADER:**
  CAI Yan, MD, PhD
  Novo Nordisk

## TRACK 2
### Regulation, Development & Practices

**Session T 2-3**

**Variation Management During Drug Development**

**Chairperson**
Wendy YAN, MD, MBA
Global Regulatory Strategist, Global Regulatory Affairs Asia, Bayer Healthcare Global R&D Center

**Center for Drug Evaluation, SFDA (Speaker Invited)**

The Dilemma and Difficulties in China on Both Clinical Protocol Variation and CMC Variation During the Review in CDE and after the SFDA Approval

Janet LV
Head of Regulatory in Asia Pacific, Product Development in Asia Pacific, Shanghai Roche Pharmaceuticals Ltd.

The Regulations and Regulatory Practices on Variations - US & EU Perspectives

**Alberto GRIGNOLO, PhD**
Corporate Vice President, Global Strategy and Services of PAREXEL International

## TRACK 3
### Data Management and Statistics

**Session T 3-3**

**Data Monitoring and Adaptive Designs: Is China Ready?**

**Chairpersons**
Roger QU, PhD
Senior Director, Department of Statistics, Pfizer (China) Research and Development Center

**LUO Zhen, PhD**
Associate Director, Clinical Statistics, Pfizer (China) Research and Development Center

**DMC from Inside**
Irving HWANG, PhD
President, Irving Consulting Group (ICG)

**MC and Adaptive Designs: Regulatory Perspective**

FDA (Speaker Invited)

**DMC in China**
YAO Chen, Professor
Vice Director, Peking University Clinical Research Institute, Head of Department of Biostatistics, Peking University First Hospital, China
## TRACK 4
**CMC/GMP**
**Drug Standard and Quality**

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**CO-CHAIRPERSONS**

- **GUI Min, PhD**
  Director, CMC AP and China CMC & Operation, Global Regulatory Science, Bristol-Myers Squibb

- **Cheng (Charles) TONG, PhD**
  Director, Global CMC, Pharma Therapeutics Pharmaceutical Sciences, Worldwide Research and Development, Pfizer Inc.

**Center for Drug Evaluation, SFDA (Speaker Invited)**

**Drug Development Utilizing QbD**

- **GUI Min, PhD**
  Bristol-Myers Squibb

**Practical Considerations for Implementation of Real Time Release Testing (RRTT)**

- **Cheng (Charles) TONG, PhD**
  Pfizer Inc.

**Joint Inspection/Continuous Verification**

- **LI Chi**
  Technical Manager, GSK (Tianjin) Co., Ltd.

<table>
<thead>
<tr>
<th>Chairperson</th>
<th>Speaker Invited</th>
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</table>
| **Michael IBARA**
Senior Director, Operational Excellence, Worldwide Safety and Regulatory Operations, Pfizer Inc. |  |  |

<table>
<thead>
<tr>
<th>Chairperson</th>
<th>Overview of the QbD Principles Introduced in ICHQ8, and Implementation of QbD in China</th>
</tr>
</thead>
</table>
| **GUI Min, PhD**
Director, CMC AP and China CMC & Operation, Global Regulatory Science, Bristol-Myers Squibb |  |

<table>
<thead>
<tr>
<th>Chairperson</th>
<th>Practical Considerations for Implementation of Real Time Release Testing (RRTT)</th>
</tr>
</thead>
</table>
| **Michael IBARA**
Pfizer Inc. |  |

<table>
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<tr>
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<th>What We Can Learn from TCM and Its Theory for the Oncology Clinical Development and Evaluation of Chemical and Biologics Aiming to Improving Quality of Life</th>
</tr>
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</table>
| **PENG Jian, MD, Associate Professor**
Clinical Research Director, AP Expansion/Life Cycle Management of AP R&D, sanofi-aventis (Former Director, Division 9, CDE SFDA) |  |

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| **PENG Jian, MD, Associate Professor**
sanofi-aventis, China |  |

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<th>Traditional Chinese Medicines (TCM) Development – What We Can Learn?</th>
</tr>
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</table>
| **PENG Jian, MD, Associate Professor**
sanofi-aventis, China |  |

## TRACK 5
**Capability & Capacity Building, Clinical Development**

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<thead>
<tr>
<th>Session T 5-3</th>
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<tbody>
<tr>
<td>Modernize Clinical Development through New Technology</td>
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</tr>
</tbody>
</table>

**Chairperson**

- **Stephen MCHALE**
  CEO, Explorys, USA

**Michael IBARA**
Pfizer Inc.

**Speaker Invited**

## TRACK 6
**Medical and Scientific Affairs**

<table>
<thead>
<tr>
<th>Session T 6-3</th>
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</table>

**CO-CHAIRPERSONS**

- **GU Zheng, MD**
  Senior Medical Director, sanofi-aventis, China

- **Min IRWIN, MD, PhD**
  Medical Director, Bayer China

**Publication and DA: From Concept, Strategy, Resource Planning, Execution and Communication**

- **Joyce Li**
  VP Medical, NovaMed Pharma

**Building Diversified Medical Deliverables**

- **Wilbur LIU**
  Assistant Director, Medical Excellence Function Head, S-A Medical Affairs, sanofi-aventis

**Establish A-Player Team**

- **Jane LIN**
  Medical Director, Baxter China

**Outcomes Research Impact In Medical Practices**

- **ZHANG Danyi, MD**
  CMO of Vital Strategic Research Institute

**ROUNDTABLE DISCUSSION**

**Operational Excellence-Debate and Group Discussion of Specific Cases**

**Facilitator**

- **GU Zheng, MD**
  Senior Medical Director, sanofi-aventis, China
## Conference Agenda

### CONFERENCE DAY 3 | WEDNESDAY, MAY 18

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<tr>
<th>Time</th>
<th>Parallel Track</th>
<th>Track 1: Clinical Research and Drug Safety</th>
<th>Track 2: Regulation, Development &amp; Practices</th>
<th>Track 3: Data Management and Statistics</th>
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<tbody>
<tr>
<td>8:30 – 10:00</td>
<td></td>
<td>Session T 1-4 IRB/IEC Practices and Issues in China</td>
<td>Session T 2-4 The Regulatory Requirement and Practice of ANDA in the USA</td>
<td>Session T 3-4 Adopting CDISC Standards and Improving Data Quality</td>
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<tr>
<td>10:00 – 10:30</td>
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<td>REFRESHMENT BREAK</td>
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</tbody>
</table>

**Track 1: Clinical Research and Drug Safety**

**Session T 1-4**

**IRB/IEC Practices and Issues in China**

**Co-Chairpersons**
- **Paul DAI, MD**
  Senior Director, Regional Head of ICRO AMAC & Greater China Region, Beijing Novartis Pharma Co., Ltd., China
- **MAO Yimin, Professor**
  Dept. of Gastroenterology, Renji Hospital Shanghai Jiao Tong University; School of Medicine, Shanghai Institute of Digestive Disease

**Panel Discussion**

What is the Impact of the Newly Issued IRB/IEC Guideline?

**Panelists:**
- **LIU Haitao, MD**
  Clinical Research Institute, Peking University
- **XIONG Ningning**
  Jiangsu Provincial Hospital of Traditional Chinese Medicine
- **Eva YANG**
  Head of Clinical Operations of Asia Pacific, Bayer Healthcare

**Track 2: Regulation, Development & Practices**

**Session T 2-4**

The Regulatory Requirement and Practice of ANDA in the USA

**Chairperson**
- **LI Ning, PhD**
  Senior Group Director, Medical Policy, sanofi-aventis, China
- **FDA (Speaker Invited)**
- **(Speaker Invited)**
  Zhejiang Hisun Pharmaceutical Co., Ltd

The Experience Of Filing And Obtaining ANDA In The USA

**Chairperson**
- **Jack ZHENG**
  Chief Executive Officer & President, eVe-nus Pharmaceutical laboratories, Inc

**Track 3: Data Management and Statistics**

**Session T 3-4**

Adopting CDISC Standards and Improving Data Quality

**Chairperson**
- **Rachel YANG, MD, PhD**
  Director, Product Strategy, Health Sciences Global Business Unit, Oracle Corporation

Practical Use of CDISC Standards: Today and Tomorrow

**Wayne KUBICK**
  Senior Director, Product Strategy, Oracle Health Sciences Global Business Unit, CDISC Board of Director

CDISC Protocol Representation

**Claire TAN**
  Senior Director, Biostatistics, Quintiles Medical Development (Shanghai) Co., Ltd. Beijing Branch
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<tr>
<td>CMC/cGMP</td>
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<tr>
<td>Drug Standard and Quality</td>
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</table>

**Session T 4-4**

US FDA CMC/GMP New Guidance and Hot Topics

**Chairperson**

Chi-wan CHEN, PhD  
Executive Director, Global CMC, Pfizer  
Member of FDA Alumni Association

**PANEL PRESENTATION AND CASE STUDY**

Guidance on CMC for Phase 1 and Phase 2/3 Investigational New Drug Applications (INDs)  
Chuck HOIBERG, PhD  
Executive Director, Pfizer, USA  
Member of FDA Alumni Association  

Process Validation Guidance: A Life Cycle Approach  
Mark TUCKER, PhD  
Senior Technical Director, Roche/Genetech, USA; Member of FDA Alumni Association

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>QA/QC in Clinical Development, Regulatory Requirements and Practices</td>
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</tbody>
</table>

**Session T 7-1**

Regulatory Agency’s Efforts to Ensure Quality Execution of Clinical Research Globally

**Chairperson**

Hannah CHEN, MD  
CQA Regional Manager, AP, GlaxoSmithKline

SFDA Inspection & Certification Program  
SFDA (Speaker Invited)

US FDA Inspection Program and Common Findings in Asia  
Byungja MARCIANTE  
Senior Assistant Director, US FDA Shanghai Office, China
# Conference Agenda

**CONFERENCE DAY 3 | WEDNESDAY, MAY 18 (continued)**

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<tbody>
<tr>
<td><strong>TRACK 1</strong></td>
<td><strong>TRACK 2</strong></td>
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<tr>
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<td><strong>Regulation, Development &amp; Practices</strong></td>
</tr>
<tr>
<td>session T 1-4 (continued)</td>
<td>session T 2-5</td>
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</tbody>
</table>

**Chairperson**

**SU Ling, PhD**
Senior Vice President, Head of Development Greater China, Beijing Novartis Pharma Co., Ltd., China

**SFDA (Speaker Invited)**

**PMDA (Speaker Invited)**

**KFDA (Speaker Invited)**

**Panel Discussion**

Efficient and high-quality site management
- Study site management
- Investigator’s responsibilities
- Site resource management
- Management of clinical research center
- Clinical research coordinator

**LJ Haiyan, MD, Professor**
Director, Drug Clinical Trial Center, Peking University Third Hospital, China; Vice Director, Peking University Clinical Research Institute

**Hannah CHEN, MD**
Clinical QA Regional Manager, AP, GlaxoSmithKline

**Grace WU**
Head of Clinical Operations, Pfizer (China) Research & Development Co., Ltd.

**HONG Minghuang, Professor**
Cancer Center, Sun Yat Sen University

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**CONFERENCE DAY 3 | WEDNESDAY, MAY 18 (continued)**

| 12:00 – 13:30 | LUNCH |
## Conference Agenda

### Conference Day 3 | Wednesday, May 18 (continued)

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<td>TRACK 7</td>
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<td><strong>Drug Standard and Quality</strong></td>
<td><strong>Session T 7-1 (Continued)</strong></td>
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<td><strong>Session T 4-4 (Continued)</strong></td>
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<td>Executive Director, Global CMC, Pfizer</td>
<td>MHRA Inspection Program</td>
</tr>
<tr>
<td>Member of FDA Alumni Association</td>
<td>Gerald HEDDELL</td>
</tr>
<tr>
<td><strong>PANEL PRESENTATION AND CASE STUDY</strong></td>
<td>Director, Inspection, Enforcement and Standards Division, UK</td>
</tr>
<tr>
<td><strong>Question-Based Review of Abbreviated New Drug Applications (ANDAs)</strong></td>
<td><strong>PANEL DISCUSSIONS</strong></td>
</tr>
<tr>
<td>Chi-wan CHEN, PhD</td>
<td><strong>Preparing for Pre-Approval Inspection: It is Much More Than Audit</strong></td>
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<td>Pfizer</td>
<td>Mark TUCKER, PhD</td>
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<td>Senior Technical Director, Roche/Genetech, USA; Member of FDA Alumni Association</td>
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## Conference Agenda

### Conference Day 3 | Wednesday, May 18 (continued)

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<td>Clinical Research and Drug Safety</td>
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<tr>
<td><strong>Session T 1-5</strong></td>
<td>From Compliance to Beyond – How to Organize and Manage the Safety Data Throughout Product Life Cycle</td>
</tr>
</tbody>
</table>
| **Co-Chairpersons** | Conny MO, MD  
Head of US Drug Safety Unit, Safety Evaluation and Reporting, Worldwide Safety & Regulatory Operations, Pfizer (China) Research & Development Co., Ltd.  
Catherine XIE, MD  
Safety Evaluation and Reporting Shanghai Site Planner, Pfizer (China) Research and Development Co., Ltd. |
| **Presentation Quiz, Awards and Panel Discussion** | Overview in evolving regulatory requirements from global major HAs  
China safety regulation and implementation challenge  
Safety signal detection in professional assessment of ICSR |
| **EMA (Speaker Invited)** |  
**SFDA (Speaker Invited)** |

| **Track 2**   | Regulation, Development & Practices |
| **Session T 2-6** | The 2010 China Drug Registration Annual Report |
| **Chairperson** | Laurence HUANG  
Executive Director, Regulatory Affairs  
AstraZeneca China |
| **SFDA (Speaker Invited)** |  
**WU Zhiang, Professor**  
Shenyang Pharmaceutical University |

| **Track 3**   | Data Management and Statistics |
| **Session T 3-5** | Joint Panel Discussion: How to Ensure End-To-End Quality - A Quantitative Evaluation |
| **Co-Chairpersons** | William WANG, PhD  
Head, Asia Pacific Hub, Biostatistics and Research Decision Sciences (BARDS), Merck Research Laboratories, Merck & Co., Inc  
ZHANG Lixin  
Biometrician, Biostatistics and Research Decision Sciences (BARDS), Merck Research Laboratories, Merck & Co., Inc |
| **Panel Discussion** | The life of a data point  
Quality and integrity of data |

<p>| 15:00 – 15:30 | Refreshment Break |</p>
<table>
<thead>
<tr>
<th>TRACK 4</th>
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</table>
| **CMC/cGMP**  
**Drug Standard and Quality** | **QA/QC in Clinical Development, Regulatory Requirements and Practices** |

### Session T 4-5

**Biologics Regulations and Change Management**

**Chairperson**

Duu-Gong WU, PhD  
Executive Director, Consulting Division, PharmaNet Inc. USA  
Member of FDA Alumni Association

**TOPICS:**

- ICH Q5E biological process change
- Biotech comparability
- Biosimilars

Center for Drug Evaluation, SFDA (Speaker Invited)

David LIN, PhD  
BCG Consulting  
Member of FDA Alumni Association

### Session T 7-2

**Regulatory Agency, Industry and Institution’s Efforts to Ensure Quality Execution of Clinical Research in China, Japan and Korea**

**Chairperson**

Spring WANG, MD  
Senior Medical Director, Asia Pacific, Cephalon

KFDA Inspection Program for Quality and Compliance Efforts  
KFDA (Speaker Invited)

PMDA (Speaker Invited)

**QA Management at Institutions/Hospitals**

Li Haiyan, MD, Professor  
Director, Drug Clinical Trial Center, Peking University Third Hospital, China; Vice Director, Peking University Clinical Research Institute
## Conference Agenda

**CONFERENCE DAY 3 | WEDNESDAY, MAY 18 (continued)**

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<td><strong>Session T 2-7</strong></td>
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<td>From Compliance to Beyond – How to Organize and Manage the Safety Data throughout Product Life Cycle</td>
<td>Standardization and Internationalization of Traditional Chinese Medicines (TCM) R&amp;D</td>
</tr>
<tr>
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<td><strong>Chairperson</strong></td>
</tr>
<tr>
<td>Conny MO, MD</td>
<td>YE Zuguang</td>
</tr>
<tr>
<td>Head of US Drug Safety Unit, Safety Evaluation and Reporting, Worldwide Safety &amp; Regulatory Operations, Pfizer (China) Research &amp; Development Co., Ltd.</td>
<td>Director, China Academy of Chinese Medical Sciences</td>
</tr>
<tr>
<td>Catherine XIE, MD</td>
<td><strong>SFD (Speaker Invited)</strong></td>
</tr>
<tr>
<td>Safety Evaluation and Reporting Shanghai Site Planner, Pfizer (China) Research and Development Co., Ltd.</td>
<td>Center for Drug Evaluation, SFD (Speaker Invited)</td>
</tr>
<tr>
<td><strong>PRESENTATION</strong></td>
<td><strong>China TCM Standardization and Modernization</strong></td>
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<tr>
<td><strong>QUIZ, AWARDS AND PANEL DISCUSSION</strong></td>
<td><strong>Henry SUN, PhD</strong></td>
</tr>
<tr>
<td>• Overview in evolving regulatory requirements from global major HAs</td>
<td>Group Vice-President, Tasly Pharmaceuticals, Inc.</td>
</tr>
<tr>
<td>• China safety regulation and implementation challenge</td>
<td><strong>FDA (Speaker Invited)</strong></td>
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<td><strong>Ethnicity and Drug Development in China</strong></td>
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<td></td>
<td>HU Pei, PhD</td>
</tr>
<tr>
<td></td>
<td>Professor and Director, Clinical Pharmacology Research Center, Peking Union Medical College Hospital, China</td>
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17:30 **CONFERENCE ADJOURNED**
### TRACK 4
**CMC/cGMP**  
**Drug Standard and Quality**

### TRACK 7
**QA/QC in Clinical Development, Regulatory Requirements and Practices**

<table>
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| **Chairperson** Duu-Gong WU, PhD  
Executive Director, Consulting Division, PharmaNet Inc. USA  
Member of FDA Alumni Association |
| **Duu-Gong WU, PhD**  
Executive Director, Consulting Division, PharmaNet Inc. USA |
| **Mark ROSOLOWSKY, PhD**  
VP, Global Research Science-CMC, Bristol-Myers Squibb |

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| **Chairperson** Spring WANG, MD  
Senior Medical Director, Asia Pacific, Cephalon |
| **Quality Risk Management** |
| **Karen J. ATKIN, MD**  
Vice President, Research and Development, AstraZeneca China |
| **A Road to Quality Assurance** |
| **Helen LI**  
Emerging Market Asia Lead, Pfizer Medical Quality Assurance |

**PANEL DISCUSSION**