Asia Regulatory Conference 2013
Regulatory Convergence and Cooperation
to Improve Access and Quality
January 28-30, 2013 | Raffles Convention Centre | Singapore

PROGRAM COMMITTEE CHAIRS
Mr. Arun Mishra
Senior Director, Global Regulatory Affairs
GlaxoSmithKline, UK

Associate Professor
John C. W. Lim, MD, SM, MSc
Chief Executive Officer
Health Sciences Authority, Singapore

PROGRAM COMMITTEE MEMBERS
Ms. Eileen Ang
Head Regulatory Affairs, Asia Pacific
GlaxoSmithKline, Singapore

Patrick Brady, PharmD
Science and Regulatory Affairs
PhRMA, United States

Raymond Chua, MD, MBA, MPH, FRCP
Group Director, Health Products
Regulation Group
Health Sciences Authority, Singapore

Mr. Alistair Davidson
Senior Director, Global Regulatory Development, Asia Pacific
PPD, UK

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Deputy Director General,
Department of International Cooperation
SFDA, China

Professor Bruno Flamion
Professor of Physiology and Pharmacology
University of Namur, Belgium

Alberto Grignolo, PhD
Corporate Vice President
PAREXEL Consulting, United States

Kurajiro Kishi, DVM, PhD
Director, Global Scientific and Regulatory Affairs
JPMA, Japan

Cordula Landgraf, RPh
Head of Networking
Swissmedic, Switzerland

Ms. Stephanie Lane
Director, International Government Affairs
EFPIA, Belgium

OVERVIEW
Join health authority representatives and industry professionals from Asian and ICH member countries as they continue to discuss regulatory aspects of ICH, APEC and ASEAN convergence initiatives, good regulatory practices, quality and GMP, global drug development, and pharmacovigilance.

OBJECTIVES
This three-day conference offers a unique opportunity for key stakeholders from health authorities, local and multinational pharmaceutical companies, and clinical research to meet and exchange views, discuss topics of interest and identify focus areas for ongoing efforts to increase patient access to new and improved medicines. This conference will provide a forum to:

• Facilitate discussion on common issues in the regulatory and technical areas in Asia
• Encourage greater convergence of regulatory requirements in Asia
• Strengthen cooperation between Asian regulatory authorities and pharmaceutical industry

Conference speakers will include top-level regulatory authorities from several Asian countries as well as leading experts in the ICH process. In addition, speakers will include representatives of various regulatory agencies from other regions and the multinational and local pharmaceutical industry.

WHO SHOULD ATTEND
Representatives of Health Authorities, Regulatory Affairs professionals, and other professionals involved in or interested in the aspects surrounding registration of medicinal products and regulatory convergence initiatives in Asia.

In particular professionals involved in:
• Ministries of Health and Medicines Regulatory Authorities
• Regulatory Affairs
• Clinical Research and Development
• Safety and Pharmacovigilance
• Clinical Trial and Project Management
• CMC/Quality (Quality, Manufacturing and Controls)

Co-organized by:
DIA is a neutral, nonprofit, global professional association of nearly 18,000 members who work in every facet of the discovery, development, and life cycle management of pharmaceuticals, medical devices, and related products.

IFPMA represents the research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry’s 1.3 million employees research, develop and provide medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

The Health Sciences Authority (HSA) is a statutory board of the Singapore Ministry of Health consisting of three Professional Groups: the Applied Sciences Group, the Blood Services Group and the Health Products Regulation Group. Its vision is to be the leading innovative authority protecting and advancing national health and safety.

The organization serves three key functions: It is the national regulator for health products; it secures the national blood supply through its operation of the national blood bank - Bloodbank@HSA; and it represents the national expertise in forensic medicine, forensic science and analytical chemistry testing capabilities. These support other regulatory and compliance agencies in the administration of justice and in safeguarding public health.
DAY ONE: RESEARCH AND DEVELOPMENT

7:30–8:30 AM  BREAKFAST AND ATTENDEE REGISTRATION

9:00–9:30 AM  OPENING CEREMONY

Welcome from Drug Information Association (DIA)
Ling Su, PhD
Strategic Advisor, Life Sciences
Sidley Austin LLP, China
President, DIA Board of Directors

Welcome from the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and Japan Pharmaceutical Manufacturers Association (JPMA)
Mr. Toshiaki Miyoshi
Managing Director, JPMA, Japan

Program Chairpersons Opening Remarks
Mr. Arun Mishra
Senior Director, Global Regulatory Affairs
GlaxoSmithKline, UK

Welcome Remarks by Guest of Honour
Amy Khor, PhD
Minister of State of the Ministry of Health and the Ministry of Manpower
Singapore

9:30–10:30 AM  Regulators and Industry Working Together to Have Safer and Better Access to Medicine

Associate Professor John C. W. Lim, MD, SM, MSc
Chief Executive Officer, Health Sciences Authority (HSA), Singapore

Ms. Barbara J. Sabourin
Acting Director General, Therapeutic Products, Health Canada

10:30–11:00 AM  BREAK

11:00 AM–12:00 PM  Path to the Future: Status and Future of Research and Development

SESSION CHAIRPERSON
Yves Juillet, MD
DIA Board President
Senior Vice-President, Industrie Sante, France

Science is constantly moving forward. Implementing these new concepts or even creating them in drug Research and Development is key. It implies for Regulatory Authorities and Industry researchers a permanent adaptation to these new paradigms thanks to the development of Regulatory Science.

Murray M. Lumpkin, MD, MSc
Commissioner’s Senior Advisor and Representative for Global Issues
Immediate OC

Dr. James Garner
Vice President & General Manager
Takeda Global Research & Development Center (Asia)
Singapore

12:00–1:30 PM  LUNCHEON
DAY 1 | MONDAY, JANUARY 28, 2013 (continued)

1:30–3:00 PM

Asia's Role in Drug Development: A Global and Regional Perspective

SESSION CHAIRPERSONS

Romi Singh, PhD
Executive Director, Global Regulatory Affairs and Safety
Amgen Inc., United States

Tomas Salmonson, PhD
Chairman CHMP
Medical Products Agency (MPA), Sweden

Historically, drug registrations in Asia followed, and to a large extent depended on, the Western drug development. However, over the recent years, there has been an increasing trend of Asia becoming a hub of global drug innovation and development. This session will discuss how Asia contributes to the global drug development and provide examples of how data generated primarily in Asia is used for registration in the West (US, EU).

Contribution of Asia in Execution of Global Clinical Trials

Yoshimasa Shimoto, PhD
Vice President, Asia Development (Region Head)
Daiichi Sankyo Co., Ltd., R&D Division
Japan

Asia's Role in Drug Development - an European Perspective

Tomas Salmonson, PhD
Chairman CHMP
Medical Products Agency (MPA), Sweden

3:00–3:45 PM BREAK

3:45–5:15 PM

Asia's Role in Drug Development: A Global and Regional Perspective - continued

Joseph C. Scheeren, PharmD
Senior Vice President, Head Global Regulatory Affairs
Bayer Healthcare Pharmaceuticals, United States

Innovative R&D Approaches: Opportunities in Asia

Jogarao V. Gobburu, PhD
Professor, School of Pharmacy and School of Medicine
University of Maryland, United States

Asian Collaboration of Safety Biomarker Qualification Activity in Near Future

Ms. Etsuko Usui
Manager, Regulatory Policy
Novartis Pharma K.K., Japan

DAY 2 | TUESDAY, JANUARY 29, 2013

DAY TWO: THEME – GOOD REGULATORY PRACTICES

7:30–8:30 AM BREAKFAST AND ATTENDEE REGISTRATION

9:00–10:45 AM

Global Review Practices: Industry & Regulatory Working Together

SESSION CHAIRPERSONS

Cordula Landgraf, RPh
Head of Networking
Swissmedic, Switzerland

Steven K. Galson, MD, MPH
VP Global Regulatory Affairs
Amgen Inc., United States

“Coming Together is a Beginning, Keeping Together is Progress, Working Together is Success” (Henry Ford). In this sense, the session will look at how Industry and Regulatory already work together and what could be done by both sides in terms of effective and efficient review processes to further strengthen and improve this cooperation. Is the model of work sharing between Regulatory Agencies the way to enable effective resource utilization to finally streamline approval? And how could the review process evolve to balance early access to new drugs with the need for comprehensive data?

Elements of an Effective and Efficient Review Process from an Agency Point of View

Ms. Dato' Eisah A. Rahman
Senior Director of Pharmaceutical Services
Ministry of Health Malaysia
Malaysia

How Does Industry See the Review Process Evolving to Address the Needs of Tomorrow?

Paul Huckle, PhD, MPharm, RPh
Chief Regulatory Officer & Senior Vice President
Global Regulatory Affairs
GlaxoSmithKline, United States


Professor Stuart Walker
Founder, Centre For Innovation in Regulatory Science (CIRS)
United Kingdom

Results of APEC GRP Project

Ms. Chao-Yi Wang
Deputy Director, Division of Drug and New Biotechnology Products
Food and Drug Administration, TFDA
Chinese Taipei

10:45–11:15 AM BREAK

5:30–7:00 PM WELCOME RECEPTION
Global CMC Reviews: Challenges and Opportunities

**SESSION CHAIRPERSON**

Dra. Lucky Slamet  
Head, National Agency of Drug and Food Control  
Indonesia

Chi-wan Chen, PhD  
Executive Director, Global CMC  
Pfizer Inc  
United States

This session will discuss CMC challenges that are faced by the industry in obtaining a right first time approaches to securing successful filing and regulatory approval of pharmaceuticals, biological and vaccines in Asia. The session will cover not only the challenges encountered by industry but also the available opportunities for ensuring a smooth filing and approval from a regulator perspective.

Dinesh Khokal, PhD  
Regulatory Consultant, Generics and Biosimilars Branch  
Pre-marketing Division, Health Products Regulation  
Group Health Sciences Authority  
Singapore

Zhen Chen, PhD  
Deputy Office Director  
Office of New Drug Pharmaceutical Science  
CDE, SFDA  
China

Chi-wan Chen, PhD  
Executive Director, Global CMC  
Pfizer Inc  
United States

Clinical Reviews

**SESSION CHAIRPERSON**

Mark J. Goldberger, MD, MPH  
Member of FDA Alumni Association, Former Director, Office of Drug Evaluation IV, CDER, FDA, Divisional Vice President, Regulatory Policy and Intelligence, Pharmaceutical Products Group, Abbott  
United States

Participants will hear from regulators and from industry about the critical elements of a product review. How do regulators “get the most bang for their buck and what are they most likely to be looking for. There will also be a discussion of the steps that a sponsor can take to facilitate the review process.

**Role of Clinical Review in SFDA/CDE: Yesterday, Today and Tomorrow**

Mr. Yi Feng  
Director, Evaluation Management and Coordination Department, CDE SFDA, China

**How to Win the Lottery of the Review Process**

Krishna Prasad, MBBS, MD, FRCPE  
Clinical Assessor/Consultant Cardiologist, Medicines and Healthcare Products Regulatory Agency (MHRA), Licensing Division, United Kingdom

**Sound Clinical Reviews: Mind over Matter – Any Role for the Heart?**

Aamir Shaikh, MD  
Founder, Assansa, India

**Panelist**

Ning Li, MD, PhD  
Head of Asia Regional Regulatory and Medical Policy, Sanofi, China

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5TH ANNUAL MEETING  
DIA CHINA 2013

May 12-15, 2013  
Beijing, China
Biosimilars

SESSION CHAIRPERSON

Mr. Cecil J. Nick
FTOPRA, Vice President (Technical)
PAREXEL Consulting
United Kingdom

Biosimilarity is a concept first introduced into European legislation almost a decade ago to allow regulatory approval of similar biological medicines following submission of limited yet targeted data showing similarity to the reference biological product based on the totality of physico-chemical, biological, non—clinical and clinical testing. This concept has now spread across the globe with guidelines and regulations issued by all major regulatory agencies including WHO and those in US, Japan, Canada and Korea.

This session will explore various view points on the critical considerations applicable to making affordable yet safe and effective similar biological medicines available globally.

Biosimilarity and the Challenges in Designing a Global Regulatory Program

Mr. Cecil J. Nick
FTOPRA, Vice President (Technical)
PAREXEL Consulting
United Kingdom

The Regulatory Pathway of Biosimilars - From Regulatory Guidance to the Assessment of Data

Pekka Kurki, MD, PhD
Research Professor
Finnish Medicines Agency
Finland

A Global Regulatory Biosimilar Program - Rising to the Challenge

Dr. Stanley SS Hong
President of Research & Development
Celltrion Inc.
Hong Kong

Supply Chain Integrity: The Need for Global Collaboration

SESSION CHAIRPERSON

Mr. Brian Johnson
Senior Director, Supply Chain Security
Pfizer Inc
United States

Supply chain security threats to our industry are on the rise globally. Collaboration is essential between all stakeholders in the supply chain to fight these crimes. This session will explore the threats our industry faces and any trends we are seeing. We will explore the benefits of a holistic approach to the problem from different stakeholder perspectives and explore the following questions. How can manufacturers organize around these threats? How can trade organizations help facilitate industry wide collaborations? How can regulatory convergence help? What specific initiatives are mobilizing in the Asia/Pacific Region? We hope to shed some light on the problem and discuss mechanisms to prevent, detect, and respond to supply chain security threats.

Supply Chain Security from a Pharmaceutical Company Perspective

Mr. Brian Johnson
Senior Director, Supply Chain Security
Pfizer Inc, United States

Supply Chain Security

Dr. C. Michelle Limoli
Director, Harmonization and Multilateral Relations Office
Office of the Commissioner, FDA, United States

APEC Supply Chain Security Strategy

Mark Paxton, PhD, JD
Regulatory Counsel
Office of the Commissioner, FDA, United States

Supply Chain Security - the Role of an Industry Consortium

Mr. Tim Valko
Executive Director, Risk Management
Amgen, Inc., United States

ASEAN Regulator Working Group Panel Discussion

SESSION CHAIRPERSONS

Vincent I. Ahonkhai, MD, FAAP
Deputy Director, Regulatory Affairs
Integrated Development
Bill & Melinda Gates Foundation, United States

Ms. Dato’ Eisah A. Rahman
Senior Director of Pharmaceutical Services
Ministry of Health Malaysia
Malaysia

Ms. Siti Aida Abdullah
Deputy Director, National Pharmaceutical Control Bureau, Ministry of Health - Jalan Universiti, Malaysia

Mdm. Wilai Bundittanukala
Former Director, Drug Control Division Food and Drug Administration, Ministry of Public Health, Thailand

Mdm. Jamilah Metussin
Pharmacist, Department of Pharmaceutical Services, Ministry of Health, Jalan Menteri Besar, Bandar Seri Begawan, Brunei Darussalam

Hjh. Rosni Hj. Jair
Senior Scientific Officer, Drug Quality Section, Department of Pharmaceutical Services, Ministry of Health, Jalan Menteri Besar, Bandar Seri Begawa Brunei Darussalam

Ms. Soulyvanh Keokinnaly
Technical Officer, Food and Drug Department, Lao PDR

Supply Chain Security

Differences in the regulatory requirements of individual ASEAN Member States has a huge impact on economic growth, social progress, and cultural development. This panel will discuss how the ASEAN Regulator Working Group is working to eliminate technical barriers to trade posed by regulations without compromising product quality, efficacy, and safety. Panel members will highlight achievements made toward regulatory convergence through shared practices, work-sharing and transparency.
Emerging Trends

SESSION CHAIRPERSONS

Mr. Alistair Davidson
Senior Director, Global Regulatory Development, Asia Pacific
PPD
United Kingdom

Toshiyoshi Tominaga, PhD
Professor and Director
Center for Drug and Food Clinical Evaluation
Osaka City University Hospital (OCUH)
Japan

This session will oversee some upcoming topics which are likely to need serious regulatory consideration in Asia in the near future. These may be already developed to some form in other parts of the world, but are still evolving and this gives an opportunity for the regulatory authorities in Asia as well as Industry partners to start to consider how these issues can be incorporated within the ongoing regulatory timetable.

Health Technology Assessments is a key area for the near-medium term as governments and regulatory authorities strive to deliver access of the best possible healthcare products, while keeping the costs under control. Other presentations will look at emerging technical challenges which will pose questions for regulators and Industry in the region over the next few years.

Evolving the Fourth Pillar: Health Technology Assessments (HTAs) in Asia

Mr. David Grainger
Global Public Policy Director
Eli Lilly & Company, Australia

Toshiyoshi Tominaga, PhD
Professor and Director
Center for Drug and Food Clinical Evaluation
Osaka City University Hospital (OCUH)
Japan

Bringing Transparency, Quality and Predictability into the Indian Regulatory Environment - An Example of e-Governance in Gujarat State of India

Dr. H G Koshia
Commissioner, Food & Drug Control Administration
India

Overview of Regulatory Convergence in Asia

Ms. Gloria Hung
Asia Regional Regulatory Supervisor
Pfizer Inc., Hong Kong

Recent Convergence Efforts

CAPT. Justina A. Molzon, JD, MPharm
Associate Center Director for International Programs
CDER, FDA, United States

Industry’s Role in APEC RHSC

Wen Chang, PhD
Vice President, North Asia Strategy and China Regulatory Sciences
Bristol-Myers Squibb Company, China

TFDA’s View on Regulatory Convergence and Its Efforts to Implement

Ms. Chao-Yi Wang
Deputy Director, Division of Drug and New Biotechnology Products
Food and Drug Administration, TFDA
Chinese Taipei
Counterfeit Medical Products Pose a Significant Danger to Public Health

Counterfeit medical products pose a significant danger to public health in both developing and developed countries. The global nature of manufacturing and trade in medical products makes it crucial that all countries work together in a concerted effort to reduce the growing market for counterfeit medical products. In this session, three key speakers representing WHO, INTERPOL and Pharmaceutical Security Institute (PSI) will highlight their respective roles and responsibilities, as well as their efforts in combating this global problem of counterfeit medical products. Sensitivities surrounding this topic and the challenge of achieving effective collaborations among all stakeholders to achieve the common goal of protecting public health and safety will also be discussed.

INTERPOL’s Successful Model in Combating Cyber Pharmaceutical Crime

Ms. Cecelia Fant
Specialized Officer
INTERPOL
France

PSI – A Unique Ally and Key to Effective Partnerships

Mr. Thomas T. Kubic
President & CEO
Pharmaceutical Security Institute
United States

Counterfeit and Supply Chain

Mr. Mohd Hatta Ahmad
Head of Pharmacy Enforcement
Food and Drug Administration
Ministry of Public Health
Malaysia

Pharmacovigilance and Risk Management

SESSION CHAIRPERSONS

Dr. Kenneth Hartigan-Go
Director, Food and Drug Administration
Philippines

Florence Houn, MD, MPH, FACP
VP, Celgene Regulatory Policy and Strategy
FDA Alumni Association International Network, Co-Chair, United States

It is well recognized that despite rigorous pre-market regulation process, post-market surveillance is essential to ensure that the benefit/risk balance of health products remains favourable throughout the product’s life cycle. In the recent years, known or potential safety issues that require monitoring are identified prior to product registration and ways of communicating these issues to healthcare professionals and patients, as well as enhanced surveillance methods are developed. These risk mitigating strategies are presented in the form of a risk management plan, specific for each product. In this session, representatives from both regulatory agencies and the industry will share on elements of pharmacovigilance and the implementation of risk management plans.

Pharmacovigilance in Singapore

Associate Professor Chan Cheng Leng
Deputy Group Director, Health Products Regulation Group
Division Director Vigilance, Compliance, Enforcement Division
Health Sciences Authority, Singapore

Pharmacovigilance Updates in Japan and Risk Management Plans

Mr. Kosuke Haneda
Reviewer, Office of Safety II
Pharmaceuticals and Medical Devices Agency (PMDA), Japan


Ms. Liew Siew Huey
Associate Manager, Drug Safety & Epidemiology, Novartis, Singapore

Current Challenges to Cope with Risk Management of Medicines

Professor Hubert Leufkens
Professor, Utrecht University
Chair, Dutch Medicines Evaluation Board, Netherlands

Path to the Future: Regulatory Panel Discussion

SESSION CHAIRPERSON

Yves Juillet, MD
Senior Vice-President
Industrie Sante, France

The purpose of this Regulatory Panel discussion at the close of the Conference is to gain and share insights on the practical meaning and implications of regulatory convergence and cooperation among regulators for the acceleration of patient access to medicines and the protection and promotion of the quality of medicinal products. After 3 days of sessions and discussions around the main theme of the Conference, this final session will aim to envision a path to a future of greater benefit for regional global patients – recognizing both the opportunities and the remaining challenges, and possible ways to address them. Based on the discussions during first 3 days of the Conference, the Session Chair will identify 2-3 themes relevant to the Path to the Future and will solicit comments from each panelist.

Cordula Landgraf, RPh
Head of Networking
Swissmedic, Switzerland

Murray M. Lumpkin, MD, MSc
Commissioner’s Senior Advisor and Representative for Global Issues, Immediate OC

Toshiyoshi Tominaga, PhD
Professor and Director, Center for Drug and Food Clinical Evaluation, Osaka City University Hospital (OCUH), Japan

Mr. Arun Mishra
Senior Director, Global Regulatory Affairs
GlaxoSmithKline, UK

Associate Professor John C. W. Lim, MD, SM, MSc
Chief Executive Officer, Health Sciences Authority (HSA), Singapore

4:30 PM CLOSING REMARKS
REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

Asia Regulatory Conference 2013
Event #13901 • January 28-30, 2013
Raffles City Convention Centre
252 North Bridge Road
Singapore 179103

REGISTRATION RATES

<table>
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<th>Category</th>
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☐ Please indicate that this form is part of a group registration by checking this box and list below the names of the other three registrants from your company.

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TRAVEL AND HOTEL
The most convenient airport is the Changi Airport. Please visit www.diahome.org for a list of local hotels.

DIA does not have a dedicated hotel room block for this program. The Fairmont Singapore and the Swissôtel – The Stamford are the closest hotels to the Convention Center. Additional hotels are listed on the DIA website.

Singapore has many hotel options available. Should you wish to review other area hotels the Hotelopia website comes recommended. They will be happy to assist you with a reservation: www.hotelopia.com.

The Official Singapore Tourism Website is another excellent resource and will be happy to provide assistance: www.yoursingapore.com.

CANCELLATION POLICY: On or before JANUARY 21, 2013

Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200

Government or Academia or Nonprofit (Member or Nonmember) = $100

Tutorial (if applicable) = $50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for canceling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

Participants with Disabilities: Participants with Disabilities: Reasonable accommodations will be made available to persons with disabilities who attend an educational activity. Contact the DIA office in writing at least 15 days prior to event to indicate your needs.

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For event questions, please contact Ellen Diegel, Event Planner, by phone at +1.215.293.5810 or by email at Ellen.Diegel@diahome.org.

EXHIBIT INFORMATION
For event questions, please contact Jeff Korn, Exhibits Manager, by phone at +1.215.442.6184 or by email at Jeff.Korn@diahome.org.

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Degrees ☐ Dr. ☐ Mr. ☐ Ms. 

Job Title 

Company 

Address (As required for postal delivery to your location) 

City State Zip/Postal Country 

Email ☐ Required for confirmation

Phone Number Fax Number Required for confirmation