

# 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

#### Dr. Jianhua Ding

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.

*(Continued from page 1)*

## PROGRAM COMMITTEE MEMBERS

**Mr. Nobuki Sato**

Japan Liaison Executive  
IFPMA, Switzerland

**Zili Li, MD, MPH**

Executive Director and Head of Emerging  
Market Strategy & Liaison  
Merck & Co., United States

**Dr. Christina Lim-Tong**

Senior Director (International Relations),  
Health Products Regulation Group  
Health Sciences Authority, Singapore

**Larisa Nagra Singh, MPharm**

Vice President Global Functional  
Resourcing, Asia Australia  
Quintiles, Singapore

**Jerry Stewart, MD, MS, RPh**

Regulatory Policy Head, Emerging Markets  
Pfizer Inc, United States

**Mr. Adrian Waterson**

Regional Regulatory Director, Asia Pacific  
AstraZeneca, UK

**Kum Cheun Wong, PharmD**

Head, Asia Pacific Policy & Liaison, Drug  
Regulatory Affairs  
Novartis Asia Pacific, Singapore

## ADVISORY COMMITTEE

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Senior Vice-President, Industrie Sante,  
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Associate Director for International  
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Senior Director, Pharmaceutical Services  
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Ministry of Health, Malaysia

**Romi Singh, PhD**

Executive Director  
Amgen, United States

**Toshiyoshi Tominaga, PhD**

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

**Mr. Mike D. Ward**

Manager, International Programs Division  
Health Canada  
Ottawa, Canada

## 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**

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**Concept of Adaptive Licensing and Its Feasibility for a New Pathway of Drug Development From the Regional and Global Regulators' Perspectives****Raymond Chua, MD, MBA, MPH, FRCP**Group Director, Health Products Regulation Group  
Health Sciences Authority  
Singapore

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

5:30–7:00 PM WELCOME RECEPTION

**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 co-operation. 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**Is There an Internationally Acceptable Framework for Benefit Risk Assessment of Medicines That Will Engage a Regulatory and Industry Collaboration for Improved Decision-Making?****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

11:15 AM-12:30 PM BREAKOUT SESSION

**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

12:30-2:00 PM LUNCHEON

5TH ANNUAL MEETING

**DIA CHINA 2013**

May 12-15, 2013

Beijing, China



2:00–3:30 PM BREAKOUT SESSION

**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

3:30–4:00 PM BREAK

4:00–5:30 PM

**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

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.

**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

5:30 PM

END OF DAY TWO

## DAY THREE – THEME: 21ST CENTURY GLOBAL REGULATORY CHALLENGES

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

9:00–10:30 AM

**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

10:30–11:00 AM BREAK

11:00 AM–12:30 PM

**Asia Regional Update on Convergence**

SESSION CHAIRPERSON

**Mr. Jerry Stewart, JD, MS, RPh**

Regulatory Policy Head, Emerging Markets  
Pfizer Inc, United States

**Ms. Chao-Yi Wang**

Deputy Director, Division of Drug and New Biotechnology Products  
Food and Drug Administration, TFDA  
Chinese Taipei

This session will present both industry's and the regulatory authorities' views on the status of regulatory convergence in Asia. Examples of Regulatory convergence and divergence will be discussed, including recommendations on how to progress more convergence in areas such as clinical development, submission standards, risk-benefit assessments and approval time lines. Highlights from APEC RHSC, PhRMA and other organizations will help to paint a picture of the current regulatory environment and emerging topics on harmonization for attendees to consider.

**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

12:30–2:00 PM LUNCHEON

2:00–3:30 PM BREAKOUT SESSION

**Counterfeit**

SESSION CHAIRPERSONS

**Ms. Ruth Lee**

Director, Enforcement Branch  
Health Products Regulation Group  
Health Sciences Authority  
Singapore

**Mr. Raymond Velez**

Regional Security Manager  
Eli Lilly and Co.  
Singapore

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

**New EU Legislation: Impact on Risk Management and Post Market Surveillance in Asia****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

3:30–4:30 PM

**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

**Toshiyoshi Tominaga, PhD**

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

**Murray M. Lumpkin, MD, MSc**

Commissioner's Senior Advisor  
and Representative for Global  
Issues, Immediate OC

4:30 PM CLOSING REMARKS

**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

**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

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**TRAVEL AND HOTEL**

The most convenient airport is the Changi Airport. Please visit [www.diahome.org](http://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](http://www.hotelopia.com).

The Official Singapore Tourism Website is another excellent resource and will be happy to provide assistance.: [www.yoursingapore.com](http://www.yoursingapore.com).

**CANCELLATION POLICY: On or before JANUARY 21, 2013**

**Administrative fee that will be withheld from refund amount:**

**Member or Nonmember = \$200**

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**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 cancelling 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.

**EVENT INFORMATION**

For event questions, please contact **Ellen Diegel**, Event Planner, by phone at **+1.215.293.5810** or by email at [Ellen.Diegel@diahome.org](mailto: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](mailto:Jeff.Korn@diahome.org).

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 Last Name

\_\_\_\_\_  
 First Name M.I.

\_\_\_\_\_  
 Degrees  Dr.  Mr.  Ms.

\_\_\_\_\_  
 Job Title

\_\_\_\_\_  
 Company

\_\_\_\_\_  
 Address (As required for postal delivery to your location) Mail Stop

\_\_\_\_\_  
 City State Zip/Postal Country

email **Required for confirmation**

\_\_\_\_\_  
 Phone Number Fax Number **Required for confirmation**