Final Program

5th Asian Regulatory Conference
Kuala Lumpur, Malaysia
11 – 13 March 2008

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

In close cooperation with the Ministry of Health of Malaysia

In collaboration with the World Health Organization (WHO)

Supported by the Pharmaceutical Association of Malaysia (PhAMA)

Welcome Address

Selamat Datang to the 5th IFPMA Asian Regulatory Conference

We are pleased to invite you to the 5th IFPMA Asian Regulatory Conference taking place in Kuala Lumpur, Malaysia from 11 – 13 March 2008. The Conference is being organized in close cooperation with the **Ministry of Health of Malaysia,** with the collaboration of the **World Health Organization (WHO)** and with the support of the **Pharmaceutical Association of Malaysia (PhAMA)**.

This meeting will build upon the established forum between regulatory authority representatives from over 20 Asian countries and the research-based pharmaceutical industry to discuss common issues in the regulatory and technical areas in the Asia Pacific region.

The Conference program will focus on many of the pressing challenges facing regulatory agencies and the pharmaceutical industry, both locally and internationally.

- ICH and Global Cooperation Group: How Asia fits in the global picture?
- Good Regulatory Practices: Are agencies ready?
- Quality: How to ensure quality of products?
- ASEAN Harmonization: Current status and future perspectives
- Global Drug Development: Asian role and contribution
- Pharmaceutical industry self regulation and business ethics: Global and regional challenges
- Pharmacovigilance & Maintenance of product information: How agencies and industry work together to protect patients?
- Future Regulatory Challenges: Is Asia ready?

We look forward to seeing you at the 5th IFPMA Asian Regulatory Conference.

Odette Morin, Director, Regulatory and Scientific Affairs, IFPMA
Alistair Davidson, Chairman of the IFPMA Program Organizing Committee

Region covered by the Conference

Speakers, discussants and participants will be invited from the Ministries of Health and regulatory authorities of the following countries and regions:

Australia
Bangladesh
Brunei Darussalam
Cambodia
Chinese Taipei
Chinese Hong Kong
India
Indonesia
Japan
Korea, South
Laos
Macau SAR
Malaysia
Myanmar
Pakistan
People's Republic of China
Philippines
Singapore
Sri Lanka
Thailand
Vietnam

Conference speakers will also 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 WHO, various regulatory agencies from other regions and the multinational and local pharmaceutical industry.

Program Organizing Committee

Mr. Alistair Davidson, **Chair**, Program Organizing Committee, Vice-President, International Regulatory Affairs, GlaxoSmithKline, UK

Mr. Matthieu Beauchemin, Coordination Assistant, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Switzerland

Dr. Laetitia Bigger, Scientific and Regulatory Analyst, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Switzerland

Mr. Allen Chu, Director, Regulatory Affairs, Asian Operations, Eli Lilly, Australia

Ms. Julie Dennis, Senior Director Asia Region, Worldwide Regulatory Strategy – International, Pfizer, UK

Ms. Alison Ford, Director, Policy & Intelligence, International Regulatory Affairs, GlaxoSmithKline, UK

Dr. Michael Gebauer, Head of Regulatory Affairs, Asia Pacific, Bayer Schering Pharma, Singapore

Mr. Keh Song Hock, Executive Director, Pharmaceutical Association of Malaysia (PhAMA), Malaysia

Mr. Seiji Miyazawa, Director, International Affairs, Japan Pharmaceutical Manufacturers Association (JPMA), Japan

Dr. Odette Morin, Director, Regulatory and Scientific Affairs, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Switzerland

Dr. Thierry Nebout, Senior Consultant, Medical Sciences, Servier, France

Mr. Mark Paxton, Associate Vice President, International Regulatory Affairs, Pharmaceutical Research and Manufacturers of America (PhRMA), USA

Dr. Jürgen Piper, Head of Swissmedic Liaison, Product Information Management, Pharma Development, Drug Regulatory Affairs, F. Hoffmann-La Roche Ltd, Switzerland

Dr. Taryn Rogalski-Salter, Global Head, Regulatory CMC, Novartis Pharmaceuticals Corporation, USA

Ms. Claire Short, Associate Director, International Regulatory Affairs, AstraZeneca, UK

And previous Members: Mr. Colin Vickers, Dr. Monica Dressler-Meyer, Ms. Vicky Roden

MONDAY 10 MARCH 2008

16h00 – 18h30 **REGISTRATION**

18h30 WELCOME RECEPTION - COCKTAIL

TUESDAY 11 MARCH 2008

07h30 – 08h30 **REGISTRATION**

08h30 – 09h30 **OPENING CEREMONY**

08h30 **Welcome to Kuala Lumpur**
Mr. Yew Wei Tarng, Pharmaceutical Association of Malaysia (PhAMA) Vice-President

08h40 **Welcoming address**
Dr. Harvey Bale, Director General, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

08h50 **Keynote address and official opening**
Y.Bhg. Tan Sri Datuk Dr Hj. Ismail Merican, Director General of Health, Malaysia on behalf of The Honorable Minister of Health, Malaysia

09h10 **Welcome from the WHO**
Dr. Lembit Rägo, Coordinator, Quality Assurance and Safety: Medicines (QSM), Department of Medicines Policy and Standards, World Health Organization (WHO), Switzerland (ICH Steering Committee, GCG and MedDRA Board Observer for WHO)

09h20 **Developments since the 4th Asian Regulatory Conference and introduction to the conference program**
Mr. Alistair Davidson, Chair of the IFPMA Program Organizing Committee, Vice-President, International Regulatory Affairs, GlaxoSmithKline, UK

09h30 – 10h00 REFRESHMENT BREAK

10h00 – 11h00 **PLENARY SESSION: ICH AND GLOBAL COOPERATION GROUP: HOW ASIA FITS IN THE GLOBAL PICTURE?**

Session Chairs:
Dr. Toshiyoshi Tominaga, International Planning Director, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW), Japan (ICH Steering Committee and Global Cooperation Group Member for MHLW)

Dr. Yves Juillet, Senior Advisor, Les Entreprises du Médicament (LEEM), France (Chair of IFPMA Regulatory Policy and Technical Standards Committee)

Objectives' summary:
- Interaction with stakeholders outside the three ICH parties - Partnership in Harmonization
- Challenges facing ICH

10h00 **Overview of ICH activities, with focus on new ones**
Dr. Justina Molzon, Associate Director, International Affairs, Center for Drug Evaluation and Research, Food and Drug Administration (FDA), USA (ICH Steering Committee and Global Cooperation Group Member for FDA)

10h15 **Introduction on ICH Global Cooperation Group (GCG) current activities – training opportunities**
Mr. Kohei Wada, General Manager, Asia Clinical Development Department, Daiichi Sankyo Co. Ltd, Japan (ICH Global Cooperation Group Co-chair, ICH Steering Committee Member for JPMA)

10h30 **Partnership with APEC – life sciences innovation forum**
Mr. Ding Jianhua, Director, Division of Pharmaceuticals, Drug Registration Department, State Food and Drug Administration (SFDA), People's Republic of China (GCG representative for APEC)

10h45 **Questions and Answers**

11h00 – 12h15 **PLENARY SESSION: GOOD REGULATORY PRACTICES: ARE AGENCIES READY?**

Session Chairs:

Dr. Young-Ok Kim, Team Director, Drug Equivalence Team, Drug Evaluation Department, Korea Food & Drug Administration (KFDA), Korea

Mrs. Ismet Samji, Director CVM and Regulatory Business Support, International Regulatory Affairs, GlaxoSmithKline, UK

Objectives' summary:
Good Regulatory Practice (GRP) can be considered as the systems and processes that ensure quality throughout the regulatory process**,** in order to protect and promote human healthcare. In the rapidly changing global regulatory environment GRP needs to be able to adapt to the challenges triggered by new technologies and new scientific outcomes. The acceptance of GRP is based on the Health Authorities' (HAs) independence in decision-making and the shared responsibility of HAs and the pharmaceutical industry. The HAs of several countries have already established GRP in terms of "good review and evaluation" practices and it is the objective of this session to share these practices and consider opportunities where best practices could be utilized in Asia.

11h00 **European good regulatory practices:** Assisting new EU countries to EU accession
Mr. Thomas Lönngren, Executive Director, European Medicines Agency (EMEA), EU

11h15 **US good regulatory practices**
Dr. Justina Molzon, Associate Director, International Affairs, Center for Drug Evaluation and Research, Food and Drug Administration (FDA), USA (ICH Steering Committee and Global Cooperation Group Member for FDA)

11h30 **The ASEAN viewpoint on good regulatory practices**
Ms. Maria Lourdes Santiago, Chief, Laboratory Services Division, Bureau of Food and Drug (BFAD), Philippines

11h45 **Monitoring regulatory performance in the emerging markets**: Critical success factors and models for the regulatory review of medicines
Prof. Stuart Walker, Director, CMR International Institute for Regulatory Science, UK

12h05 **Questions and Answers**

12h15 – 13h30 LUNCH BREAK

13h30 – 15h30 **PLENARY SESSION: QUALITY: HOW TO ENSURE QUALITY OF PRODUCTS?**

Session Chairs:

Ms. Abida Syed M. Haq, Deputy Director, Centre for Compliance & Licensing, National Pharmaceutical Control Bureau (NPCB), Malaysia

Mr. Malcolm Holmes, Director, Quality Assurance, GlaxoSmithKline, UK

Objectives' summary:
Quality of pharmaceuticals is essential to ensuring the provision of safe and efficacious medicines to patients. This session aims to focus on some key quality areas pertinent to the submission, approval and maintenance of products of high quality and safety on the market including discussion of measures employed by industry and regulators to assure quality whilst maximizing use of resource.

Assuring quality in the pharmaceutical product
The overall theme of this section is to pull together the threads of GMP & inspections for both drug product & drug substance, appropriate use of resources including mutual recognition agreements.

13h30 **Update on ICH quality topics**
Dr. Robert Baum, Executive Director, Regulatory CMC Policy, Pfizer Global Research & Development, Pfizer, USA (ICH Quality Expert for PhRMA)

13h50 **GMP & inspections**
Mr. Malcolm Holmes, Director, Quality Assurance, GlaxoSmithKline, UK

14h10 **API/Drug substance GMP assurance**
Mr. David Cockburn, Principal Scientific Administrator, Inspections Sector, European Medicines Agency (EMEA), EU

14h25 **Maintaining quality in supply chain**
Ms. Judith Villanueva, Regional Quality Assurance Manager, Zuellig Pharma Asia Pacific, Chinese Hong Kong

Assuring quality in the regulatory submission – The Certificate of Pharmaceutical Product (CPP)

14h40 **Rationale use of the CPP – An industry view**
Mr. Fraser Stodart, Director, Africa, Middle East and Central and Eastern Europe, Worldwide Regulatory Affairs and Quality Assurance, Pfizer, UK (EFPIA Chair of CPP Task force)

14h55 **Rationale use of the CPP – An authority view**
Professor Leticia-Barbara Gutierrez, Director, Bureau of Food and Drugs (BFAD)**,** Philippines

15h10 **Questions and Answers**

15h20 **Introduction to the breakouts**

15h30 – 16h00 REFRESHMENT BREAK

PARALLEL BREAKOUTS
16h00 – 17h30

ENSURING QUALITY OF PHARMACEUTICAL PRODUCTS

Session Chairs:

Mr. David Cockburn, Principal Scientific Administrator, Inspections Sector, European Medicines Agency (EMEA), EU

Ms. Karen Maigetter, Head of Regional Management, Pharmaceuticals Division, Drug Regulatory Affairs, F. Hoffmann-La Roche Ltd, Switzerland

Objectives' summary:
Identify alternatives to maximize inspection resources such as acceptance of CPP as evidence of GMP standards, adoption of risk based approaches & mutual recognition agreements such as PIC/S.

16h00 **PIC/S**
Ms. Abida Syed M. Haq, Deputy Director, Centre for Compliance & Licensing, National Pharmaceutical Control Bureau (NPCB), Malaysia

16h15 **Anti-counterfeiting initiative**
Dr. Yves Juillet, Senior Advisor, Les Entreprises du Médicament (LEEM), France (Chair of IFPMA Regulatory Policy and Technical Standards Committee)

16h30 **WHO's prequalification project: How to ensure quality medicines are supplied to countries?**
Dr. Lembit Rägo, Coordinator, Quality Assurance and Safety: Medicines (QSM), Department of Medicines Policy and Standards, World Health Organization (WHO), Switzerland (ICH Steering Committee, GCG and MedDRA Board Observer for WHO)

16h45 **Questions and Answers**

THE CERTIFICATE OF PHARMACEUTICAL PRODUCT

Session Chairs:

Dr. John Lim, Chief Executive Officer, Health Sciences Authority (HSA), Singapore

Mr. Fraser Stodart, Director, Africa, Middle East and Central and Eastern Europe, Worldwide Regulatory Affairs and Quality Assurance, Pfizer, UK (EFPIA Chair of CPP Task force)

Objectives' summary:
The overall theme of this session is to discuss the value of the CPP in regulatory review and opportunities to use alternative documentation.

16h00 **WHO model certificate of a pharmaceutical product**
Dr. Lembit Rägo, Coordinator, Quality Assurance and Safety: Medicines (QSM), Department of Medicines Policy and Standards, World Health Organization (WHO), Switzerland (ICH Steering Committee, GCG and MedDRA Board Observer for WHO)

16h15 **Issuing agency perspective**
Dr. Murray Lumpkin, Deputy Commissioner for International and Special Programs, Office of the Commissioner, Food and Drug Administration (FDA), USA

16h30 **Issuing industry perspective**
Dr. Michael Gebauer, Head of Regulatory Affairs, Asia Pacific, Bayer Schering Pharma, Singapore

16h45 **Questions and Answers**

WEDNESDAY 12 MARCH 2008

08h30 – 10h30 **PLENARY SESSION: ASEAN HARMONIZATION: CURRENT STATUS AND FUTURE PERSPECTIVES**

Session Chairs:

Ms. Eisah Abdul Rahman, Chair of ASEAN ACCSQ/P-PWG, Deputy Director of Pharmaceutical Services, Ministry of Health, Malaysia

Dr. Taryn Rogalski-Salter, Global Head, Regulatory CMC, Novartis Pharmaceuticals Corporation, USA

Objectives' summary:
The session is aimed at providing an understanding and overview of progress with implementation of the ASEAN harmonization process. It will provide views and practical feedback from regulators and industry on the impact of harmonization within ASEAN region now and in the future. It is also an opportunity for participants to discuss and share experiences gained during implementation.

08h30 **The origin and current status of ASEAN harmonization**
Dr. Yuppadee Javroongrit, Co-chair of ASEAN ACCSQ/P-PWG, Assistant Director & Head of International Affairs & IND Section, Drug Control Division, Food and Drug Administration (FDA), Ministry of Public Health, Thailand (ICH GCG Observer for ASEAN)

08h50 **ASEAN stability implementation**
Dr. Lucky Slamet, Deputy for Therapeutic Products, Narcotic, Psychotropic and Addictive Substance Control, Directorate General of Food and Drug Control, Ministry of Health, National Agency of Drug and Food Control (NA-DFC), Indonesia

09h05 **Experience of ASEAN implementation, an agency perspective**
Ms. Lee Hui-Keng, Head, Policy & Planning, Health Products Regulation Group, Health Sciences Authority (HSA), Singapore

09h20 **Experience of ASEAN implementation, an agency perspective**
Mr. Nguyen Thanh Lam, Deputy Head of Business Administration Division, Vietnam

09h35 **Experience of ASEAN implementation, an industry perspective**
Ms. Celine Ting, Chair of ASEAN Pharmaceutical Research Industry Association (APRIA) (Managing Director, Eisai (Singapore) Pte Ltd., Singapore)

09h50 **The future of ASEAN harmonization - The next steps**
Ms. Eisah Abdul Rahman, Chair of ASEAN ACCSQ/P-PWG, Deputy Director of Pharmaceutical Services, Ministry of Health, Malaysia

10h05 **Questions and Answers**
Panel session
Speakers to be joined by **Mr. Thomas Lönngren**

10h30 – 11h00 REFRESHMENT BREAK

11h00 – 12h30 **PLENARY SESSION: GLOBAL DRUG DEVELOPMENT: ASIAN ROLE AND CONTRIBUTION**

Session Chairs:

Mr. Thomas Lönngren, Executive Director, European Medicines Agency (EMEA), EU

Dr. Amar Kureishi, Vice President & Head Medical Affairs, Asia Pacific, Bayer Pte Ltd, Singapore

Objectives' summary:
Global Clinical Development aims to promote and protect public health in a truly global manner and give all prescribers and patients in all regions access to important new medicines. The industry and regulators are working hard to achieve this goal but true global development presents challenges for both regulators and industry. This session aims to investigate this further, share experience from within and outside the Asia region and discuss ways forward.

11h00 **The impact of global development: a US FDA perspective**
Dr. Murray Lumpkin, Deputy Commissioner for International and Special Programs, Office of the Commissioner, Food and Drug Administration (FDA), USA

11h20 **The impact of global clinical development, the Japanese perspective**
Dr. Toshiyoshi Tominaga, International Planning Director, Pharmaceutical Affairs, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW), Japan (ICH Steering Committee and GCG Member for MHLW)

11h40 **Industry perspective on global development**
Dr. Ross Horsburgh, Regional Vice President Asia Pacific, Kendle, Singapore

12h00 **Strategies for global clinical development**: The critical elements of quality and timelines
Dr. Neil McAuslane, CMR International Institute for Regulatory Science, UK

12h20 **Introduction to parallel breakouts**

12h30 – 14h00 LUNCH BREAK

PARALLEL BREAKOUTS
14h00 – 16h00

CLINICAL TRIAL APPLICATION PROCESSES AND REQUIREMENTS

Session Chairs:

Dr. Murray Lumpkin, Deputy Commissioner for International and Special Programs, Office of the Commissioner, Food and Drug Administration (FDA), USA

Dr. S. Edmund Tsuei, Head, Pharma Development Operations, Asia, Roche Products Pty Ltd, Australia

Objectives' summary:
In order to facilitate global development the process of harmonization in respect to IND/CTA requirements has to proceed further. Technical requirements, timelines and medical practice are the most challenging in regard to global study planning.

14h00 **EU clinical trial directive:** The EMEA road map to 2010
Mr. Thomas Lönngren, Executive Director, European Medicines Agency (EMEA), EU

14h20 **IND processes and global clinical trials in Korea**
Dr. In-Sook Park, Deputy Director, Chemistry & Cardiovascular Drug Team, Drug Evaluation Department, Korea Food & Drug Administration (KFDA), Korea

14h40 **Requirements for clinical trial applications in China**
Mr. Ding Jianhua, Director, Division of Pharmaceuticals, Drug Registration Department, State Food and Drug Administration (SFDA), People's Republic of China (GCG representative for APEC)

15h00 **Clinical trial application process in Thailand**
Dr. Yuppadee Javroongrit, Co-chair of ASEAN ACCSQ/P-PWG, Assistant Director & Head of International Affairs & IND Section, Drug Control Division, Food and Drug Administration (FDA), Ministry of Public Health, Thailand (ICH GCG Observer for ASEAN)

15h15 **Industry perspective and experiences of CTA process, timelines, across the Asia region**
Dr. S. Edmund Tsuei, Head, Pharma Development Operations, Asia, Roche Products Pty Ltd, Australia

15h30 **Questions and Answers**

ASIA INVOLVEMENT IN GLOBAL CLINICAL TRIALS

Session Chairs:

Dr. Herng-Der Chern, Executive Director, Centre for Drug Evaluation (CDE), Chinese Taipei

Dr. Stephen D. Wise, Director & Associate Professor of National University of Singapore, Department of Medicine, Lilly-NUS Centre for Clinical Pharmacology, Singapore

Objectives' summary:
Performing global studies is a challenge for both Authority and companies. Harmonization of interest and needs in respect to study outline and clinical practice as well as regulatory requirements have to be considered.

14h00 **The challenge and future direction for Asian drug development**
Mr. Kazuhiko Mori, Associate Center Director, Center for Product Evaluation, Pharmaceutical and Medical Devices Agency (PMDA), Japan

14h20 **Clinical trials in Taiwan from 1994 to 2007 and beyond - A perspective of regulatory environment and strategy**
Dr. Herng-Der Chern, Executive Director, Centre for Drug Evaluation (CDE), Chinese Taipei

14h40 **Global clinical development in India**
Dr. Romi Singh, Executive Director, Global Regulatory Affairs & Safety, Amgen Inc., USA

15h00 **Global clinical development in Asia**
Dr. Stephen D. Wise, Director & Associate Professor of National University of Singapore, Department of Medicine, Lilly-NUS Centre for Clinical Pharmacology, Singapore

15h20 **Update on clinical trials in Asia and action plan with authority in Japan**
Mr. Tetsuto Nagata, Senior Manager, Industrial Relations, Regulatory Policy and Intelligence, Pfizer, Japan

15h40 **Questions and Answers**

16h00 – 16h30 REFRESHMENT BREAK

16h30 – 17h30 **WRAP UP SESSION: GLOBAL DRUG DEVELOPMENT: ASIAN ROLE AND CONTRIBUTION**

Session Chairs:
Mr. Thomas Lönngren, Executive Director, European Medicines Agency (EMEA), EU

Dr. Amar Kureishi, Vice President & Head Medical Affairs, Asia Pacific, Bayer Pte Ltd, Singapore

Panelists:

Dr. Yuppadee Javroongrit, Co-chair of ASEAN ACCSQ/P-PWG, Assistant Director & Head of International Affairs & IND Section, Drug Control Division, Food and Drug Administration (FDA), Ministry of Public Health, Thailand (ICH GCG Observer for ASEAN)

Dr. Murray Lumpkin, Deputy Commissioner for International and Special Programs, Office of the Commissioner, Food and Drug Administration (FDA), USA

Dr. S. Edmund Tsuei, Head, Pharma Development Operations, Asia, Roche Products Pty Ltd, Australia

Dr. Herng-Der Chern, Executive Director, Centre for Drug Evaluation (CDE), Chinese Taipei

Mr. Kazuhiko Mori, Associate Center Director, Center for Product Evaluation, Pharmaceutical and Medical Devices Agency (PMDA), Japan

Dr. Romi Singh, Executive Director, Global Regulatory Affairs & Safety, Amgen Inc., USA

19h00 – 22h00 CONFERENCE DINNER

THURSDAY 13 MARCH 2008

08h30 – 10h00 **PHARMACEUTICAL INDUSTRY SELF REGULATION AND BUSINESS ETHICS: GLOBAL AND REGIONAL CHALLENGES**

Session Chairs:

Mr. Richard Bergström, Director General, Läkemedelsindustriföreningen (LIF), Sweden (Chair of International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code Compliance Network)

Dr. Wong Kok Seng, Medical Director, Pfizer (M) Sdn Bhd, Malaysia (PhAMA Ethics Committee)

Objectives' summary:
The promotion of innovative medicines is a key part of the discovery, production and marketing of medicines for the benefit of patients, by being an essential element of informing health care professionals about new medicines and new uses for existing medicines.
The new IFPMA Code came into effect on 1st January 2007 and ever since the IFPMA has engaged in regional activities to promote the Code and facilitate its implementation at the national level. Key elements of the new Code are more restrictive provisions on travel, gift and scientific events, and the establishment of both a code complaint procedure and a code compliance network gathering code experts from all over the world.

08h30 **Global ethical promotion challenges & the IFPMA Code of pharmaceutical marketing practices**
Mr. Richard Bergström, Director General, Läkemedelsindustriföreningen (LIF), Sweden (Chair of International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code Compliance Network)

08h45 **Dispute resolution under the IFPMA Code: Review of the Code operating procedure**
Dr. Frédérique Santerre, Director, Health Care Systems, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Switzerland

09h00 **Malaysia ethical promotion, trends and challenges**
Dr. Wong Kok Seng, Medical Director, Pfizer (M) Sdn Bhd, Malaysia (PhAMA Ethics Committee)

09h15 **China ethical promotion, trends and challenges**
Mr. Jeff Schultz, Executive Director, R&D-based Pharmaceutical Association in China (RDPAC), People's Republic of China

09h30 **Questions and Answers**

10h00 – 10h30 REFRESHMENT BREAK

10h30 – 12h00 **PLENARY SESSION: PHARMACOVIGILANCE & MAINTENANCE OF PRODUCT INFORMATION: HOW AGENCIES AND INDUSTRY WORK TOGETHER TO PROTECT PATIENTS?**

Session Chairs:

Dr. Leonie Hunt, Director, Drug Safety and Evaluation Branch, Therapeutic Goods Administration (TGA), Australia

Mr. Allen Chu, Director, Regulatory Affairs, Asian Operations, Eli Lilly, Australia

Objectives' summary:
Putting patient safety first is a primary goal for both Industry and Regulatory Authorities globally. This applies in both a pre and post marketing environment.
This session aims to:
- discuss global efforts in risk management throughout the life cycle of a drug;
- highlight any recent global changes & learning in pharmacovigilance & product information implementation;
- share recent experiences and developments in pharmacovigilance & product information in Asia; and
- provide a forum for the industry to share experience and concerns of the current global trends and regulatory requirements.

10h30 **Global risk management**
Ms. Kaori Nomura, Chief, Safety Information Division, Office of Safety, Pharmaceuticals and Medical Devices Agency (PMDA), Japan (ICH E2B (R3) rapporteur for MHLW)

10h50 **Recent trends in pharmacovigilance in Australia – Pharmacovigilance and impact on product information**
Dr. Leonie Hunt, Director, Drug Safety and Evaluation Branch, Therapeutic Goods Administration (TGA), Australia

11h05 **Evaluation of safety reports in Asia: Regulator's perspective & awareness**
Ms. Tan Lie Sie, Principal Assistant Director, Centre for Post Registration, National Pharmaceutical Control Bureau (NPCB), Malaysia

11h20 **Industry perspective on how to communicate globally on safety issues including safety impact on product information**
Dr. Martin Huber, Vice President, Global Pharmacovigilance, Schering-Plough Research Institute, USA

11h40 **Questions and Answers**

12h00 – 13h30 LUNCH BREAK

13h30 – 15h00 **PLENARY SESSION: FUTURE REGULATORY CHALLENGES: IS ASIA READY?**

Session Chairs:

Ms. Eisah Abdul Rahman, Chair of ASEAN ACCSQ/P-PWG, Deputy Director of Pharmaceutical Services, Ministry of Health, Malaysia

Mr. Mark Paxton, Associate Vice President, International Regulatory Affairs, Pharmaceutical Research and Manufacturers of America (PhRMA), USA

Objectives' summary:
In recent years there has been a huge increase in both clinical and regulatory development in Asia, matching the continued economic growth and business interest to the pharmaceutical and healthcare industries. In this session some of the newer developments and concepts for regulatory development will be explored, as well as recommendations for seeking flexibility, adopting already-existing best practices and creating plans for future regulatory excellence in this region.

13h30 **Attractiveness of Asia region for R&D and business**
Mr. Mark Paxton, Associate Vice President, International Regulatory Affairs, Pharmaceutical Research and Manufacturers of America (PhRMA), USA

13h45 **Biosimilars**
Mr. Jacques Mascaro, Head of European Regulatory Affairs, F. Hoffmann-La Roche Ltd., Switzerland

14h00 **Orphan drugs**
Mr. Lamine Messaoudi, Associate Director, Global Pharma Regulatory Affairs, Pacific Asia Africa, Abbott, USA

14h15 **The view of the ultimate stakeholders: doctors and patients**
Dr. Chan Siew Pheng, President of the Malaysian Diabetes Association, Malaysia

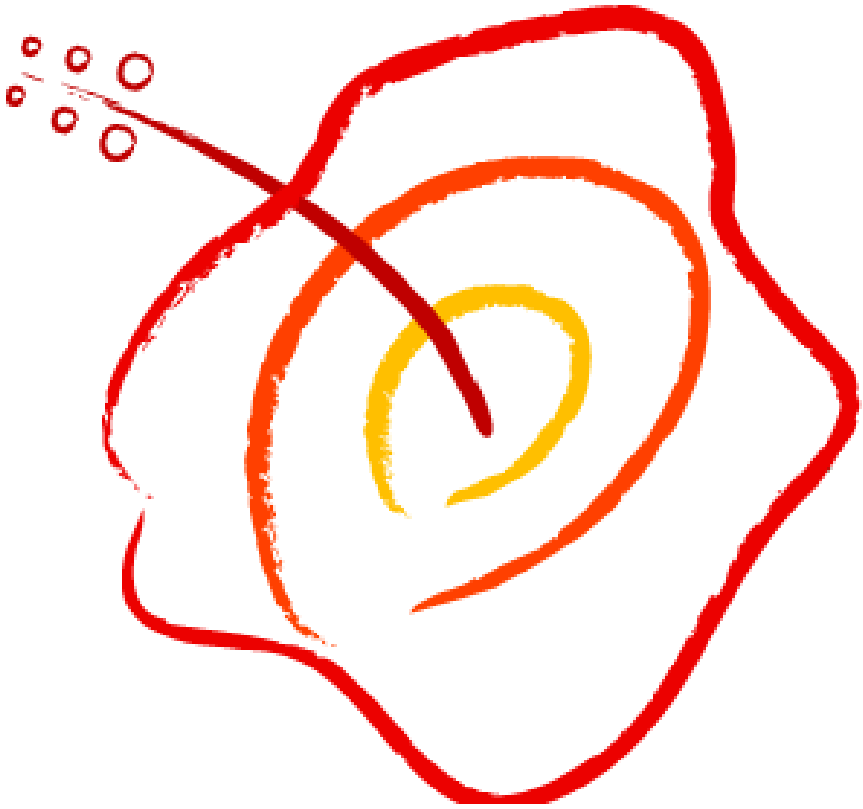
14h30 **Challenges and options for managing an evolving environment**
Mr. Alistair Davidson, Chair of the IFPMA Program Organizing Committee, Vice-President, International Regulatory Affairs, GlaxoSmithKline, UK

14h45 **Questions and Answers**

15h00 – 15h10 **CLOSING REMARKS**

15h00 **Mr. Alistair Davidson**, Chair of the IFPMA Program Organizing Committee, Vice-President, International Regulatory Affairs, GlaxoSmithKline, UK

15h10 – 15h40 refreshment break



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Conference official website **www.ifpma.org/arc-2008**

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