Asia Regulatory Conference:
Asia's Role in Global Drug Development

April 26-28, 2011
Grand Hilton Hotel, Seoul, Republic of Korea

PROGRAM COMMITTEE CHAIR

André W. Broekmans
Vice President, Most of World Regulatory Policy & Regulatory Affairs, MSD, The Netherlands
(ICH SC and GCG Member)

PROGRAM COMMITTEE CO-CHAIR

Sun Hee Lee
Director, Drug Evaluation Department
Korea Food and Drug Administration (KFDA), Republic of Korea
(ICH GCG Member)

PROGRAM COMMITTEE MEMBERS

Laetitia Bigger
Manager, Regulatory & Scientific Affairs
IFPMA, Switzerland

Julie Dennis
Senior Director, Worldwide Regulatory Strategy, Emerging Markets, Pfizer, UK

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Head of Regulatory Affairs & Market Access
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Tiffany Hoang
Regional Senior Manager
Global Regulatory Strategy, Policy & Safety - Asia Pacific
MSD, Singapore

In-Jin Jang
Seoul National University, Republic of Korea

(Program Committee Members and Advisory Committee continued on page 2)

CONTACT INFORMATION
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Drug Information Association, Inc.
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Regional Offices
Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

Co-sponsored by the APEC Harmonization Center, DIA, and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

Join representatives from more than 20 Asian and ICH regulatory agencies and industry professionals to discuss regulatory aspects of ICH, APEC and ASEAN harmonization initiatives, good regulatory practices, quality and GMP, global drug development, and pharmacovigilance. This three-day conference provides a unique opportunity to:

- Strengthen cooperation between Asian regulatory authorities and pharmaceutical industry
- Facilitate discussion on common issues in the regulatory and technical areas in the Asia Pacific region
- Encourage greater harmonization of regulatory requirements in the Asia Pacific region

WHO SHOULD ATTEND

Professionals involved directly and/or indirectly in regulatory and clinical research, or who are considering initiating their activities in this professional area, including:

- Research professionals (clinical, laboratory, site members, and CRAs)
- CROs and SMOs
- Service providers
- Clinical investigators (active and potential)
- Ethics committees
- Regulatory agencies
- Medical education institutions
- Pharmaceutical sponsors

Simultaneous translation in Korean will be available.

Presented by

AHC APEC Harmonization Center

IFPMA International Federation of Pharmaceutical Manufacturers & Associations

DIA® www.diahome.org

PROGRAM COMMITTEE MEMBERS *(Continued from page 1)*

Yuppadee Javroongrit
Assistant Director and Head of International Affairs and IND Section Drug Control Division
Thai FDA, Thailand
(ICH GCG Observer for ASEAN, Co-Chair of ASEAN ACCSQ PPWG)

Tae-Gyun Kim
Deputy Director, Center for Drug Development Assistance
Korea Food and Drug Administration (KFDA),
Republic of Korea

Yil-Seob Lee
Director, Medical & Regulatory Affairs
GlaxoSmithKline, Republic of Korea

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

Christina Lim
Group Director, Health Products Regulation Group
Health Sciences Authority (HSA), Singapore
(ICH GCG Member)

Arun Mishra
Director, Global Regulatory Affairs
GlaxoSmithKline, UK

Seiji Miyazawa
Director, International Affairs
JPMA, Japan

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Director, Regulatory and Scientific Affairs
IFPMA, Switzerland
(Director of ICH Secretariat, ICH SC and GCG Member)

Chang Won Park
Deputy Director, Drug Approval and Review Management Division, Korea Food and Drug Administration (KFDA),
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Kui Lea Park
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Korea Food and Drug Administration (KFDA),
Republic of Korea

Jae-Gook Shin
Professor & Director
Department of Clinical Pharmacology & Clinical Trial Center
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Amgen, USA

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Hanmi Pharmaceuticals, Republic of Korea

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Deputy Director, Advanced Therapy Products Division
Korea Food and Drug Administration (KFDA), Republic of Korea

Adrian Waterson
Asia Regulatory Director
AstraZeneca, UK

Tae Moo Yoo
Director, Drug Approval and Review Management Division, Korea Food and Drug Administration (KFDA), Republic of Korea

ADVISORY COMMITTEE

Yves Juillet
DIA President Elect
Senior Advisor, LEEM, France, (APEC Harmonization Center Advisory Board Member)

Tatsuo Kurokawa
Chiba University Graduate School of Pharmaceutical Sciences, Japan

Justina A. Molzon
Associate Director, International Programs, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), USA (ICH SC and GCG Member, Chair of the APEC RHSC Subcommittee on Training)

Lembit Rägo
Coordinator, Quality Assurance & Safety for Medicines (QSM)
World Health Organization (WHO), Switzerland, (WHO ICH SC and GCG Observer)

Sang-Goo Shin
President
KoNECT – Korea National Enterprise for Clinical Trials
Republic of Korea

Larisa Nagra Singh
Senior Director, Clinical Operations Asia Pacific, ICON Clinical Research, India

Ling Su
Senior Vice President and Head of Development Greater China
Novartis, P.R. China

Mike Ward
Manager, International Program Division, Health Products and Food Branch, Health Canada, Canada, (ICH SC and GCG Member, Chair of the APEC RHSC)

Regulatory participants from more than 20 countries and regions:

Australia | Bangladesh | Brunei Darussalam | Cambodia | Canada | Chinese Taipei | European Union | Hong Kong | India | Indonesia | Japan | Laos | Macau SAR | Malaysia | Myanmar | New Zealand | Pakistan | People's Republic of China | Philippines | Republic of Korea | Singapore | Sri Lanka | Thailand | USA | Vietnam

Networking Opportunities

Build on existing contacts and make new ones.

This meeting provides extensive networking opportunities - all included in your registration fee.

Welcome Reception

Tuesday, April 26, 2011, 5:30 PM-7:00 PM

See page 8 for details.

Network on the Exhibition Floor

See page 8 for details.

PLEASE NOTE: All refreshment breaks, lunches, and reception will be held in the Emerald Hall and Foyer.

DAY 1 | TUESDAY, APRIL 26

7:30 AM-8:30 AM CONFERENCE REGISTRATION

9:00 AM-9:40 AM OPENING CEREMONY

SESSION CHAIRS

Dr. Sun Hee Lee
Director, Drug Evaluation Department, Korea Food & Drug Administration (KFDA), Republic of Korea (ICH Global Cooperation Group (GCG) Member)

Dr. André W. Broekmans
Vice President, Most of World Regulatory Policy & Regulatory Affairs, MSD, The Netherlands (Program Committee Chair, ICH Steering Committee (SC) Member)

Opening Remarks
Dr. Seung Hee Kim
Director General, National Institute of Food and Drug Safety Evaluation, Korea Food & Drug Administration (KFDA), Republic of Korea (Director of APEC Harmonization Center)

Congratulatory Remarks
Dr. Yun Hong Noh
Commissioner, Korea Food & Drug Administration (KFDA), Republic of Korea

Congratulatory Remarks
Dr. Bup Wan Kim
President, Korea Health Industry Development Institute, (KHIDI), Republic of Korea

Welcome from the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
Dr. Odette Morin
Director, Regulatory and Scientific Affairs, IFPMA, Switzerland (Director of ICH Secretariat, ICHSC and GCG Member)

Welcome from the Drug Information Association (DIA)
Dr. Yves Juillet
DIA President Elect

9:40 AM–10:00 AM REFRESHMENT BREAK

10:00 AM–12:00 PM PLENARY SESSION

Update on ICH Activities, Focus on New Activities

SESSION CHAIRS

Dr. Sun Hee Lee
Director, Drug Evaluation Department, Korea Food & Drug Administration (KFDA), Republic of Korea (ICH GCG Member)

Dr. André W. Broekmans
Vice President, Most of World Regulatory Policy & Regulatory Affairs, MSD, The Netherlands (Program Committee Chair, Steering Committee (SC) and GCG Member)

20 Years of ICH: Learning and Accomplishments
Dr. Justina A. Molzon
Associate Director, International Programs, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), USA (ICH SC and GCG Member, Chair of the APEC RHSC Subcommittee on Training)

Japan's Experience with ICH and the Implementation of Guidelines
Mr. Shinobu Uzu
Director, International Planning, Ministry of Health, Labour and Welfare (MHLW), Japan (ICH SC Member and GCG Co-Chair)

Expanding Participation in ICH Technical Working Groups to Regional Harmonization Initiatives (RHIs) and Drug Regulatory Agencies (DRAs)
Mr. Mike Ward
Manager, International Program Division, Health Products and Food Branch, Health Canada, Canada, (ICH SC and GCG Member, Chair of the APEC RHSC)

KFDA's Perspectives on the Implementation of ICH Guidelines
Dr. Sun Hee Lee
Director, Drug Evaluation Department, Korea Food & Drug Administration (KFDA), Republic of Korea (ICH GCG Member)

12:00 PM-1:00 PM LUNCH BREAK

1:00 PM–3:30 PM PLENARY SESSION

Regional Harmonization Initiatives

SESSION CHAIRS

Dr. Justina A. Molzon
Associate Director, International Programs, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), USA (ICH SC and GCG Member, Chair of the APEC RHSC Subcommittee on Training)

Ms. Weon Do
Head of Regulatory Affairs and Market Access, sanofi-aventis, Republic of Korea

The Role of APEC in Advancing Harmonization Efforts in a More Strategic, Effective and Sustainable Fashion
Mr. Mike Ward
Manager, International Program Division, Health Products and Food Branch, Health Canada, Canada, (ICH SC and GCG Member, Chair of the APEC RHSC)

AHC Activities: Current Status and Future Prospects
Dr. Kui Lea Park
Director, Center for Drug Development Assistance, Korea Food & Drug Administration (KFDA), Republic of Korea

ASEAN Regulatory Harmonization Activities and Future Perspectives
Dr. Yuppadee Javroongrit
Assistant Director & Head of International Affairs & IND Section Drug Control Division, Food and Drug Administration (FDA), Ministry of Public Health, Thailand (ASEAN ICH GCG Observer, Co-Chair of ASEAN ACCSQ PPWG)

Tripartite Symposium on Rationalization of Clinical Trial Requirements
Ms. Hee Young Park
Korea Food & Drug Administration (KFDA), Republic of Korea

Mr. Shinobu Uzu
Director, International Planning, Ministry of Health, Labour and Welfare (MHLW), Japan (ICH SC Member and GCG Co-Chair)

Dr. Li Jinju
Division Director, Division of Drug Research Supervision Department of Drug Registration, State Food and Drug Administration (SFDA), P.R. China

3:30 PM–4:00 PM REFRESHMENT BREAK

4:00 PM-5:30 PM PARALLEL TRACKS

Track 1: Fighting Counterfeit Medicines in Emerging Countries: Addressing Infrastructure and Capacity Gaps

SESSION CHAIRS

Dato' Eishah A. Rahman
Senior Director, Pharmaceutical Services Division, Ministry of Health, Malaysia

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

Counterfeit Medicines in Asia Today

Mr. Thomas Kubic
President and CEO of the Pharmaceutical Security Institute, USA

The Malaysian Experience with Meditag

Dato' Eishah A. Rahman
Senior Director, Pharmaceutical Services Division, Ministry of Health, Malaysia

Singapore's Experience in the Fight Against Counterfeits

Ms. Ruth Lee Choo Ai
Acting Director, Enforcement Branch, Health Products Regulation Group, Health Sciences Authority (HSA), Singapore

Track 2: Ensuring Quality – Enhance the Approach of Quality Driven by ICH Q8, Q9, Q10, and Q11: What about Practical Implementation?

SESSION CHAIRS

Dra. Kustantinah
Head, National Agency of Drug and Food Control (NA-DFC/BPOM), Indonesia

Dr. Georges France
Vice President, Global Quality Strategy and International Affiliate Quality and Compliance (IAQC), Pfizer, UK (ICH Quality Implementation Working Group (ICH Q-IWG) Member)

ICH Q-IWG Updates and Challenges

Dr. Georges France
Vice President, Global Quality Strategy and International Affiliate Quality and Compliance (IAQC), Pfizer, UK (ICH Quality Implementation Working Group (ICH Q-IWG) Member)

Dr. Jean-Louis Robert
Head of Division, National Health Laboratory, Department of Quality Control of Medicine, Luxembourg (Rapporteur of ICH Q-IWG)

CMC Requirements to Support New Technology in Development and Analytical Methods (e.g. NIR, UPLC)

Dr. Moheb Nasr
Director, Office of New Drug Quality, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), USA (ICH Q-IWG Member)

Validation and Continuous Verification: Regulatory Challenges

Dr. Yukio Hiyama
Chief, Third Section, Division of Drugs, National Institute of Health Sciences (NIHS), Ministry of Health, Labour and Welfare (MHLW), Japan (ICH Q-IWG Member)

Track 3: Practical Uses of Common Technical Documents (CTDs) in Asia

SESSION CHAIRS

Dr. Lembit Rägo
Coordinator, Quality Assurance & Safety for Medicines (QSM), Essential Medicines Pharmaceutical Policies Department, World Health Organization (WHO), Switzerland (WHO ICH SC and GCG Observer)

Mr. Kum Cheun Wong
Director, Global Regulatory Policy & Intelligence, Asia Pacific, Johnson & Johnson, Singapore

Experience and Value of CTD

Ms. Jalene Poh
Regulatory Consultant, Pharmaceuticals & Biologics Branch, Pre-Marketing Division, Health Products Regulatory Group, Health Sciences Authority (HSA), Singapore

Practical Use of ICH CTD in Facilitating Approval of Prequalification of Pharmaceutical Products and the Benefits to the WHO Program

Dr. Lembit Rägo
Coordinator, Quality Assurance & Safety for Medicines (QSM), Essential Medicines Pharmaceutical Policies Department, World Health Organization (WHO), Switzerland (WHO ICH SC and GCG Observer)

Practical Use and Value of CTD in Clinical Trials and New Drug Application (NDA), and Challenges Faced in the Asia Region

Mr. Alistair Davidson
Senior Director, Regulatory Affairs, Asia-Pacific, PPD, UK

5:30 PM-7:00 PM Welcome Reception — Emerald Hall & Foyer *See page 8 for details*

DAY 2 | WEDNESDAY, APRIL 27

8:30 AM–10:00 AM PLENARY SESSION

Early Clinical Development in Asia

SESSION CHAIRS

Professor I. J. Jang
Seoul National University, Republic of Korea

Chair to be confirmed

Current Status of Early Clinical Development in Asia and Plan for the Future: Industry Perspective
Dr. Ken Kobayashi
Head of Clinical Science Oncology, Johnson & Johnson, Japan

Regulatory Experience in Early Clinical Trial Approval
Speaker to be confirmed

How Asian Clinical Sites are Working for Early Clinical Trials
Professor I.J. Jang
Seoul National University, Republic of Korea

10:00 AM–10:30 AM REFRESHMENT BREAK

10:30 AM–12:30 PM PLENARY SESSION

Late Clinical Development in Asia

SESSION CHAIRS

Dr. Herng-Der Chern
Distinguished Researcher, Center for Drug Evaluation (CDE), Chinese Taipei

Mr. Adrian Waterson
Asia Regulatory Director, AstraZeneca, UK

Simultaneous Multi-regional Clinical Trials
Dr. Moira Daniels
Vice President, Regulatory Affairs, AstraZeneca, UK

Acceptance of Clinical Data – The Challenge of Generalizability
Dr. Yuki Ando
Principal Reviewer of Biostatistics, Office of New Drug II, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Towards Simultaneous Regulatory Approval
Dr. Herng-Der Chern
Distinguished Researcher, Center for Drug Evaluation (CDE), Chinese Taipei

12:30 PM-1:30 PM LUNCH BREAK

1:30 PM-3:30 PM **PARALLEL TRACKS**

Track 1: Establishing the Asia Pacific Region as an Important Partner in Global Pediatric Development

SESSION CHAIRS

Dr. Min Soo Park
Director, Clinical Trials Center, Chair, Department of Clinical Pharmacology, Yonsei University, Republic of Korea

Mrs. Angelika Joos
Head, Regulatory Policy, EU & Most of World, MSD (Europe), Belgium

Participation in Asia in Global Pediatric Programs, Including Cultural Barriers to Conduct Pediatric Clinical Trials
Dr. Hidefumi Nakamura
Director, Division of Clinical Research, National Center for Child Health and Development, Japan

How to Extrapolate Clinical Development Results to Asia Children: Usefulness of Bridging the Program with Adults
Dr. An Vermeulen
Head, Modeling & Simulation Department, Johnson & Johnson, Belgium

FDA's Experience with Global Pediatric Development
Dr. Jean W. Temeck
Lead Medical Officer, Office of Pediatric Therapeutics (OPT), Office of International and Special Programs (OISP), Office of the Commissioner (OC), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), USA

Position of WHO ICDRA on Global Pediatric Development
Ms. Agnes Chan
Regulatory Consultant, Pharmaceuticals & Biologics Branch, Health Products Regulation Group, Health Sciences Authority (HSA), Singapore

Track 2: Ensuring Quality: Harmonizing and Optimizing Inspection Approach in the Global Environment

SESSION CHAIRS

Dr. Yukio Hiyama
Chief, Third Section, Division of Drugs, National Institute of Health Sciences (NIHS), Ministry of Health, Labour and Welfare (MHLW), Japan (ICH Q-IWG Member)

Dr. Georges France
Vice President, Global Quality Strategy and International Affiliate Quality and Compliance (IAQC), Pfizer UK (ICH Q-IWG Member)

Control Strategy and Batch Release: Challenges for a Global and an Harmonized Approach
Dr. Jacques Morénas
Assistant Director, Inspectorate and Companies Department, The French Health Products Safety Agency (AFSSAPS), France (ICH Q-IWG Member, PIC/S)

Quality Risk Management in the WHO Prequalification Process
Dr. Lembit Rägo
Coordinator, Quality Assurance & Safety for Medicines (QSM), Essential Medicines Pharmaceutical Policies Department, World Health Organization (WHO), Switzerland (WHO ICH SC and GCG Observer)

(Parallel Tracks continued on next page)

1:30 PM-3:30 PM PARALLEL TRACKS (CONTINUED)

API: Role of EDQM in Globalization, Input on Inspections and Standards

Dr. Susanne Keitel
Director, European Directorate for the Quality of Medicines & Healthcare (EDQM), Council of Europe, France

Panel Discussion: CMC Harmonization and Regulatory Challenges

CHAIR

Dr. Georges France
Vice President, Global Quality Strategy and International Affiliate Quality and Compliance (IAQC), Pfizer UK (ICH Q-IWG Member)

PANELISTS

Dr. Moheb Nasr
Director, Office of New Drug Quality, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), USA (ICH Q-IWG Member)

Dr. Yukio Hiyama
Chief, Third Section, Division of Drugs, National Institute of Health Sciences (NIHS), Ministry of Health, Labour and Welfare (MHLW), Japan (ICH Q-IWG Member)

Dr. Jacques Morénas
Assistant Director, Inspectorate and Companies Department, The French Health Products Safety Agency (AFSSAPS), France (ICH Q-IWG Member, PIC/S)

Dr. Lembit Rägo
Coordinator, Quality Assurance & Safety for Medicines (QSM), Essential Medicines Pharmaceutical Policies Department, World Health Organization (WHO), Switzerland (WHO ICH SC and GCG Observer)

Dr. Susanne Keitel
Director, European Directorate for the Quality of Medicines & Healthcare (EDQM), Council of Europe, France

Dra. Kustantinah
Head, National Agency of Drug and Food Control (NA-DFC/ BPOM), Indonesia

Track 3: Ethical Business Practices: Towards Better Marketing Compliance

SESSION CHAIRS

Dr. Megan Kearney
Principal Medical Adviser, Therapeutic Goods Administration (TGA), Australia

Mr. In-Bum Kim
Sr. Director, Korean Research-based Pharmaceutical Industry Association (KRPIA), Republic of Korea

Latest Developments on Ethical Business Practices (EBP) in Australia

Dr. Megan Kearney
Principal Medical Adviser, Therapeutic Goods Administration (TGA), Australia

Ms. Deborah Monk
Director, Innovation and Industry Policy, Medicines Australia, Australia

Update on New RDPAC Code and Latest Developments in China

Ms. Jennifer Chen
Director, Legal Affairs, R&D-based Pharmaceutical Association Committee (RDPAC), P.R. China

Code Compliance Governance in Japan

Mr. Yota Kikuchi
Manager, Promotion Code & Public Affairs, sanofi-aventis, Japan (Vice Chair of Japan Pharmaceutical Manufacturers Association (JPMA) Promotion Code Working Committee)

3:30 PM–4:00 PM REFRESHMENT BREAK

4:00 PM–5:30 PM PLENARY SESSION

Similar Biotherapeutic Products (SBPs) in Asia: Opportunities and Challenges in Regulatory Evaluation

SESSION CHAIRS

Dr. Sannie Chong
Acting Director, Generics and Biosimilars Branch, Health Sciences Authority (HSA), Singapore

Dr. Fermin Ruiz de Erenchum
Leader, Special Regulatory Task Force, Hoffmann-La Roche Ltd., Switzerland (Chair of IFPMA Biotherapeutic Group)

Do We Have a Common Understanding? Definitions of SBPs and Key Principles in Evaluating SBPs

Dr. Peter Richardson
Responsible for Biological Quality of Medicines, Human Medicines Development and Evaluation, European Medicines Agency (EMA), UK

Evolving Regulatory Landscape for SBPs in Asia

Dr. Fermin Ruiz de Erenchum
Leader, Special Regulatory Task Force, Hoffmann-La Roche Ltd., Switzerland (Chair of IFPMA Biotherapeutic Group)

Chinese Taipei's Perspectives of Regulation of Biosimilar Medicine

Ms. Joyce Wang
Division of Drugs & New Biotechnology Products, Food and Drug Administration, Department of Health, Chinese Taipei

(Session continued on next page)

DAY 3 | THURSDAY, APRIL 28

8:30 AM–10:00 AM PLENARY SESSION

Electronic Submissions and eCTD as Vehicle to Reconcile Differences in Technical Regulatory Requirements

SESSION CHAIRS

Mr. Gary M. Gensinger
Deputy Director, Office of Business Informatics, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), USA

Mr. John W. Kiser
Senior Director, Global Pharmaceutical Regulatory Affairs, Submission Operations & Strategic Initiatives, Abbott Laboratories, USA

The Advantages and Challenges of Electronic Regulatory Submissions in eCTD and Non-eCTD Electronic Submissions (NeeS) Formats – An Industry Perspective

Mr. John W. Kiser
Senior Director, Global Pharmaceutical Regulatory Affairs, Submission Operations & Strategic Initiatives, Abbott Laboratories, USA

Benefits to Implementing eCTD – A Regulatory Perspective

Mr. Gary M. Gensinger
Deputy Director, Office of Business Informatics, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), USA

Practical Use and Challenges Faced – An Asian Regulator Perspective

Ms. Jalene Poh
Regulatory Consultant, Pharmaceuticals & Biologics Branch, Pre-Marketing Division, Health Products Regulation Group, Health Sciences Authority (HSA), Singapore

10:00 AM-10:30 AM REFRESHMENT BREAK

10:30 AM-12:30 PM PLENARY SESSION

Pharmacovigilance: How Do Regulatory Agencies and Industry Work Together to Protect Patients?

SESSION CHAIRS

Dr. Suzette Henares-Lazo
Acting Director IV, Food and Drug Administration (FDA), Philippines

Dr. Paul Eisenberg
Senior Vice President, Global Regulatory Affairs and Safety, Amgen, USA

Current Status and New Directions for Pharmacovigilance in Korea

Dr. Joungwon Oh
Deputy Director, Pharmaceutical Safety Bureau, Korea Food and Drug Administration (KFDA), Republic of Korea

Integrating Risk Management into Global Drug Development – Opportunities and Challenges

Dr. Paul Eisenberg
Senior Vice President, Global Regulatory Affairs and Safety, Amgen, USA

Post-Marketed Surveillance – A Shared Responsibility

Dr. Rebecca Wang
Head of Drug Safety Operation, Regional Center for Asia Pacific, Roche, P.R. China

The Role of MedDRA in Pharmacovigilance Activities

Dr. Patricia Mozzicato
Chief Medical Officer, MedDRA Maintenance & Support Services Organization (MSSO), USA

12:30 PM–1:30 PM LUNCH BREAK

1:30 PM–3:00 PM PLENARY SESSION

Good Regulatory Practices, Including Assessment Report, Efficient Use of Certificate of Pharmaceutical Product (CPPs) and Transparency

SESSION CHAIRS

Dr. Megan Keaney
Principal Medical Adviser, Therapeutic Goods Administration (TGA), Australia

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

Good Regulatory Practices: Do We Have a Common Understanding?

Dr. Yoshiaki Uyama
Director, Division of Regulatory Research, Office of Regulatory Science, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Opportunities for Industry to Partner with Drug Regulatory Authorities (DRAs) to Further Good Regulatory Practices

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

Efficient Use of CPPs

Dr. Lembit Rägo
Coordinator, Quality Assurance & Safety for Medicines (QSM), Essential Medicines Pharmaceutical Policies Department, World Health Organization (WHO), Switzerland (WHO ICH SC and GCG Observer)

3:00 PM-3:10 PM Closing Remarks by Program Committee Chairs

3:30 PM-5:30 PM GCP SITE TOUR (OPTIONAL)

Korea National Enterprise for Clinical Trials (Seoul National University Hospital)

For International Participants Only

See page 8 for details.

Welcome Reception

TUESDAY, APRIL 26, 2011, 5:30 AM-7:00 PM

Emerald Hall & Foyer

The Welcome Reception is an excellent opportunity to renew your existing contacts and to make new ones.

Network on the Exhibition Floor — Emerald Hall & Foyer

Meet with a wide range of companies to learn about new offerings and technologies—all at one event. Virtually every facet of the biopharmaceutical industry and related fields is represented by an exhibitor offering services or products in this extraordinary exhibit hall marketplace.

Exhibition Hours

April 26	9:00 AM-7:00 PM
April 27	8:30 AM-5:30 PM
April 28	8:30 AM-1:30 PM

PLEASE NOTE: All refreshment breaks, lunches, and reception will be held in the Emerald Hall and Foyer.

GCP Site Tour

Korea National Enterprise for Clinical Trials

Seoul National University Hospital

For International Participants Only

The Korean government has been running a clinical trial research project called KONECT which stands for Korean National Enterprise for Clinical Trials over the last couple of years. Currently, the project is carried out by the Seoul National University Hospital. The Korea Food and Drug Administration (KFDA) would like to offer international attendees an opportunity to visit the GCP facilities at the University to better understand the current status of clinical trial research in Korea. If you are interested in participating, please indicate your interest on the online registration website.

TRAVEL AND HOTEL The most convenient airport is Incheon International Airport and attendees should make airline reservations as early as possible. The Grand Hilton Seoul Hotel is holding a block of rooms at the reduced rate below until March 25, 2011, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single US$ 214 (Includes Breakfast) **Double US$ 214** (Add $18 for 2nd Breakfast)

Attendees must make their own hotel reservations. Contact the Grand Hilton Seoul Hotel by telephone at +82-2-3216-5656 and mention the DIA event. The hotel is located at 201-1, Hongeun-dong, Seodaemun-gu, Seoul 120-710, Republic of Korea.

CANCELLATION POLICY: ON OR BEFORE APRIL 19, 2011

Cancellations must be made in writing and received by April 19, 2011 in order to receive a full refund minus the administrative fee of US$ 75 before the cancellation date. Registrants who do not cancel in writing by the deadline date and do not attend the event will be responsible for paying the full registration fee. Registrants are also responsible for cancelling their own hotel and airline reservations. 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.

Online Registration will be available from January 31-April 28, 2011. Click here to register online.

REGISTRATION FEES FOR CONFERENCE

Registration fee includes refreshment breaks, luncheons, and will be accepted online only.

Industry ***(on or before April 1)***	**US$ 1450** ❑
Industry ***(after April 1)***	**US$ 1850** ❑
Regulatory Agency* ***(on or before April 1)***	**US$ 950** ❑
Regulatory Agency* ***(after April 1)***	**US$ 1250** ❑
Exhibitor	**US$ 5450** ❑
MEMBERSHIP ***To join DIA now, click here!***	**US$ 140** ❑

** Regulatory Agency delegate, must be an active full-time employee of a pharmaceutical, device or other health regulatory agency, such as US FDA, KFDA, SFDA, EMA, etc. Credentials need to be presented on site.*