



12th DIA Asia New Drug Conference in Japan

- Rise to the Challenge: New Approaches of Drug Development in Asia -

March 26-27, 2018

TOC Ariake Convention Hall | Tokyo

DIAglobal.org/Asia2018

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OVERVIEW

- To deliver drugs to patients with unmet medical needs as soon as possible, regulatory agencies must strengthen their review systems and shorten their review periods. Introducing expedited review systems, for example, will accelerate the development and delivery of new drugs from the regulatory side. R&D into new drugs by both companies and academia incorporate the latest science but still face challenges in addressing these unmet medical needs. Surrounding all this effort from industry, government and academia, the global development environment is also rapidly evolving day by day; grasping the impact of this evolution has become an important foundation for successfully meeting this challenge.

- DIA's 12th Asia New Drug Conference will share information on current and anticipated steps to collaboratively move forward. These include already established accelerated review pathways as well as progress and implementation of the ICH E17 guideline for planning and designing multiregional clinical trials, which will be specifically addressed by an expert panel followed by mutual discussion between our audience and speakers.

- Experts from pharmaceutical companies and regulatory agencies will also provide the latest information about industry and regulatory challenges and initiatives, including next steps and how to proceed with tasks, in each Asian country. Topics related to risk and labeling management in various medical and regulatory environments have been prominently discussed in each country, and this conference provides a forum to further discuss these topics. We will also examine the remarkable change and recent regulatory reform introduced by the China FDA.

- DIA's 12th DIA Asia New Drug Conference presents an opportunity for you to discover and consider new approaches for drug development in Asia. Now is the time for us to rise to meet this challenge. Now is the time for you to participate.

WHO SHOULD ATTEND

The program will benefit those with the following interests:

- Clinical development
- Medical affairs and market
- Regulatory affairs
- Academic organizations
- Clinical study sites
- Regulatory agencies
- CROs and SMOs

Simultaneous Translation Available

Tabletop Exhibit Opportunities Available

For more information, contact DIA Japan
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Drug Information Association

Global Center: Washington, DC | Americas | Europe, Middle East & Africa | China | Japan | India

9:00-9:30 REGISTRATION**9:30-9:40 WELCOME AND OPENING REMARKS**

Ko SEKIGUCHI
Director, DIA Japan

9:40-10:10 KEYNOTE ADDRESS

SESSION CHAIR

Ari FUJISHIRO
Senior Director, Regulatory Affairs Group, Asia Development Department,
R&D Division, Daiichi Sankyo Co., Ltd.

Evolution of Asian Regulatory Perspectives on Drug Development - Towards Convergence/Harmonization, Collaboration and Networking

Yoshikazu HAYASHI, PhD
Associate Center Director (for New Drug Review), PMDA

10:10-11:55 SESSION 1**Expedited Review Pathways in Asia**

SESSION CHAIR

Masayoshi SHIBATSUJI
Coordination Officer for Review of Breakthrough Products (SAKIGAKE)
/ Coordination Officer for the Practical Application of Innovation,
Advancements, PMDA

Earlier access to new drugs has recently been realized as a result of improved regulations to approve new drugs earlier at the global level. In this session, Asian regulatory experts will explain expedited review pathways in each region, followed by a panel discussion, to deeply discuss various strategies that deliver innovative new drugs earlier to patients in Asia.

Expedited Pathways for Biopharmaceuticals in Korea

Kyungtak NAM
Senior Scientific Officer, Biopharmaceuticals Review Management
Division, Biopharmaceuticals & Herbal Medicine Evaluation Department,
NIFDS, MFDS, Republic of Korea

Expedited Review Process and Timeline (TFDA)

Lien-Cheng CHANG, PhD
Section Chief, Division of Medicinal Products, TFDA, MoHW,
Chinese Taipei

Expedited Program in China

Wendy YAN, MBA
Senior Vice President, Global Head of Regulatory Affairs, BeiGene,
China

Panel Discussion

PANELISTS
All speakers in Keynote Address and Sessions 1

11:55-13:10 LUNCH BREAK**13:10-15:00 SESSION 2 (PART 1)****Regulatory and Industry Challenges to ICH E17 Implementation**

SESSION CHAIR

Yoshiaki UYAMA, PhD
Director, Office of Medical Informatics and Epidemiology, PMDA

At the November 2017 ICH Geneva meeting, the ICH E17 guideline "General Principles for Planning and Design of Multi-Regional Clinical Trials (MRCTs)" was finalized. Promoting multiregional drug development increases the number of regions participating in a MRCT; regional regulatory authorities and industry are being expected to challenge in consistency evaluation between overall and regional results, and sample size allocations to regions. In this session, several regulatory authorities will provide their perspective on current difficulties with not only planning and designing MRCTs but also data interpretation and challenges from implementing this guideline. Panel discussion will exchange various opinions from regulatory authorities and additional industry panelists.

Overview of ICH E17

Yoshiaki UYAMA, PhD
Director, Office of Medical Informatics and Epidemiology, PMDA

T-CDE's Experiences to Review MRCT Results and Expectations for E17 Guideline

I-Chun LAI, MD, MS
Director, Center of Consultation, T-CDE, Chinese Taipei

MFDS's Experiences to Review MRCT Data

Mee Ryung AHN, PhD
Senior Scientific Officer, Gastroenterology and Metabolism Products
Division, Drug Evaluation Department, NIFDS, MFDS, Republic of Korea

PMDA's Experiences to Review MRCT Results and Expectations for E17 Guideline

Yoko AOI, PhD
Planning and Coordination Officer, Office of International Cooperation,
PMDA

15:00-15:30 COFFEE BREAK**15:30-16:30 SESSION 2 (PART 2)****Panel Discussion**

PANELISTS
All speakers in Sessions 2 and

Osamu KOMIYAMA
Senior Manager, Regulatory Policy, Regulatory Affairs, Pfizer Japan Inc.

Yasuto OTSUBO
Reviewer, Office of New Drug II, PMDA

16:30-17:45 SPECIAL LECTURE**Dynamic ASEAN Pharmaceutical Environment with Challenges and Opportunities**

SESSION CHAIR

Shun JIN, MBA
Head, Regulatory Affairs, Asia Pacific, Abbott Laboratories (Singapore) Pte Ltd

In ASEAN, the regulatory environment is changing very fast. The dynamic regulatory requirement brings challenges to the industry. In 2017, the pharmaceutical law in Vietnam has been updated and implemented. Industry is trying to digest the new requirements in this regulation and the speaker form DAV will give the explanation on the key updates in the new regulation. In addition, there will be another presentation from industry perspective. The session explores the ASEAN pharmaceutical environment from the onset of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG), Technical Working Groups (TWG), Implementation Working Group (IWG) and ASEAN guidelines. Providing insights on the latest development in PPWG, updates and future area of guidance discussion. Discussing the challenges faced by industry members and opportunities for industry in creating favourable regulatory environment in expediting approval of innovative medicines for patients in ASEAN.

Regulatory Environment in Vietnam (tentative)

Mai Huong NGUYEN
Officer, Drug Registration Division, Drug Administration of Vietnam
(DAV), Vietnam

ASEAN Pharmaceutical Environment: Industry Perspective on Challenges, Opportunities and Prospects of Partnerships

Kum Cheun (KC) WONG
Head of Asia Pacific, Regulatory & Development Policy, Novartis Asia
Pacific Pharmaceuticals Pte. Ltd., Singapore

17:45-19:30 NETWORKING RECEPTION**Private Social Function Policy**

DIA does not allow hospitality functions to be held during any DIA meeting sessions, scheduled exhibit hours, or social events. Therefore, the hours noted below are the only hours that are acceptable for hospitality functions.

Sunday, March 25	All times are acceptable
Monday, March 26	Before 8:00 and after 21:00
Tuesday, March 27	Before 8:00 and after 19:00

9:00-9:30 REGISTRATION**9:30-10:50 SESSION 3 (PART 1)****Chance of Collaboration among Asian Health Authorities – GCP & AMR**

SESSION CHAIR

Hiroshi WATANABE, MD, PhD

Head of Center for Clinical Sciences (CCS), National Center for Global Health and Medicine (NCGM)

Professor, Department of Clinical Pharmacology & Therapeutics, Hamamatsu University School of Medicine

As with globalization of drug development, collaboration among national and regional regulatory agencies has grown more important. Recent regulatory activities to this end include the GCP inspections to ensure reliability of clinical study results conducted for new drug application around the world, and a multilateral approach to the current global problem of drug-resistant bacteria. This session will introduce recent trend of the GCP inspections and efforts to promote the clinical development of antibiotics for antimicrobial resistance (AMR) and the potential of collaboration among regulators in Asia in this area.

GCP Inspection in Japan**Hiroshi DOGUCHI, DVM, PhD**

GCP Inspector, Office of Non-clinical and Clinical Compliance, PMDA

TFDA GCP Inspection**Lien-Cheng CHANG, PhD**

Section Chief, Division of Medicinal Products, TFDA, MoHW, Chinese Taipei

GCP Inspection in China (tentative)**Cathy LIU**

Senior GCP Strategy Lead, Product Development Quality Assurance (PDQA), Roche PD Shanghai, China

GCP Inspection under MFDS (tentative)**Jung Eun JO**

Clinical Trials Management Division, Pharmaceutical Safety Bureau, MFDS, Republic of Korea

10:50-11:10 COFFEE BREAK**11:10-11:50 SESSION 3 (PART 2)****Chance of Collaboration among Asian Health Authorities – GCP & AMR**

SESSION CHAIR

Hiroshi Watanabe, MD, PhD

Head of Center for Clinical Sciences (CCS), National Center for Global Health and Medicine (NCGM)

Professor, Department of Clinical Pharmacology & Therapeutics, Hamamatsu University School of Medicine

AMR (tentative)**Junko SATO, PhD**

Office Director, Office of International Cooperation, PMDA

The AMR Projects**Antonio Fredelindo Dela Resma VILLANUEVA, MD**

Project Manager, Department of International Trial, Center for Clinical Sciences (CCS), National Center for Global Health and Medicine (NCGM)

11:50-13:05 LUNCH**13:05-15:30 SESSION 4****Drug Development in China: Regulatory Reform and the Impact**

SESSION CHAIR

Ling SU, PhD

Professor and Director, Institute of Drug Regulatory Science, Shenyang Pharmaceutical University / Venture Partner, Lilly Asia Ventures

The regulatory reform in China that started in mid-2015 has entered the third year and is progressing well. In 2017, the China Food and Drug Administration (CFDA) became a regulatory member of ICH. These changes have brought about major changes in the pharmaceutical R&D and regulatory processes in China. The clinical trial review and approval process, the increasing trend

of in- and out-license collaborations and simultaneous development, and the Marketing Authorization Holder program are among the most notable areas enhanced by the reform. In these session, speakers from the CFDA and the industry will share with the audience the update of the reform progress and their experience and perspectives on how the reform has changed the drug development in China.

Update on Regulatory Reform**Dan ZHANG, MD, MPH**

Executive Chairman, Fountain Medical Development Ltd., China

Experience of MAH Pilot in China**Ning LI, MD, PhD**

CEO, Shanghai Junshi TopAlliance Biosciences, China

Experience of In-Licensing Product and Leveraging on Overseas Early Clinical Data for China Development**Min DONG, PhD**

SVP, Clinical Development, EOC Pharma, China

Accelerating the Development of Life-Changing Medicines for Chinese Patients through Innovation and Partnership**George CHEN, MD, MBA**

Senior VP, Global Medicines Development, Head of China Development Unit, AstraZeneca China

Panel Discussion

PANELISTS

All speakers in this Session

15:30-16:00 COFFEE BREAK**16:00-17:30 SESSION 5****What's New for Labeling and Risk Management in East Asia?**

SESSION CHAIR

Rie MATSUI, RPh

Director, Regional Labeling Head for Asia, International Labeling Group, Pfizer Japan Inc.

Labeling is the major "routine" risk minimization element in the risk management plan (RMP). This session provides updates on labeling and risk management in East Asia, in response to regulations that have been revised and/or newly issued in this region. The status of implementing RMPs, including patient information, in Korea, as well as labeling and labeling updates in China will be discussed. This session will also address one of the hottest topics across all regions, the status of electronic labeling. Panel discussion will address how ICH E17 will impact RMPs and labeling in this region.

Regulation for RMP under MFDS and Recent Experiences**Bee KIM**

Country Patient Safety Head, Korea, Novartis Patient Safety, GDD (Global Drug Development), Novartis Korea Ltd., Republic of Korea

Labeling Regulation in China**Jason Chen, MPharm**

International Labeling Asia Team Lead, Pfizer (China) R&D Co., Ltd., China

Emerging Trends of Electronic Labelling in Asia Pacific**Vicky HAN**

Senior Director, Asia Pacific Regulatory Policy Lead, Global Regulatory Affairs, Janssen Asia Pacific, Johnson & Johnson Pte. Ltd., Singapore

Panel Discussion

PANELISTS

All speakers in this Session

17:30-17:35 CLOSING REMARKS

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that the DIA.

Speakers and agenda are subject to change without notice.

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Event #18302 • March 26-27, 2018 | TOC Ariake Convention Hall, Tokyo

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Early Bird Deadline: March 12, 2018

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