



ICH Day

as a Part of DIA Asia 2019 Conference

April 18, 2019 at TOC Ariake | Tokyo



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Pharmaceuticals and Medical Devices Agency (PMDA)

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DIA volunteers, members, and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications, and educational materials, throughout the year, all around the world.

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OVERVIEW

We will be providing a comprehensive training for the ICH by taking advantage of the timing when various Asian countries have become a part of ICH structure.

Asia, the future, changing with ICH

This year, the ICH has determined to allow multiple Asian regulators to join ICH as official members, drastically changing from 3 originating regions of the US, EU and Japan. These countries are all moving to a new era when they can introduce common pharmaceutical regulations and discuss issues on the same foundation. To meet the unmet medical needs, regulators are trying to accelerate the drug development, including the introduction of an expedited review process. Asian academies/companies also change the methods using a various new technologies to find a solution. It is becoming necessary to pay an effort to understand both the cutting-edge science and technology and changes in medical needs, flexibly responding to patient expectations.

We will be expecting your active participation!

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

*The views and opinions expressed in this training session and associated training materials are those of the individual presenter and should not be attributed to the International Council for Harmonisation (ICH) organization, its members, officers, employees, participants, observers or volunteers.

For registration, visit DIA web site;

<https://www.diaglobal.org/productfiles/7785151/19302.pdf>



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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**

Akio Uemura, PhD
Representative Director, DIA Japan

9:40-10:10 KEYNOTE ADDRESS

SESSION CHAIR

Ling Su, PhD

Professor, Shenyang Pharmaceutical University, China

For the People in Asia, and the World - Making Maximal Use of Drug Development Potential in Asia - Shinobu Uzu

Associate Executive Director (New Drug Review), Center for Product Evaluation, PMDA, Japan

10:10-11:40 SESSION 1**ICH Guideline E2A, E2B(R3) Training**

SESSION CHAIR

Miyako Shionoiri

Associate Director, PV System Management Group, Safety and Risk Management Department, Daiichi Sankyo Co., Ltd.

Overview of the guideline. / Definition of the terms. / Serious Adverse Event or Adverse Drug Reaction. / Expectedness of an Adverse Drug Reaction. / Standards For Expedited Reporting. / Implementation of the electronic transmission of Individual Case Safety Reports (ICSRs). / Key success factors of the guideline implementation in Japan from agency and industry perspective.

E2A: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting

Yuki Marumo

Review Planning Div., Office of Review Management, PMDA, Japan

E2B(R3)-1: Electronic Transmission of Individual Case Safety Reports (ICRs) - 1 (Regulatory Agency's Viewpoint)

Takashi Misu, PhD

Senior Reviewer, Office of Pharmacovigilance I, PMDA, Japan

E2B(R3)-2: Electronic Transmission of Individual Case Safety Reports (ICRs) - 2 (Industry's Viewpoint)

Miyako Shionoiri

Associate Director, PV System Management Group, Safety and Risk Management Department, Daiichi Sankyo Co., Ltd.

11:40-12:40 LUNCH BREAK**12:40-14:10 SESSION 2****ICH Guideline E5, 17 Training**

SESSION CHAIR

Ryuta Nakamura, PhD

Director, Office of New Drug II, PMDA, Japan

Overview of the guideline. / Definition of the terms, / Assessment of the foreign clinical data for extrapolation to the new region. / Developmental strategies for global development. / The value of multi-regional clinical trials in drug development. / Clinical trial design and protocol-related issues of MRCTs. / The current status and challenges of the guideline implementation in Japan.

E5/E17: Ethnic Factors in the Acceptability of Foreign Clinical Data; Planning and Design of Multi-regional Clinical Trials -1 (Regulatory Agency's Viewpoint)

Yoko Aoi, PhD

Principal Planning and Coordination Officer, Office of International Cooperation, PMDA, Japan

E5/E17: Ethnic Factors in the Acceptability of Foreign Clinical Data; Planning and Design of Multi-regional Clinical Trials -1 (Industry's viewpoint)

Osamu Komiyama

Senior Manager, Regulatory Policy, Pfizer Japan

Panel Discussion

All Session Speakers

14:10-14:35 SESSION 3**ICH Guideline M7 Training**

SESSION CHAIR

Kiyohiro Hashimoto

Takeda Pharm., Co., Ltd., Japan

Overview of the guideline. / Current status of 2nd addendum preparation (selection of additional impurities). / Actual examples to assess and control the

limit of DNA Reactive (Mutagenic) impurities.

ICH Guideline M7 Training

Masamitsu Honma, MD, PhD

Director, Division of Genetics and Mutagenesis, National Institute of Health Science, Japan

14:35-15:05 COFFEE BREAK**15:05-15:55 SESSION 4****ICH Guideline Q5A-E, Q6B Training**

SESSION CHAIR

Tomonori Nakagawa

Otsuka Pharm. Co., Ltd., Japan

Overview of the guideline. / Specific requirements on biological product comparing chemical products. / Key success factors of the guideline implementation in Japan. / Any considerations on new modalities?

Q5A-E: Quality of Biotechnological/biological Products

Yasuhisa Ideno

Reviewer, Office of Cellular and Tissue-based Products, PMDA, Japan

Q6B: Test Procedures and Acceptance Criteria for Biotechnological/biological Products

Yasuhisa Ideno

Reviewer, Office of Cellular and Tissue-based Products, PMDA, Japan

15:55-16:20 SESSION 5

Elements Considered for the ICH Q12 Guideline Currently under Development

SESSION CHAIR

Tomonori Nakagawa

Otsuka Pharm., Co., Ltd., Japan

Overview of the draft guideline. / Current status of public comments. / Anticipated challenges for the future implementation

Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management

Satomi Yagi

Reviewer, Office of New Drug IV, PMDA, Japan

16:20-17:50 SESSION 6**Regulatory Reform and ICH implementation in Asian Countries**

SESSION CHAIR

Junko Sato, PhD

Director, Office of International Programs, PMDA, Japan

Since its inception in 1990, ICH has gradually evolved, and 'New' ICH has established as non-profit, non-governmental legal entity under Swiss law in 2015, having been disseminating more information on ICH processes to a wider number of stakeholders. Under this new frame work, multiple Asian regulators has joined ICH as official members recently, and need to implement the international technical standards and guidelines of pharmaceutical development.

In this session, Asian regulatory/academic experts will share the interpretation of each guideline, their opportunities and challenges on pharmaceutical development under their new ICH era.

Regulatory Reform

Speaker from CDE (Invited)

NMPA, China

ICH Implementation Status

Speaker from CDE (Invited)

NMPA, China

Regulatory Reform and the ICH Implementation Status

Speaker from MFDS (Invited)

MFDS, Korea

ICH Related Training by CORE

James Leong

Centre of Regulatory Excellence(CoRE)/ Duke-NUS Medical School, Singapore

Panel Discussion

All Session Speakers

17:50-19:30 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.

Wednesday, April 17

Thursday, April 18

All times are acceptable

Before 8:00 and after 21:00