ICH/DIA Joint Tokyo Workshop

After ICH Japan Meeting

November 12, 2016
Tokyo TOC Ariake

PROGRAM CHAIRPERSON
Tatsuo Kurokawa, PhD
President DIA
President Japan Self-Medication Industry

PROGRAM CO-VICE CHAIRS
Junko Sato, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)
Hironobu Saito, PhD
Pharmaceutical Manufacturers Association (JPMA)

PROGRAM ADVISORS
Joan Blair, MA
U.S. Food and Drug Administration (FDA)
Sabine Luik, MD, MBA
European Federation of Pharmaceutical Industries and Associations (EFPIA)
Jerry Stewart, JD, MS, RPH
Pharmaceutical Research and Manufacturers of America (PhRMA)

PROGRAM COMMITTEE: FROM ICH
Yoshiihro Katsura, MS
Pharmaceuticals and Medical Devices Agency (PMDA)
Michelle Limoli, PharmD
U.S. Food and Drug Administration (FDA)
Emi Tomotake
Pharmaceutical Manufacturers Association (JPMA)
Masafumi Yokota, DVM, PhD
Pharmaceutical Manufacturers Association (JPMA)

PROGRAM COMMITTEE: FROM DIA
Rie Matsui, RPh
Pfizer Japan Inc.
Satoshi Saeki, MS
Astellas Pharma Development Inc.
Yoshiaki Uyama, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

PURPOSE

• With the ICH reform, the new ICH organization will reinforce the foundations of ICH to make it better-equipped to face the challenges of global pharmaceutical development and regulation.
• The future ICH activities have almost the same direction with those of DIA, which has served as a global forum with increasing its global reach.
• It will be a great opportunity to have a joint workshop with collaboration between ICH and DIA in good timing when the ICH Osaka Meeting (Nov 5-10, 2016) and DIA Japan Annual Meeting (Nov 13-15, 2016) will be held, in order to share major outcomes from the ICH Osaka Meeting as well as to discuss its implications.

9:30–11:00 SESSION 1: ICH REFORM AND DIA CONTRIBUTION

Overview of ICH Reform and Its Vision
Impact of ICH Reform on Asia and Japan Contribution
DIA’s Contribution to ICH – Role of a Platform

11:30–13:00, 14:00–15:30 SESSION 2: UPDATE ON ICH GUIDELINES (3 TRACKS)

In this session, each track will cover not only update on the ICH Osaka Meeting but also follow-up discussions with Key members from major ICH regions.

Track 1  E17 – Impact on Development Strategy
Track 2  E6 – Impact on Clinical Operations
Track 3  E2 – Global Safety Monitoring

Each track will have morning (11:30 – 13:00: mainly update on ICH Osaka Meeting) and afternoon (14:00 – 15:30: focus on advanced discussions) sessions.

16:00–18:00 SESSION 3: PANEL DISCUSSION – THE FUTURE ACTIVITIES

In this session, the future activities of ICH (including new topics of ICH guideline) and contribution of DIA will be discussed among key members in ICH Management Committee.
8:50-9:20 REGISTRATION

9:20-9:30 WELCOME AND OPENING REMARKS

Ko Sekiguchi
Director
DIA Japan

9:30-11:00 SESSION 1: ICH REFORM AND DIA CONTRIBUTION

SESSION CHAIRS
Kazumichi Kobayashi
Chair
DIA Advisory Council of Japan

Junko Sato, PhD
International Coordination Officer
Pharmaceuticals and Medical Devices Agency(PMDA)

Overview of ICH Reform and Its Vision
Lenita Lindström-Gommers
Directorate General for Health and Food Safety
European Commission(EC)

Impact of ICH Reform to Asia and Japan Contribution
Toshiyoshi Tominaga, PhD
Associate Executive Director for International Programs
Pharmaceuticals and Medical Devices Agency (PMDA)

DIA’s Contribution for ICH – Role of a Platform
Tatsuo Kurokawa, PhD
President
DIA
President
Japan Self-Medication Industry

SESSION 2: UPDATE on ICH GUIDELINES (3 Tracks)

In this session, each track will cover not only update on the ICH Osaka Meeting but also follow-up discussions with Key members from major ICH regions.

11:30-13:00 MORNING SESSION

Track 1
E17 – Impact on Development Strategy
SESSION CHAIR
Yoshiaki Uyama, PhD
Director, Office of Medical Informatics and Epidemiology
Pharmaceuticals and Medical Devices Agency(PMDA)

Overview of E17 Guideline and Update from ICH Osaka Meeting
Yoshiaki Uyama, PhD
E17 EWG Rapporteur
Director, Office of Medical Informatics and Epidemiology
Pharmaceuticals and Medical Devices Agency(PMDA)

Regulator’s Expectations for E17 GL
-From PMDA’s Perspectives
Yoko Aoi, PhD
Reviewer, Office of New Drug IV
Pharmaceuticals and Medical Devices Agency(PMDA)

-From FDA’s Perspectives
Lisa LaVange, PhD
Director, Office of Biostatistics
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration(FDA)

-From EMA’s Perspectives
Armin Koch, PhD
Director of the Institute for Biostatistics
Hannover Medical School

Track 2
E6 – Impact on Clinical Operations
SESSION CHAIR
Satoshi Saeki, MS
Associate Director
Business Process Improvement & Innovation
Quality, Innovation, and Learning Services (QuILS)
Astellas Pharma Development Inc.

Overview and Status Update of E6 GL
Ryosuke Sakai
Office of Non-clinical and Clinical Compliance
Pharmaceuticals and Medical Devices Agency(PMDA)

Regulator’s Expectations and Future Impacts on E6 GL
-From PMDA’s Perspectives
Makoto Hirose
Office Director, Office of Non-clinical and Clinical Compliance
Pharmaceuticals and Medical Devices Agency(PMDA)

-From FDA’s Perspectives
Theresa M. Mullin, PhD
Director, Office of Strategic Programs
U.S. Food and Drug Administration(FDA)

Track 3
E2 – Global Safety Monitoring
SESSION CHAIRS
Gerald Dal Pan, M.D., M.H.S.
Director, Office of Surveillance and Epidemiology
U.S. Food and Drug Administration(FDA)

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

Overview and Status Update of Benefit Risk Balance Evaluation & Risk Management Plan
E. Stewart Geary, MD
Senior Vice President, Chief Medical Officer
Eisai, Co., Ltd.

Regulator’s Expectations on Risk Management and the Future for ICH E2
-From PMDA’s Perspectives
Shinobu Uzu
Chief Safety Officer
Pharmaceuticals and Medical Devices Agency(PMDA)

-From FDA’s Perspectives
Rania Mouchantaf, PhD
Manager Marketed Pharmaceuticals and Medical Devices MHPD
Health Canada

-From Canada’s Perspectives

14:00-15:30 AFTERNOON SESSION

Track 1

Industry’s Expectations for E17 GL
-From JPMA’s Perspectives
  Osamu Komiyama
  Senior Manager
  Pfizer Japan Inc.

-From PhRMA’s Perspectives
  Laurie Letvak, MD
  Head, Clinical Policy and Medical Ethics
  Novartis Pharmaceuticals Corporation

-From EFPIA’s Perspectives
  Vibeke Bjerregaard, MSc
  Senior Regulatory Manager, Regulatory Affairs Policy
  Novo Nordisk A/S

Panel Discussion
  All speakers above

Track 2

Expectations and Challenges for E6 GL from Industry and Academia Perspectives
-From TransCelerate’s Perspectives
  Ann Meeker-O’Connell
  Senior Director / Head
  Johnson & Johnson Consumer Products

-From JPMA’s Perspectives
  Satoshi Matsushita
  R&D QA/ Director
  Janssen Pharmaceutical K.K.

-From Clinical Site’s Perspectives
  Yasuhiro Fujiwara, MD, PhD
  Director-General, Strategic Planning Bureau National Cancer Center Department of Breast and Medical Oncology
  National Cancer Center Hospital

Panel Discussion
  All speakers above

Track 3

Expectations and Challenges for Label as Driver and Risk Management Plan from industry and Drug Development Perspective
-From US and EU HQ Perspective
  Claudia Hey, PhD
  Senior Director, Head Europe Global Regulatory and Scientific Policy (GRASP)
  Merck KGaA

-From Japan Perspective
  Hiromichi Shirasawa, MD
  Vice President and Executive Officer, Head of Japan Development
  MSD K.K.

Panel Discussion
  All speakers above

15:30-16:00 COFFEE BREAK

16:00-18:00 SESSION 3: PANEL DISCUSSION - The Future Activities

In this session, the future activities of ICH (including new topics of ICH guideline) and contribution of DIA will be discussed.

SESSION CO-CHAIRS

Kazuhiko Mori
  Director, Councilor for Pharmaceutical Affairs
  Ministry of Health, Labour & Welfare (MHLW)

Hironobu Saito, PhD
  Chair, JPMA ICH Committee
  Pharmaceutical Manufacturers Association (JPMA)

PANELISTS

Peter Honig, MD, PhD
  Senior Vice President and Head of Worldwide Safety and Regulatory
  Pfizer Inc.

Tatsuo Kurokawa, PhD
  President
  DIA
  Japan Self-Medication Industry

Lenita Lindström-Gomers
  Directorate General for Health and Food Safety
  European Commission(EC)

Theresa M. Mullin, PhD
  Director, Office of Strategic Programs
  U.S. Food and Drug Administration(FDA)

Pär Tellner
  Director, Team Leader, Regulatory Affairs
  European Federation of Pharmaceutical Industries and Associations (EFPIA)

Naoyuki Yasuda
  Office Director, Office of International Programs
  Pharmaceuticals and Medical Devices Agency(PMDA)

Gerald Dal Pan, M.D., M.H.S.
  DIA Leader of “Council of Regulatory”
  Director, Office of Surveillance and Epidemiology
  U.S. Food and Drug Administration(FDA)
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Administrative fee that will be withheld from refund amount:
Industry (Member or Nonmember) = ¥10,000
Government/Academia/Nonprofit/Medicals (Member or Nonmember) = ¥5,000

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.

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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.

Contact the DIA Japan office in Tokyo for further information.

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Please check the applicable category:
☐ Academia  ☐ Government  ☐ Industry

Early Bird Deadline: Oct 21, 2016
* To register for Academia Membership, please send this form to DIA Japan office by fax or e-mail.

REGISTRATION FORM: Register online or forward to DIA Japan, Nihonbashi Life Science Building 6F, 2-3-11 Nihonbashi-honcho, Chuo-ku, Tokyo 103-0023 Japan
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