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

Yoshihiro 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)

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PURPOSE

- With the ICH reform, the new ICH organization will reinforce the foundations of ICH to make it better-equipped to face the 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.

Simultaneous Translation Available

DIA DEVELOP INNOVATE ADVANCE

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

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

Gerald Dal Pan, M.D., M.H.S.
Director, Office of Surveillance and Epidemiology
U.S. Food and Drug Administration(FDA)

-From Canada's Perspectives

Rania Mouchantaf, PhD
Manager Marketed Pharmaceuticals and Medical Devices MHPD
Health Canada

13:00-14:00 LUNCH BREAK

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
Chief Medical Office
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
BioResearch Quality and Compliance, Consumer
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
President
Japan Self-Medication Industry

Lenita Lindström-Gommers
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)

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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ICH/DIA Joint Workshop

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Address: 4F East Hall 3-5-7 Ariake Koutou-ku, Tokyo 135-0063

DIA will send participants a confirmation mail within 10 business days after receipt of their registration.

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Early Bird Deadline: Oct 21, 2016

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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.

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