ICH Public Meeting:
ICH Japan Symposium 2013

December 10, 2013

Tsuda Hall, Shibuya-ku, Tokyo, Japan

Program

ICH Public Conference

Organized by the

Japan Pharmaceutical Manufacturers Association (JPMA)
Pharmaceutical and Medical Device Regulatory Science Society of Japan (PMRJ)

Supported by the

Ministry of Health, Labour and Welfare (MHLW)
Federation of Pharmaceutical Manufacturers' Associations of JAPAN
The Pharmaceutical Manufacturers' Association of Tokyo
Osaka Pharmaceutical Manufacturers Association
Japan Pharmaceutical Association

Working Language: Japanese
Simultaneous English-Japanese Translation: Not Available

PROGRAM

10:00-10:10 **Welcoming Address**
Chair, ICH Project Committee, JPMA Dr. Hironobu Saito

10:10-10:30 **Recent Developments of ICH**
International Planning Director, MHLW Mr. Naoyuki Yasuda

10:30-10:50 **Overviews of ICH Topics**
Director, Global Scientific and Regulatory Affairs, JPMA
Dr. Kurajiro Kishi

Topics for the Electronic Exchange of Information
Session Chair: Mr. Koji Shomoto - JPMA
Dr. Mihoko Okada– MHLW (KUMW)*

10:50-11:10 M2: Electronic Standards for the Transfer of Regulatory Information
M2 Topic Leader, JPMA Mr. Koji Shomoto

11:10-11:30 E2B (R3) IWG: Revision of the Electronic Submission of Individual Case Safety Reports
E2B (R3) IWG Topic Leader, JPMA Mr. Manabu Inoue

11:30-11:50 M8 EWG/IWG: Electronic Common Technical Document: eCTD
M8 EWG/IWG Rapporteur, MHLW (PMDA) Mr. Taku Watanabe

11:50-12:05 Discussion (Questions & Answers)

12:05-13:00 **Lunch Break**

Efficacy Topics
Session Chair: Mr. Yasuhiko Imai - JPMA
Dr. Yoji Sato– MHLW (NIHS)*

13:00-13:20 E2C (R2) IWG: Periodic Benefit-Risk Evaluation Report (PBRER)
E2C (R2) IWG Topic Leader, JPMA Ms. Yoko Hattori

13:20-13:40 E14 IWG: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs
E14 IWG Deputy Topic Leader, MHLW (PMDA) Ms. Yuki Ando

13:40-13:55 Discussion (Questions & Answers)

Quality Topics
Session Chair: Dr. Tsuneo Okubo - JPMA
Dr. Haruhiro Okuda - MHLW (NIHS)*

13:55-14:15 Q3D: Guideline for Elemental Impurities
Q3D Topic Leader, MHLW (PMDA) Dr. Chikako Yomota

14:15-14:35 Q7 IWG: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
Q7 IWG Topic Leader, MHLW (PMDA) Mr. Masatoshi Morisue
14:35-14:50 Discussion (Questions & Answers)

Safety Topics

Session Chair: Dr. Kazuichi Nakamura - JPMA
Dr. Akiyoshi Nishikawa - MHLW (NIHS)*

15:05-15:25 S1: Rodent Carcinogenicity Studies for Human Pharmaceuticals
S1 Expert, MHLW (PMDA) Dr. Mizuho Nonaka
15:25-15:45 S10: Photosafety Evaluation
S10 Rapporteur, MHLW (TMIPH*) Dr. Dai Nakae
15:45-16:05 M7: Assessment and Control of DNA Reactive (mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk
M7 Topic Leader, JPMA Dr. Tsuneo Hashizume
16:05-16:25 Safety Brainstorming Group
Safety Topics Coordinator, JPMA Dr. Kazuichi Nakamura
16:25-16:40 Discussion (Questions & Answers)

16:40-16:45 **Closing Remarks**
Director, Global Scientific and Regulatory Affairs, JPMA
Dr. Kurajiro Kishi

*KUMW: Kawasaki University of Medical Welfare
NIHS: National Institute of Health Sciences
TMIPH: Tokyo Metropolitan Institute of Public Health

Scientific Program Committee

Mr. Naoyuki Yasuda	International Planning Director, Ministry of Health, Labour and Welfare
Dr. Nobumasa Nakashima	Office Director, Office of International Program, Pharmaceuticals and Medical Devices Agency
Ms. Yasuko Inokuma	Deputy Director, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare
Dr. Jun Kitahara	Division Director, Division of Regulatory Cooperation, Office of International Programs, Pharmaceuticals and Medical Devices Agency
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Dr. Kurajiro Kishi	Director, Global Scientific and Regulatory Affairs, Japan Pharmaceutical Manufacturers Association

Organization Committee

Mr. Shigeki Tsuda	Senior Managing Director, Pharmaceutical and Medical Device Regulatory Science Society of Japan
Dr. Kimiko Mogami	Executive Director, Educational Activities for Pharmaceutical Professionals Pharmaceutical and Medical Device Regulatory Science Society of Japan
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