ICH Public Meeting:
ICH Japan Symposium 2012

July 25, 2012

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
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 Mr. Kohei Wada

10:10-10:35 **Recent Developments of ICH**
International Planning Director, MHLW Mr. Naoyuki Yasuda

10:35-11:00 **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)

11:00-11:15 M2: Electronic Standards for the Transfer of Regulatory Information
M2 Topic Leader, JPMA Mr. Koji Shomoto

11:15-11:30 E2B (R3): Revision of the Electronic Submission in Individual Case Safety Reports
E2B (R3) Rapporteur, MHLW(PMDA) Ms. Ayumi Endo

11:30-11:45 M5: Data Elements and Standards for Drug Dictionaries
M5 Topic Leader, MHLW (PMDA) Ms. Maiko Suzuki

11:45-12:00 M8: Electronic Common Technical Document
M8 Deputy Topic Leader, JPMA Ms. Akiyo Fujikawa

12:00-12:15 Discussion (Questions & Answers)

12:15-13:10 **Lunch Break**

Efficacy Topics
Session Chair: Dr. Osamu Inagaki - JPMA
Dr. Hidefumi Nakamura – MHLW (NCCHD CRC)

13:10-13:25 E2C (R2): Clinical Safety Data Management; Periodic Benefit Risk Evaluation Report (PBRER)
E2C (R2) Topic Leader, MHLW (PMDA) Ms. Hazuki Takaura

13:25-13:40 E3 IWG: Structure and Content of Clinical Study Report: Q&A
E3 IWG Topic Leader, MHLW (PMDA) Dr. Kayo Shinohara

13:40-13:55 E14 IWG: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs: Q&A
E14 IWG Topic Leader, JPMA Dr. Maki Ito

13:55-14:10 Discussion (Questions & Answers)

Safety Topics

Session Chair: Dr. Kazuichi Nakamura - JPMA
Dr. Hiroshi Onodera- MHLW (PMDA)

14:10-14:25	S1: Rodent Carcinogenicity Studies for Human Pharmaceuticals	
	S1 Topic Leader, JPMA	Mr. Shigeru Hisada
14:25-14:40	S10: Photosafety Evaluation	
	S10 Rapporteur, MHLW (TMIPH)	Dr. Dai Nakae
14:40-14:55	M3 (R2) IWG: Revision of Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals: Q&A	
	M3 (R2) Topic Leader, JPMA	Dr. Fumio Sagami
14:55-15:10	M7: Genotoxic Impurities	
	M7 Topic Leader, JPMA	Dr. Shigeki Sawada
15:10-15:25	Discussion (Questions & Answers)	

15:25-15:40 **Coffee Breaks**

Quality Topics

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

15:40-15:55	Q3D: Guideline for Metal Impurity	
	Q3D Topic Leader, JPMA	Dr. Masayuki Mishima
15:55-16:10	Q11: Development and Manufacture of Drug Substances	
	Q11 Deputy Topic Leader, MHLW (PMDA)	Dr. Kazunori Takagi
16:10-16:20	Quality Brainstorming	
	Topic Leader, MHLW (PMDA)	Dr. Yoshihiro Matsuda
16:20-16:35	Discussion (Questions & Answers)	

16:35-16:40 **Closing Remarks**

Director, Global Scientific and Regulatory Affairs, JPMA
Dr. Kurajiro Kishi

Scientific Program Committee

Mr. Naoyuki Yasuda	International Planning Director, Ministry of Health, Labour and Welfare
Dr. Toshiyoshi Tominaga	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
Mr. Kohei Wada	Chair, ICH Project Committee, Japan Pharmaceutical Manufacturers Association (Vice President/General Manager, Global Project Management Department, R&D Division Daiichi Sankyo Co., Ltd)
Dr. Kurajiro Kishi	Director, Global Scientific and Regulatory Affairs, Japan Pharmaceutical Manufacturers Association

Organization Committee

Mr. Shigeki Tsuda	Senior Executive Director, Pharmaceutical and Medical Device Regulatory Science Society of Japan
Dr. Kimiko Mogami	Executive Director, Pharmaceutical and Medical Device Regulatory Science Society of Japan
Mr. Kohei Wada	Chair, ICH Project Committee, Japan Pharmaceutical Manufacturers Association (Vice President/General Manager, Global Project Management Department, R&D Division Daiichi Sankyo Co., Ltd)
Dr. Kurajiro Kishi	Director, Global Scientific and Regulatory Affairs, Japan Pharmaceutical Manufacturers Association
Ms. Sayuri Masuko	JPMA ICH Secretariat, Japan Pharmaceutical Manufacturers Association

For further information, please contact JPMA ICH Coordinator:
Dr. Kurajiro Kishi, Tel.: +81-3-3241-0326, Fax: +81-3-3242-1767
E-mail:kishi@jpma.or.jp
JPMA postal address: Japan Pharmaceutical Manufacturers Association, Torii Nihonbashi Bldg., 3-4-1, Nihonbashi Honcho, Chuo-ku, Tokyo 103-0023, Japan