ICH Public Meeting:
ICH Japan Symposium 2010

December 2, 2010
Tsuda Hall, Sendagaya, Shibuya-ku, Tokyo, Japan

Program

ICH Public Conference
Organized by the
Pharmaceutical and Medical Device Regulatory Science
Society of Japan (PMRJ)
Japan Pharmaceutical Manufacturers Association (JPMA)
Supported by the
Ministry of Health, Labour and Welfare
Federation of Pharmaceutical Manufacturers` Association of JAPAN
Pharmaceutical Manufacturers’ Association of Tokyo
Osaka Pharmaceutical Manufacturers Association
Japan Pharmaceutical Association

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

10:00-10:05  Welcoming Address
             Chair, ICH Committee, JPMA  Mr. Kohei Wada

PLENARY SESSION

10:05-10:15  ICH and recent developments
             Deputy Director, MHLW  Ms. Michiko Suzuki

10:15-10:40  Overview of ICH topics
             Director, JPMA  Dr. Kurajiro Kishi

Topics for the electronic exchange of information

Session Chair: Mr. Koji Shomoto - JPMA
               Dr. Mihoko Okada - MHLW

10:40-10:50  M2: Electronic Standards for the Transfer of Regulatory Information
             Topic Leader M2, JPMA  Mr. Takeshi Adachi

10:50-11:00  E2B (R3): Revision of the Electronic Submission
             in Individual Case Safety Reports
             Rapporteur E2B (R3), MHLW(PMDA)  Ms. Ayumi Endo

11:00-11:10  M5: Data Elements and Standards for Drug Dictionaries
             Deputy Topic Leader M5, MHLW (PMDA)  Ms. Izumi Oba

             Deputy topic Leader M2, JPMA  Mr. Koji Shomoto

11:20-11:30  Questions & Answers

Efficacy topics

Session Chair: Mr. Takuya Sakuhiro - JPMA
               Ms. Tomoko Okudaira – MHLW (PMDA)

11:35-11:45  E2C(R1): Clinical Safety Data Management; Periodic Safety Update
             Reports for Marketed Drugs (PSUR) Brainstorming Session
             Topic Leader E2C(R1), MHLW (PMDA) Ms. Tomoko Okudaira

11:45-11:55  E14: The Clinical Evaluation of QT/QTc Interval Prolongation and
             Proarrhythmic Potential for Non-Antiarrhythmic Drugs
             Topic Leader E14, JPMA  Dr. Maki Ito

11:55-12:05  Questions & Answers
12:05-13:05 ~ Lunch break ~

**Safety topics**
*Session Chair: Dr. Kazuichi Nakamura - JPMA  
Dr. Yasuo Ohno - MHLW (NIHS)*

Topic Leader S6 (R1), JPMA Dr. Kazuto Watanabe

Rapporteur S10, MHLW (TMIPH) Dr. Dai Nakae

13:30-13:40 M3 (R2): Revision of Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals  
Topic Leader M3 (R2), JPMA Dr. Fumio Sagami

Topic Leader M6/GTDG, JPMA Dr. Wataru Toriumi

13:50-14:00 M7: Genotoxic Impurities  
Topic Leader M7, MHLW (NIHS) Dr. Masamitsu Honma

14:00-14:10 Questions & Answers

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

14:15-14:25 Q3D: Guideline for Metal Impurity  
Topic Leader Q3D, JPMA Dr. Masayuki Mishima

14:25-14:35 Q4B: Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions  
Topic Leader Q4B, JPMA Mr. Masaaki Wada

14:35-14:45 Q11: Development and Manufacture of Drug Substances  
Topic Leader Q11, MHLW (PMDA) Dr. Kazunori Takagi

14:45-14:55 Q-IWG: Quality Implementation Working Group  
Topic Leader Q-IWG, MHLW (PMDA) Dr. Yoshihiro Matsuda

14:55-15:05 Questions & Answers

15:05-15:20 ~ Coffee break ~
SPECIAL SESSION

Pharmacovigilance Brainstorming
Session Chair: Mr. Kohei Wada-JPMA
Mr. Daisaku Sato- MHLW

15:20-15:40 Panel 1 General Overview
MHLW
Mr. Daisaku Sato

15:40-16:00 Panel 2: Industry
JPMA
Ms. Yoko Hattori

16:00-16:20 Panel 3: Regulator
MHLW (PMDA)
Ms. Tomoko Okudaira

16:20-16:35 Questions & Answers

16:35-16:40 Closing Remarks
Director, JPMA
Dr. Kurajiro Kishi
Scientific Program Committee

Mr. Shinobu Uzu  International Planning Director,
Ministry of Health, Labour and Welfare
Dr. Toshiyoshi Tominaga  Office Director,
Office of International Program,
Pharmaceuticals and Medical Devices Agency
Ms. Michiko Suzuki  Deputy Director, Evaluation and Licensing Division,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare
Mr. Masaaki Tsukano  Division Director,
Division of Regulatory Cooperation,
Office of International Programs,
Pharmaceuticals and Medical Devices Agency
Mr. Kohei Wada  Chair, ICH Committee,
Japan Pharmaceutical Manufacturers Association
(DP/General Manager, Asia Development, R&D Division
Daiichi Sankyo Co., Ltd)
Dr. Kurajiro Kishi  Director, Medical & Scientific Department,
Japan Pharmaceutical Manufacturers Association

Organization Committee

Dr. Osamu Doi  Chief Executive,
Pharmaceutical and Medical Device Regulatory Science
Society of Japan
Mr. Shigeki Tsuda  Senior Executive Director,
Pharmaceutical and Medical Device Regulatory Science
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Mr. Kohei Wada  Chair, ICH Committee,
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