ICH Public Meeting:
ICH Japan Symposium 2009

June 12, 2009
Tower Hall Funabori, Edogawa-ku, Tokyo, Japan

Program

ICH Public Conference
Organized by the
Society of Japanese Pharmacopoeia &
Japan Pharmaceutical Manufacturers Association
Sponsored 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: English/Japanese
Simultaneous English-Japanese Translation 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  
Director, MHLW  
Mr. Shinobu Uzu

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

Topics for the electronic exchange of information  
Session Chair: Mr. Takeshi Adachi - JPMA  
Dr. Mihoko Okada - MHLW

10:40-10:50  M2 (SDOs): Electronic Standards for the Transfer of Regulatory Information  
Topic Leader M2, MHLW (PMDA)  
Mr. Yasuhiro Araki

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  
Topic Leader M5, JPMA  
Mr. Toshikazu Yoshinaga

Topic Leader M2, JPMA  
Mr. Takeshi Adachi

11:20-11:30  Questions & Answers

Efficacy topics  
Session Chair: Mr. Tetsuto Nagata - JPMA  
Dr. Yoshiaki Uyama - MHLW (PMDA)

11:30-11:45  E2F: Development Safety Update Report  
Topic Leader E2F, JPMA  
Ms. Noriko Akagi

11:45-11:55  E7 (R1): Revision of Studies in Support of Special Populations: Geriatrics  
Topic Expert E7 (R1), MHLW (PMDA)  
Dr. Kazuishi Sekino

11:55-12:00  E14: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs  
Topic Leader E14, JPMA  
Dr. Maki Ito

12:00-12:15  E16: Genomic Biomarkers Related to Drug Response: Context, Structure and Format of Qualification Submissions  
Rapporteur E16, PhRMA  
Dr. Lois Hinman
12:15-12:25  Questions & Answers

12:25-13:20  ~ Lunch break ~

**Safety topics**

*Session Chair: Dr. Atsushi Sanbuissho - JPMA  
Dr. Yasuo Ohno - MHLW (NIHS)*

Rapporteur S2 (R1), MHLW  
Dr. Makoto Hayashi

13:30-13:45  M3 (R2): Revision of Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals  
Rapporteur M3 (R2), FDA  
Dr. Abigail Jacobs

13:45-13:55  S6 (R1): Revision of Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals  
Topic Leader S6 (R1), JPMA  
Dr. Takahiro Nakazawa

13:55-14:05  S9: Nonclinical Evaluation for Anticancer Pharmaceuticals  
Topic Expert S9, MHLW  
Dr. Dai Nakae

14:05-14:20  GTDG: Gene Therapy Discussion Group  
Co-Rapporteur GTDG, EU  
Prof. Klaus Cichutek

14:20-14:30  Questions & Answers

**Quality topics**

*Session Chair: Mr. Shigeru Matsuki - JPMA  
Dr. Haruhiro Okuda - MHLW (NIHS)*

14:30-14:45  Q4B: Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions  
Topic Leader Q4B, JPMA  
Mr. Nobukazu Igoshi

14:45-15:00  Q11: Development and Manufacture of Drug Substances  
Rapporteur Q11, EFPIA  
Dr. Brian Withers

15:00-15:15  Q-IWG: Quality Implementation Working Group  
Deputy Topic Leader Q-IWG, MHLW (NIHS)  
Dr. Yukio Hiyama

15:15-15:25  Questions & Answers

15:25-15:40  ~ Coffee break ~
SPECIAL SESSION

Implementation of ICH guidelines in Asian countries
Session Chair: Mr. Kohei Wada - JPMA

15:40-15:50  ICH-Global Cooperation Group (GCG): History & framework
    JPMA            Mr. Kohei Wada

15:50-16:00  ICH-training in non-ICH regions: Concept & procedure
    Health Canada       Mr. Mike Ward

16:00-16:10  Current Status of ICH guideline implementation in Singapore
    DRA, Singapore        Dr. Christina Lim

16:10-16:25  Training of ICH guidelines in Thailand (Clinical workshop)
    ASEAN              Dr. Yuppadee Javroongrit

16:25-16:40  Training of ICH guidelines in Korea (Quality workshop)
    DRA, Korea         Dr. Dong Sup Kim

16:40-16:50  Discussion

16:50-16:55  Closing remarks
    Executive director, PMDA       Dr. Satoshi Toyoshima
Scientific Program Committee

Mr. Shinobu Uzu
International Planning Director,
Ministry of Health, Labour and Welfare

Mr. Takayuki Okubo
Deputy Director, Evaluation and Licensing Division,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

Mr. Kazutaka Ichikawa
Director General,
Japan Pharmaceutical Manufacturers Association

Mr. Kohei Wada
Chair, ICH Committee,
Japan Pharmaceutical Manufacturers Association
(VP/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,
Society of Japanese Pharmacopoeia

Mr. Shigeki Tsuda
Senior Executive Director,
Society of Japanese Pharmacopoeia

Mr. Kazutaka Ichikawa
Director General,
Japan Pharmaceutical Manufacturers Association

Mr. Kohei Wada
Chair, ICH Committee,
Japan Pharmaceutical Manufacturers Association
(VP/General Manager, Asia Development, R&D Division
Daiichi Sankyo Co., Ltd)

Dr. Kurajiro Kishi
Director, Medical & Scientific Department,
Japan Pharmaceutical Manufacturers Association

Ms. Aya Kuramoto
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