

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

11:10-11:20 M2 (eCTD): Electronic Common Technical Document
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)

13:20-13:30 S2 (R1): Guidance on Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use

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

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|-------------|---|--------------------------|
| 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

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