

# **ICH Public Meeting: ICH Japan Symposium 2009**

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**June 12, 2009**

**Tower Hall Funabori, Edogawa-ku, Tokyo, Japan**

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## **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**

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**Working Language: English/Japanese**

**Simultaneous English-Japanese Translation Available**

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# 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. Takuya Sakuhiro - 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<br>JPMA                         | Mr. Kohei Wada           |
| 15:50-16:00 | ICH-training in non-ICH regions: Concept & procedure<br>Health Canada                   | Mr. Mike Ward            |
| 16:00-16:10 | Current Status of ICH guideline implementation in Singapore<br>DRA, Singapore           | Dr. Christina Lim        |
| 16:10-16:20 | Current Status of ICH guideline implementation in China<br>DRA, China                   | (to be confirmed)        |
| 16:20-16:30 | Current Status of ICH guideline implementation in Chinese Taipei<br>DRA, Chinese Taipei | Dr. Chao-Yi Wang         |
| 16:30-16:45 | Training of ICH guidelines in Thailand (Clinical workshop)<br>RHI, ASEAN                | Dr. Yuppadee Javroongrit |
| 16:45-17:00 | Training of ICH guidelines in Korea (Quality workshop)<br>DRA, Korea                    | Dr. Dong Sup Kim         |
| 17:00-17:10 | Questions & Answers   |                          |
| 17:10-17:15 | <b>Closing remarks</b><br>Executive director, PMDA                                      | Dr. Satoshi Toyoshima    |

### ***Scientific Program Committee***

<b>Mr. Shinobu Uzu</b>	International Planning Director, Ministry of Health, Labour and Welfare
<b>Mr. Takayuki Okubo</b>	Deputy Director, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare
<b>Mr. Kazutaka Ichikawa</b>	Director General, Japan Pharmaceutical Manufacturers Association
<b>Mr. Kohei Wada</b>	Chair, ICH Committee, Japan Pharmaceutical Manufacturers Association (VP/General Manager, Asia Development, R&D Division Daiichi Sankyo Co., Ltd)
<b>Dr. Kurajiro Kishi</b>	Director, Medical & Scientific Department, Japan Pharmaceutical Manufacturers Association

### ***Organization Committee***

<b>Dr. Osamu Doi</b>	Chief Executive, Society of Japanese Pharmacopoeia
<b>Mr. Shigeki Tsuda</b>	Senior Executive Director, Society of Japanese Pharmacopoeia
<b>Mr. Kazutaka Ichikawa</b>	Director General, Japan Pharmaceutical Manufacturers Association
<b>Mr. Kohei Wada</b>	Chair, ICH Committee, Japan Pharmaceutical Manufacturers Association (VP/General Manager, Asia Development, R&D Division Daiichi Sankyo Co., Ltd)
<b>Dr. Kurajiro Kishi</b>	Director, Medical & Scientific Department, Japan Pharmaceutical Manufacturers Association
<b>Ms. Aya Kuramoto</b>	ICH Secretariat, Japan Pharmaceutical Manufacturers Association

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