

# **ICH Public Meeting: ICH Japan Symposium 2010**

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**December 2, 2010**

**Tsuda Hall, Sendagaya, Shibuya-ku, Tokyo, Japan**

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## **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**

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**Working Language: Japanese**

**Simultaneous English-Japanese Translation: Not 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**  
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

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

- 13:10-13:20 S6 (R1): Revision of Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals  
Topic Leader S6 (R1), JPMA Dr. Kazuto Watanabe
- 13:20-13:30 S10: Photosafety Evaluation  
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
- 13:40-13:50 M6/GTDG: Virus and Gene Therapy Vector Shedding and Transmission/  
Gene Therapy Discussion Group  
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	<b>Closing Remarks</b> Director, JPMA	Dr. Kurajiro Kishi

## *Scientific Program Committee*

<b>Mr. Shinobu Uzu</b>	International Planning Director, Ministry of Health, Labour and Welfare
<b>Dr. Toshiyoshi Tominaga</b>	Office Director, Office of International Program, Pharmaceuticals and Medical Devices Agency
<b>Ms. Michiko Suzuki</b>	Deputy Director, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare
<b>Mr. Masaaki Tsukano</b>	Division Director, Division of Regulatory Cooperation, Office of International Programs, Pharmaceuticals and Medical Devices Agency
<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, Pharmaceutical and Medical Device Regulatory Science Society of Japan
<b>Mr. Shigeki Tsuda</b>	Senior Executive Director, Pharmaceutical and Medical Device Regulatory Science Society of Japan
<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. Mayumi Ota</b>	ICH Secretariat, Japan Pharmaceutical Manufacturers Association

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