# ICH Public Meeting:
# ICH Japan Symposium 2013

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**December 10, 2013**

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

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# Program

## ICH Public Conference

**Organized by the**

Japan Pharmaceutical Manufacturers Association (JPMA)
Pharmaceutical and Medical Device Regulatory Science Society of Japan (PMRJ)

**Supported by the**

Ministry of Health, Labour and Welfare (MHLW)
Federation of Pharmaceutical Manufacturers' Associations of JAPAN
The 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

10:00-10:10 **Welcoming Address**
Chair, ICH Project Committee, JPMA Dr. Hironobu Saito

10:10-10:30 **Recent Developments of ICH**
International Planning Director, MHLW Mr. Naoyuki Yasuda

10:30-10:50 **Overviews of ICH Topics**
Director, Global Scientific and Regulatory Affairs, JPMA
Dr. Kurajiro Kishi

## Topics for the Electronic Exchange of Information

*Session Chair: Mr. Koji Shomoto - JPMA*
*Dr. Mihoko Okada– MHLW (KUMW*)*

10:50-11:10 M2: Electronic Standards for the Transfer of Regulatory Information
M2 Topic Leader, JPMA Mr. Koji Shomoto

11:10-11:30 E2B (R3) IWG: Revision of the Electronic Submission of Individual Case Safety Reports
E2B (R3) IWG Topic Leader, JPMA Mr. Manabu Inoue

11:30-11:50 M8 EWG/IWG: Electronic Common Technical Document: eCTD
M8 EWG/IWG Rapporteur, MHLW (PMDA) Mr. Taku Watanabe

11:50-12:05 Discussion (Questions & Answers)

12:05-13:00 **Lunch Break**

## Efficacy Topics

*Session Chair: Mr. Yasuhiko Imai - JPMA*
*Dr. Yoji Sato– MHLW (NIHS*)*

13:00-13:20 E2C (R2) IWG: Periodic Benefit-Risk Evaluation Report (PBRER)
E2C (R2) IWG Expert, JPMA Ms. Yukiko Watabe

13:20-13:40 E14 IWG: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs
E14 IWG Deputy Topic Leader, MHLW (PMDA) Ms. Yuki Ando

13:40-13:55 Discussion (Questions & Answers)

## Quality Topics

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

13:55-14:15 Q3D: Guideline for Elemental Impurities
Q3D Topic Leader, MHLW (PMDA) Dr. Chikako Yomota

14:15-14:35 Q7 IWG: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
Q7 IWG Topic Leader, MHLW (PMDA) Mr. Masatoshi Morisue
14:35-14:50 Discussion (Questions & Answers)

## Safety Topics

*Session Chair: Dr. Kazuichi Nakamura - JPMA*
*Dr. Akiyoshi Nishikawa - MHLW (NIHS*)*

15:05-15:25 S1: Rodent Carcinogenicity Studies for Human Pharmaceuticals
S1 Expert, MHLW (PMDA) Dr. Mizuho Nonaka
15:25-15:45 S10: Photosafety Evaluation
S10 Rapporteur, MHLW (TMIPH*) Dr. Dai Nakae
15:45-16:05 M7: Assessment and Control of DNA Reactive (mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk
M7 Topic Leader, JPMA Dr. Tsuneo Hashizume
16:05-16:25 Safety Brainstorming Group
Safety Topics Coordinator, JPMA Dr. Kazuichi Nakamura
16:25-16:40 Discussion (Questions & Answers)

16:40-16:45 **Closing Remarks**
Director, Global Scientific and Regulatory Affairs, JPMA
Dr. Kurajiro Kishi

*KUMW: Kawasaki University of Medical Welfare
NIHS: National Institute of Health Sciences
TMIPH: Tokyo Metropolitan Institute of Public Health

## *Scientific Program Committee*

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| **Mr. Naoyuki Yasuda** | International Planning Director,<br>Ministry of Health, Labour and Welfare |
| **Dr. Nobumasa Nakashima** | Office Director,<br>Office of International Program,<br>Pharmaceuticals and Medical Devices Agency |
| **Ms. Yasuko Inokuma** | Deputy Director, Evaluation and Licensing Division,<br>Pharmaceutical and Food Safety Bureau,<br>Ministry of Health, Labour and Welfare |
| **Dr. Jun Kitahara** | Division Director,<br>Division of Regulatory Cooperation,<br>Office of International Programs,<br>Pharmaceuticals and Medical Devices Agency |
| **Dr. Hironobu Saito** | Chair, ICH Project Committee,<br>Japan Pharmaceutical Manufacturers Association<br>(Vice President/New Drug Regulatory Affairs Department<br>R&D Division, Daiichi Sankyo Co., Ltd) |
| **Dr. Kurajiro Kishi** | Director, Global Scientific and Regulatory Affairs,<br>Japan Pharmaceutical Manufacturers Association |

## *Organization Committee*

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| **Mr. Shigeki Tsuda** | Senior Managing Director,<br>Pharmaceutical and Medical Device Regulatory Science Society of Japan |
| **Dr. Kimiko Mogami** | Executive Director, Educational Activities for Pharmaceutical Professionals<br>Pharmaceutical and Medical Device Regulatory Science Society of Japan |
| **Dr. Hironobu Saito** | Chair, ICH Project Committee,<br>Japan Pharmaceutical Manufacturers Association<br>(Vice President/New Drug Regulatory Affairs Department<br>R&D Division, Daiichi Sankyo Co., Ltd) |
| **Dr. Kurajiro Kishi** | Director, Global Scientific and Regulatory Affairs,<br>Japan Pharmaceutical Manufacturers Association |
| **Ms. Sayuri Masuko** | JPMA ICH Secretariat,<br>Japan Pharmaceutical Manufacturers Association |

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