

# **ICH Regional Public Meeting: ICH Japan Symposium 2015**

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**July 23, 2015**

**Zendentsu Hall, Chiyoda-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

10:00-10:05 **Welcoming Address**

JPMA Dr. Kurajiro Kishi

10:05-10:45 **Future ICH: ICH Reform**

MHLW Dr. Nobumasa Nakashima

JPMA Dr. Hironobu Saito

10:45-10:50 Discussion (Questions & Answers)

## **Topics for the Electronic Exchange of Information**

*Session Chair: Mr. Manabu Inoue - JPMA*

*Dr. Mihoko Okada - MHLW (KUMW\*)*

10:50-11:05 M2 EWG: Electronic Standards for the Transfer of Regulatory Information

JPMA Mr. Katsuhiko Hashimoto

11:05-11:20 M8 EWG/IWG: The Electronic Common Technical Document: eCTD

MHLW (PMDA\*) Mr. Taku Watanabe

11:20-11:25 Discussion (Questions & Answers)

## **Safety Topics**

*Session Chair: Dr. Kazuto Watanabe - JPMA*

*Dr. Akiyoshi Nishikawa - MHLW (NIHS\*)*

11:25-11:35 S3A IWG: Q&As on the ICH Guideline on Note for Guidance on Toxicokinetics

MHLW (NIHS) Dr. Yoshiro Saito

11:35-11:50 S5 (R3) EWG: Revision of ICH Guideline on Detection of Toxicity to Reproduction for Medicinal Products and Toxicity to Male Fertility

JPMA Dr. Michio Fujiwara

11:50-12:00 S9 IWG: Q&As on ICH Guideline on Nonclinical Evaluation for Anticancer Pharmaceuticals

MHLW (TUA\*) Dr. Dai Nakae

12:00-12:15 S11 EWG: ICH Guideline on Nonclinical Safety Testing in support of Development of Pediatric Medicines

JPMA Dr. Kiyoshi Matsumoto

12:15-12:25 M7 (R1) EWG: Addendum to ICH Guideline on Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk

MHLW (NIHS) Dr. Masamitsu Honma

12:25-12:30 Discussion (Questions & Answers)

12:30-13:15 **Lunch Break**

## **Efficacy Topics**

*Session Chair: Mr. Seiki Kanazawa - JPMA*

*Dr. Yoshiaki Uyama - MHLW (PMDA)*

13:15-13:30 E6 (R2) EWG: Addendum to ICH Guideline on Good Clinical Practice (GCP)

JPMA Mr. Satoshi Matsushita

- 13:30-13:45 E9 (R1) EWG: Addendum to ICH Guideline on Defining the Appropriate Estimand for a Clinical Trial/Sensitivity Analyses  
JPMA Mr. Satoru Tsuchiya
- 13:45-14:00 E11 (R1) EWG: Addendum to ICH Guideline on Pediatric Drug Development  
JPMA Mr. Katsuaki Sato
- 14:00-14:15 E14 Discussion Group: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs  
MHLW (PMDA) Dr. Kaori Shinagawa
- 14:15-14:30 E17 EWG: ICH Guideline on Multi-Regional Clinical Trials  
MHLW (PMDA) Dr. Yoko Aoi
- 14:30-14:45 E18 EWG: ICH Guideline on Genomic Sampling Methodologies for Future Use  
MHLW (PMDA) Dr. Akihiro Ishiguro
- 14:45-15:00 M4E (R2) EWG: Revision of CTD-Efficacy Guideline  
JPMA Ms. Yukiko Watabe
- 15:00-15:10 Discussion (Questions & Answers)
- 15:10-15:25 **Break**

### Quality Topics

*Session Chair: Dr. Tsuneo Okubo – JPMA*

*Dr. Haruhiro Okuda – MHLW (NIHS\*)*

- 15:25-15:35 Q3C (R6) Maintenance EWG: Maintenance of the ICH Guideline for Residual Solvents  
MHLW (NIHS) Dr. Akihiko Hirose
- 15:35-15:50 Q7 IWG: Q&As on ICH Guideline on Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients  
JPMA Mr. Tetsuhito Takarada
- 15:50-16:05 Q11 IWG: Q&As on ICH Guideline on API Starting Materials  
JPMA Mr. Kenji Ozaki
- 16:05-16:20 Q12 EWG: ICH Guideline on Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management  
MHLW (PMDA) Dr. Yasuhiro Kishioka
- 16:20-16:30 Discussion (Questions & Answers)
- 16:30-16:35 **Closing Remarks**  
JPMA Dr. Kurajiro Kishi

\*PMDA: Pharmaceuticals and Medical Devices Agency

KUMW: Kawasaki University of Medical Welfare

NIHS: National Institute of Health Sciences

TUA: Tokyo University of Agriculture