33th ICH Public Meeting

January 15, 2016

Zendentsu Hall, Chiyoda-ku, Tokyo, Japan

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

The Federation of Pharmaceutical Manufacturers' Associations of JAPAN
The Pharmaceutical Manufacturers' Association of Tokyo
Osaka Pharmaceutical Manufacturers Association
Japan Pharmaceutical Association

Working Language: Japanese
Simultaneous English-Japanese Translation: Not Available

PROGRAM

10:00-10:05 **Welcoming Address**
JPMA Dr. Akira Kawahara

10:05-10:45 **Current ICH : Establishment of the ICH Association**
MHLW Mr. Fumihito Takanashi
JPMA Dr. Hironobu Saito
10:45-10:50 Discussion (Questions & Answers)

Topics for the Multidisciplinary (Electronic Exchange of Information)
10:50-11:10 M2 EWG: Electronic Standards for the Transfer of Regulatory Information
JPMA Mr. Katsuhiro Hashimoto
11:10-11:30 M8 EWG/IWG: The Electronic Common Technical Document: eCTD
MHLW (PMDA*) Mr. Taku Watanabe
11:30-11:40 Discussion (Questions & Answers)

Quality Topics
11:40-12:00 Q11 IWG: Q&As on ICH Guideline on API Starting Materials
JPMA Mr. Kenji Ozaki
12:00-12:20 Q12 EWG: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management
MHLW (PMDA) Dr. Yasuhiro Kishioka
12:20-12:30 Discussion (Questions & Answers)

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

Efficacy Topics
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
13:45-13:55 E14 IWG: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential For Non-Antiarrhythmic Drugs Q&A
MHLW (PMDA) Dr. Kaori Shinagawa
13:55-14:15 E17 EWG: Multi-Regional Clinical Trials
MHLW (PMDA) Mr. Shuji Kamada
14:15-14:35 E18 EWG: Genomic Sampling Methodologies for Future Use
MHLW (PMDA) Dr. Akihiro Ishiguro
14:35-14:50 Discussion (Questions & Answers)

14:50-15:10 **Break**

Safety Topics

15:10-15:25 S1: Rodent Carcinogenicity Studies for Human Pharmaceuticals
MHLW (NIHS) Dr. Akiyoshi Nishikawa

15:25-15:40 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

15:40-15:55 S9 IWG: Q&As on ICH Guideline on Nonclinical Evaluation for Anticancer Pharmaceuticals
MHLW (TUA*) Dr. Dai Nakae

15:55-16:10 S11 EWG: Nonclinical Safety Testing in support of Development of Pediatric Medicines
JPMA Dr. Kiyoshi Matsumoto

16:10-16:20 Discussion (Questions & Answers)

16:20-16:25 **Closing Remarks**
JPMA Mr. Mitsuo Mihara

*PMDA: Pharmaceuticals and Medical Devices Agency
NIHS: National Institute of Health Sciences
TUA: Tokyo University of Agriculture