ICH Regional Public Meeting:
ICH Japan Symposium 2015

July 23, 2015

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

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

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

PROGRAM

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

JPMA Dr. Kurajiro Kishi

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

PMDA Dr. Toshiyoshi Tominaga
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. Katsuhiro 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