31st ICH Public Meeting

December 11, 2014

Nagai Kinen Hall, Shibuya-ku, Tokyo, Japan

Program

ICH Public Conference

Organized by

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

Supported by

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**
Chair, ICH Project Committee, JPMA Dr. Hironobu Saito

10:05-10:20 **Future of ICH: Reform of ICH**
International Planning Director,
Ministry of Health, Labour and Welfare Dr. Nobumasa Nakashima

10:20-10:40 **Recent Developments of ICH**
Director, Global Scientific and Regulatory Affairs, JPMA
Dr. Kurajiro Kishi

10:40-10:45 Questions & Answers

Topics for the Electronic Exchange of Information

10:45-11:05 E2B (R3) IWG: Revision of the Electronic Submission of Individual Case Safety Reports
E2B (R3) IWG Topic Leader, JPMA Mr. Manabu Inoue

11:05-11:25 M8 EWG/IWG: Electronic Common Technical Document: eCTD
M8 EWG/IWG Rapporteur, MHLW (PMDA) Mr. Taku Watanabe

11:25-11:35 Questions & Answers

Safety Topics

11:35-11:55 Informal S5 (R3) EWG: Detection of Toxicity to Reproduction for Medicinal Products & Toxicity to Male Fertility
Informal S5 (R3) EWG Topic Leader, JPMA Dr. Michio Fujiwara

11:55-12:05 S9 IWG: Q&A on Nonclicnial Evaluation for Anticancer Pharmaceuticals
S9 IWG Topic Leader, JPMA Dr. Chihiro Nishimura

12:05-12:15 Questions & Answers

12:15-13:10 **Lunch Break**

Efficacy Topics

13:10-13:30 E6 (R2): Good Clinical Practice (GCP)
E6 (R2) Expert, JPMA Mr. Seiki Kanazawa

13:30-13:50 E9 (R1): Addendum to Statistical Principles for Clinical Trials
E9 (R1) Topic Leader, JPMA Mr. Satoru Tsuchiya

13:50-14:10 E11 (R1): Addendum to Paediatric Drug Development
E11 (R1): Topic Leader, JPMA Mr. Masahiro Ozaki

14:10-14:30 E17: Multi-Regional Clinical Trials
E17 EWG Rapporteur, MHLW (PMDA) Dr. Yoshiaki Uyama

14:30-14:50 E18: Genomic Sampling Methodologies for Future Use
E18 EWG Rapporteur, MHLW (PMDA) Dr. Akihiro Ishiguro

14:50-15:10 M4E (R2): Revision of CTD-Efficacy Guideline
M4E (R2) EWG Deputy Topic Leader, MHLW (PMDA)
Dr. Yukiko Komori

15:10-15:20 Questions & Answers

15:20-15:35 **Break Time**

Quality Topics

15:35-15:55 Q3D EWG/IWG: Guideline for Elemental Impurities
Q3D EWG/IWG Expert, MHLW (PMDA) Dr. Toshinori Higashi

15:55-16:15 Q7 IWG: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
Q7 IWG Topic Leader, JPMA Mr. Tetsuhito Takarada

16:15-16:35 Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management
Q12 EWG Topic Leader, NHLW (PMDA) Dr. Yasuhiro Kishioka

16:35-16:45 Questions & Answers

16:45-16:50 **Closing Remarks**
Director, Global Scientific and Regulatory Affairs, JPMA
Dr. Kurajiro Kishi