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
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

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 Nonclinical 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