28th ICH Public Meeting

July 26, 2013

Tsuda Hall, Shibuya-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**
Chair, ICH Project Committee, JPMA
Dr. Hironobu Saito

10:05-10:30 **Future of ICH**
Chair, ICH Project Committee, JPMA
Dr. Hironobu Saito

10:30-10:55 **Recent Developments of ICH**
Director, Global Scientific and Regulatory Affairs, JPMA
Dr. Kurajiro Kishi

10:55-11:00 Question & Answers

11:00-11:30 E2B (R3) informal IWG: Electronic Submission in Individual Case Safety Reports (ICSRs)
E2B (R3) IWG Rapporteur, MHLW(PMDA) Ms. Ayumi Endo

11:30-11:35 Question & Answers

11:35-12:05 M8: The Electronic Common Technical Document: eCTD
M8 Topic Leader, JPMA Ms. Akiyo Fujikawa

12:05-12:10 Questions & Answers

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

13:10-13:40 S1: Rodent Carcinogenicity Studies for Human Pharmaceuticals
S1 Topic Leader, JPMA Mr. Shigeru Hisada

13:40-13:45 Questions & Answers

13:45-14:15 S10: Photosafety Evaluation
S10 Rapporteur, MHLW (TMIPH) Dr. Dai Nakae

14:15-14:20 Questions & Answers

14:20-14:45 **Coffee Breaks**

14:45-15:15 Q3D: Guideline for Metal Impurity
Q3D Topic Leader, JPMA Dr. Masayuki Mishima

15:15-15:20 Questions & Answers

15:20-15:50 Q7 IWG: Good Manufacturing Practice Guide for Active pharmaceutical Ingredients
Q7 IWG Topic Leader, JPMA Mr. Tetsuhito Takarada

15:50-15:55 Questions & Answers

15:55-16:00 **Closing Remarks**
Director, Global Scientific and Regulatory Affairs, JPMA
Dr. Kurajiro Kishi

For further information, please contact JPMA ICH Coordinator:
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