30th ICH Public Meeting

July 10, 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

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

10:30-10:55 **Recent Developments of ICH**
Division Director for Regulatory Coordination,
Office of International Programs, MHLW (PMDA)
Dr. Junko Sato

10:55-11:00 Questions & Answers

Safety Topics

11:00-11:25 M7: Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk
M7 expert, MHLW (PMDA) Dr. Junichi Fukuchi

11:25-11:30 Questions & Answers

Topics for the Electronic Exchange of Information

11:30-11:55 M8 EWG/IWG: Electronic Common Technical Document: eCTD
M8 EWG/IWG Rapporteur, MHLW (PMDA) Mr. Taku Watanabe

11:55-12:00 Questions & Answers

12:00-13:00 **Lunch Break**

Future ICH Topics

13:00-13:20 1) Overview of Future ICH Topics
Director, Global Scientific and Regulatory Affairs, JPMA
Dr. Kurajiro Kishi

13:20-13:45 2) S5 (R3) informal WG: Detection of Toxicity to Reproduction for Medicinal Products & Toxicity to Male Fertility
S5 (R3) informal WG Topic Leader, JPMA Dr. Michio Fujiwara

13:45-13:50 Questions & Answers

13:50-14:15 3) E6 (R2): Good Clinical Practice (GCP)
E6 (R2) Topic Leader, MHLW (PMDA) Dr. Kazuhiro Matsui

14:15-14:20 Questions & Answers

14:20-14:45 4) Informal Quality Discussion Group (IQDG)
IQDG expert, MHLW (PMDA) Dr. Yoshihiro Matsuda

14:45-14:50 Questions & Answers

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

Quality Topics

15:10-15:35 1) Q3D: Guideline for Elemental Impurities
Q3D Topic Leader, MHLW (PMDA) Dr. Chikako Yomota

15:35-15:40 Questions & Answers

15:40-16:05 2) Q7 IWG: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
Q7 IWG Topic Leader, JPMA Mr. Tetsuhito Takarada

16:05-16:10 Questions & Answers

16:10-16:20 **Closing Remarks**
Director, Global Scientific and Regulatory Affairs, JPMA
Dr. Kurajiro Kishi

Scientific Program Committee

Mr. Naoyuki Yasuda	International Planning Director, Ministry of Health, Labour and Welfare
Dr. Nobumasa Nakashima	Office Director, Office of International Program, Pharmaceuticals and Medical Devices Agency
Ms. Yasuko Inokuma	Deputy Director, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare
Dr. Junko Sato	Division Director for Regulatory Coordination, Office of International Programs, Pharmaceuticals and Medical Devices Agency
Dr. Hironobu Saito	Chair, ICH Project Committee, Japan Pharmaceutical Manufacturers Association (Vice President/New Drug Regulatory Affairs Department R&D Division, Daiichi Sankyo Co., Ltd)
Dr. Kurajiro Kishi	Director, Global Scientific and Regulatory Affairs, Japan Pharmaceutical Manufacturers Association

Organization Committee

Mr. Shigeki Tsuda	Senior Managing Director, Pharmaceutical and Medical Device Regulatory Science Society of Japan
Dr. Kimiko Mogami	Executive Director, Educational Activities for Pharmaceutical Professionals Pharmaceutical and Medical Device Regulatory Science Society of Japan
Dr. Hironobu Saito	Chair, ICH Project Committee, Japan Pharmaceutical Manufacturers Association (Vice President/New Drug Regulatory Affairs Department R&D Division, Daiichi Sankyo Co., Ltd)
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