

27th ICH Public Meeting

December 14, 2012

Yakult Hall, Minato-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

Federation of Pharmaceutical Manufacturers' Associations of
JAPAN
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
- 10:05-10:35 **Recent Developments of ICH**
Deputy Director, Evaluation and Licensing Division, MHLW
Ms. Yasuko Inokuma
- 10:35-10:40 Question & Answers
- 10:40-11:05 E2B (R3): Revision of the Electronic Submission
in Individual Case Safety Reports
E2B (R3) Rapporteur, MHLW(PMDA) Ms. Ayumi Endo
- 11:05-11:10 Question & Answers
- 11:10-11:35 M5: Data Elements and Standards for Drug Dictionaries
M5 Topic Leader, JPMA Mr. Toru Kimura
- 11:35-11:40 Questions & Answers
- 11:40-12:05 E2C (R2): Clinical Safety Data Management; Periodic Benefit-Risk
Evaluation Report (PBRER)
E2C (R2) Topic Leader, JPMA Ms. Yoko Hattori
- 12:05-12:10 Questions & Answers
- 12:10-13:10 **Lunch Break**
- 13:10-13:35 S1: Rodent Carcinogenicity Studies for Human Pharmaceuticals
MHLW (NIHS) Dr. Akiyoshi Nishikawa
- 13:35-13:40 Questions & Answers
- 13:40-14:05 S10: Photosafety Evaluation
S10 Topic Leader, JPMA Dr. Kazuhiro Hosoi
- 14:05-14:10 Questions & Answers
- 14:10-14:35 M7: Assessment and Control of DNA Reactive (Mutagenic) Impurities
in Pharmaceuticals to Limit Potential Carcinogenic Risk
MHLW (NIHS) Dr. Masamitsu Honma
- 14:35-14:40 Questions & Answers
- 14:40-15:00 **Coffee Breaks**
- 15:00-15:25 Q3D: Guideline for Metal Impurity
MHLW (NIHS) Dr. Chikako Yomota
- 15:25-15:30 Questions & Answers
- 15:30-15:55 Q7: Good Manufacturing Practice Guide for Active Pharmaceutical
Ingredients
Q7 Topic Leader, JPMA Mr. Tetsuhito Takarada
- 15:55-16:00 Questions & Answers

For further information, please contact JPMA ICH Coordinator:

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