ICH Public Meeting:
ICH Japan Symposium 2010

December 2, 2010

Tsuda Hall, Shibuya-ku, Tokyo, Japan

Program

ICH Public Conference

Organized by the

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

Japan Pharmaceutical Manufacturers Association (JPMA)

Supported by the

Ministry of Health, Labour and Welfare (MHLW)

Federation of Pharmaceutical Manufacturers` Association 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 Committee, JPMA Mr. Kohei Wada

PLENARY SESSION

10:05-10:15 **ICH and recent developments**
Deputy Director, MHLW Ms. Michiko Suzuki

10:15-10:40 **Overview of ICH topics**
Director, JPMA Dr. Kurajiro Kishi

Topics for the electronic exchange of information

Session Chair: Mr. Koji Shomoto - JPMA
Dr. Mihoko Okada - MHLW

10:40-10:50 M2: Electronic Standards for the Transfer of Regulatory Information
Topic Leader M2, JPMA Mr. Takeshi Adachi

10:50-11:00 E2B (R3): Revision of the Electronic Submission in Individual Case Safety Reports
Rapporteur E2B (R3), MHLW(PMDA) Ms. Ayumi Endo

11:00-11:10 M5: Data Elements and Standards for Drug Dictionaries
Deputy Topic Leader M5, MHLW (PMDA) Ms. Izumi Oba

11:10-11:20 M2 (eCTD): Electronic Common Technical Document
Deputy topic Leader M2, JPMA Mr. Koji Shomoto

11:20-11:30 Questions & Answers

Efficacy topics

Session Chair: Mr. Takuya Sakuhiro - JPMA
Ms. Tomoko Okudaira – MHLW (PMDA)

11:35-11:45 E2C(R1): Clinical Safety Data Management; Periodic Safety Update Reports for Marketed Drugs (PSUR) Brainstorming Session
Topic Leader E2C(R1), MHLW (PMDA) Ms. Tomoko Okudaira

11:45-11:55 E14: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs
Topic Leader E14, JPMA Dr. Maki Ito

11:55-12:05 Questions & Answers

12:05-13:05 ~ **Lunch break ~**

Safety topics

Session Chair: Dr. Kazuichi Nakamura - JPMA
Dr. Yasuo Ohno- MHLW (NIHS)

13:10-13:20 S6 (R1): Revision of Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals
Topic Leader S6 (R1), JPMA Dr. Kazuto Watanabe

13:20-13:30 S10: Photosafety Evaluation
Rapporteur S10, MHLW (TMIPH) Dr. Dai Nakae

13:30-13:40 M3 (R2): Revision of Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals
Topic Leader M3 (R2), JPMA Dr. Fumio Sagami

13:40-13:50 M6/GTDG: Virus and Gene Therapy Vector Shedding and Transmission/ Gene Therapy Discussion Group
Topic Leader M6/GTDG, JPMA Dr. Wataru Toriumi

13:50-14:00 M7: Genotoxic Impurities
Topic Leader M7, MHLW (NIHS) Dr. Masamitsu Honma

14:00-14:10 Questions & Answers

Quality topics

Session Chair: Dr. Tsuneo Okubo - JPMA
Dr. Haruhiro Okuda - MHLW (NIHS)

14:15-14:25 Q3D: Guideline for Metal Impurity
Topic Leader Q3D, JPMA Dr. Masayuki Mishima

14:25-14:35 Q4B: Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions
Topic Leader Q4B, JPMA Mr. Masaaki Wada

14:35-14:45 Q11: Development and Manufacture of Drug Substances
Topic Leader Q11, MHLW (PMDA) Dr. Kazunori Takagi

14:45-14:55 Q-IWG: Quality Implementation Working Group
Topic Leader Q-IWG, MHLW (PMDA) Dr. Yoshihiro Matsuda

14:55-15:05 Questions & Answers

15:05-15:20 ~ **Coffee break ~**

SPECIAL SESSION

Pharmacovigilance Brainstorming

Session Chair: Mr. Kohei Wada-JPMA
Mr. Daisaku Sato- MHLW

15:20-15:40	Panel 1 General Overview	
	MHLW	Mr. Daisaku Sato
15:40-16:00	Panel 2: Industry	
	JPMA	Ms. Yoko Hattori
16:00-16:20	Panel 3: Regulator	
	MHLW (PMDA)	Ms. Tomoko Okudaira
16:20-16:35	Questions & Answers	

16:35-16:40 **Closing Remarks**
Director, JPMA — Dr. Kurajiro Kishi

Scientific Program Committee

Mr. Shinobu Uzu	International Planning Director, Ministry of Health, Labour and Welfare
Dr. Toshiyoshi Tominaga	Office Director, Office of International Program, Pharmaceuticals and Medical Devices Agency
Ms. Michiko Suzuki	Deputy Director, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare
Mr. Masaaki Tsukano	Division Director, Division of Regulatory Cooperation, Office of International Programs, Pharmaceuticals and Medical Devices Agency
Mr. Kohei Wada	Chair, ICH Committee, Japan Pharmaceutical Manufacturers Association (VP/General Manager, Asia Development, R&D Division Daiichi Sankyo Co., Ltd)
Dr. Kurajiro Kishi	Director, Medical & Scientific Department, Japan Pharmaceutical Manufacturers Association

Organization Committee

Dr. Osamu Doi	Chief Executive, Pharmaceutical and Medical Device Regulatory Science Society of Japan
Mr. Shigeki Tsuda	Senior Executive Director, Pharmaceutical and Medical Device Regulatory Science Society of Japan
Mr. Kohei Wada	Chair, ICH Committee, Japan Pharmaceutical Manufacturers Association (VP/General Manager, Asia Development, R&D Division Daiichi Sankyo Co., Ltd)
Dr. Kurajiro Kishi	Director, Medical & Scientific Department, Japan Pharmaceutical Manufacturers Association
Ms. Mayumi Ota	ICH Secretariat, Japan Pharmaceutical Manufacturers Association

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