ICH Public Meeting:
ICH Japan Symposium 2009

June 12, 2009

Tower Hall Funabori, Edogawa-ku, Tokyo, Japan

Program

ICH Public Conference

Organized by the
Society of Japanese Pharmacopoeia &
Japan Pharmaceutical Manufacturers Association
Sponsored by the
Ministry of Health, Labour and Welfare
Federation of Pharmaceutical Manufacturers` Association of JAPAN
Pharmaceutical Manufacturers` Association of Tokyo
Osaka Pharmaceutical Manufacturers Association
Japan Pharmaceutical Association

Working Language: English/Japanese
Simultaneous English-Japanese Translation 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**
Director, MHLW Mr. Shinobu Uzu
10:15-10:40 **Overview of ICH topics**
ICH Coordinator, JPMA Dr. Kurajiro Kishi

Topics for the electronic exchange of information
Session Chair: Mr. Takeshi Adachi - JPMA
Dr. Mihoko Okada - MHLW
10:40-10:50 M2 (SDOs): Electronic Standards for the Transfer of Regulatory Information
Topic Leader M2, MHLW (PMDA) Mr. Yasuhiro Araki
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
Topic Leader M5, JPMA Mr. Toshikazu Yoshinaga
11:10-11:20 M2 (eCTD): Electronic Common Technical Document
Topic Leader M2, JPMA Mr. Takeshi Adachi
11:20-11:30 Questions & Answers

Efficacy topics
Session Chair: Mr. Takuya Sakuhiro - JPMA
Dr. Yoshiaki Uyama - MHLW (PMDA)
11:30-11:45 E2F: Development Safety Update Report
Topic Leader E2F, JPMA Ms. Noriko Akagi
11:45-11:55 E7 (R1): Revision of Studies in Support of Special Populations: Geriatrics
Topic Expert E7 (R1), MHLW (PMDA) Dr. Kazuishi Sekino
11:55-12:00 E14: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs
Topic Leader E14, JPMA Dr. Maki Ito
12:00-12:15 E16: Genomic Biomarkers Related to Drug Response: Context, Structure and Format of Qualification Submissions
Rapporteur E16, PhRMA Dr. Lois Hinman
12:15-12:25 Questions & Answers

12:25-13:20 ~ **Lunch break** ~

Safety topics

Session Chair: Dr. Atsushi Sanbuissho - JPMA
Dr. Yasuo Ohno - MHLW (NIHS)

13:20-13:30 S2 (R1): Guidance on Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use
Rapporteur S2 (R1), MHLW Dr. Makoto Hayashi

13:30-13:45 M3 (R2): Revision of Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals
Rapporteur M3 (R2), FDA Dr. Abigail Jacobs

13:45-13:55 S6 (R1): Revision of Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals
Topic Leader S6 (R1), JPMA Dr. Takahiro Nakazawa

13:55-14:05 S9: Nonclinical Evaluation for Anticancer Pharmaceuticals
Topic Expert S9, MHLW Dr. Dai Nakae

14:05-14:20 GTDG: Gene Therapy Discussion Group
Co-Rapporteur GTDG, EU Prof. Klaus Cichutek

14:20-14:30 Questions & Answers

Quality topics

Session Chair: Mr. Shigeru Matsuki - JPMA
Dr. Haruhiro Okuda - MHLW (NIHS)

14:30-14:45 Q4B: Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions
Topic Leader Q4B, JPMA Mr. Nobukazu Igoshi

14:45-15:00 Q11: Development and Manufacture of Drug Substances
Rapporteur Q11, EFPIA Dr. Brian Withers

15:00-15:15 Q-IWG: Quality Implementation Working Group
Deputy Topic Leader Q-IWG, MHLW (NIHS)
Dr. Yukio Hiyama

15:15-15:25 Questions & Answers

15:25-15:40 ~ **Coffee break** ~

SPECIAL SESSION

Implementation of ICH guidelines in Asian countries

Session Chair: Mr. Kohei Wada - JPMA

15:40-15:50	ICH-Global Cooperation Group (GCG): History & framework	
	JPMA	Mr. Kohei Wada
15:50-16:00	ICH-training in non-ICH regions: Concept & procedure	
	Health Canada	Mr. Mike Ward
16:00-16:10	Current Status of ICH guideline implementation in Singapore	
	DRA, Singapore	Dr. Christina Lim
16:10-16:20	Current Status of ICH guideline implementation in China	
	DRA, China	(to be confirmed)
16:20-16:30	Current Status of ICH guideline implementation in Chinese Taipei	
	DRA, Chinese Taipei	Dr. Chao-Yi Wang
16:30-16:45	Training of ICH guidelines in Thailand (Clinical workshop)	
	RHI, ASEAN	Dr. Yuppadee Javroongrit
16:45-17:00	Training of ICH guidelines in Korea (Quality workshop)	
	DRA, Korea	Dr. Dong Sup Kim
17:00-17:10	Questions & Answers	

17:10-17:15	**Closing remarks**	
	Executive director, PMDA	Dr. Satoshi Toyoshima

Scientific Program Committee

Mr. Shinobu Uzu	International Planning Director, Ministry of Health, Labour and Welfare
Mr. Takayuki Okubo	Deputy Director, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare
Mr. Kazutaka Ichikawa	Director General, Japan Pharmaceutical Manufacturers Association
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, Society of Japanese Pharmacopoeia
Mr. Shigeki Tsuda	Senior Executive Director, Society of Japanese Pharmacopoeia
Mr. Kazutaka Ichikawa	Director General, Japan Pharmaceutical Manufacturers Association
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. Aya Kuramoto	ICH Secretariat, Japan Pharmaceutical Manufacturers Association

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