

ICH Tokyo Symposium: Hot Topics and Influence on Asia

November 2, 2007

Keidanren Hall, 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

Welcome Address

10:00-10:05 JPMA: Mr. Kohei Wada

Hot Topics 1 ~Morning Sessions~

Chairperson: JPMA: Dr. Kurajiro Kishi
10:05-10:40 General Update on ICH
JPMA: Dr. Kurajiro Kishi
10:40-11:15 S2 (R1)
MHLW (NIHS): Dr. Makoto Hayashi
11:15-11:50 E2F
PMDA: Dr. Junko Sato

11:50-12:50 Lunch Break

Hot Topics 2 ~ Afternoon Sessions~

Chairperson: MHLW: Dr. Toshiyoshi Tominaga
12:50-13:25 Steering Committee
FDA: Dr. Justina Molzon
13:25-13:45 Quality: Q8 (R1)
MHLW (NIHS): Dr. Haruhiro Okuda
13:45-14:20 Quality: New Paradigm
EU: Dr. Jean-Louis Robert
14:20-14:55 M2
EFPIA: Dr. Andrew Marr

14:55-15:10 Coffee Break

15:10-15:45 M3 (R2)
PhRMA: Dr. Joseph DeGeorge

Panel Discussion

Chairpersons: Health Canada: Mr. Mike Ward
JPMA: Mr. Kohei Wada
Panelists: Health Canada: Mr. Mike Ward
JPMA: Mr. Kohei Wada
APEC: Dr. Jianhua Ding,
Dr. Dong Sup Kim
ASEAN: Dr. Yuppadee Javroongrit
15:45-16:55 “Clinical Development in Asia and ICH: Implementation of ICH
Guidelines in Asian Countries“

Closing Address

16:55-17:00 PMDA: Dr. Satoshi Toyoshima

Scientific Program Committee

- Dr. Toshiyoshi Tominaga** International Planning Director,
Pharmaceutical Affairs Minister's Secretariat,
Ministry of Health, Labour and Welfare
- Mr. Takayuki Okubo** Section Chief, 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
(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** Senior Executive Director, Society of Japanese
Pharmacopoeia
- Mr. Shigeki Tsuda** Director of the Secretariat, Society of Japanese
Pharmacopoeia
- Mr. Kazutaka Ichikawa** Director General,
Japan Pharmaceutical Manufacturers Association
- Mr. Kohei Wada** Chair, ICH Committee,
Japan Pharmaceutical Manufacturers Association
(General Manager, Asia Development R&D Division,
Daiichi Sankyo Co., Ltd)
- Dr. Kurajiro Kishi** Director, Medical & Scientific Department,
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- Ms. Aya Kuramoto** ICH Secretariat,
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