

Integrated Implementation Training Workshop on Q8/Q9/Q10 Points to Consider

February 15, 2013

Zendentsu Hall, Chiyoda-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
The Pharmaceutical Manufacturers' Association of Tokyo
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Japan Pharmaceutical Association
Japan Bulk Pharmaceutical Manufacturers Association

Working Language: Japanese

Simultaneous English-Japanese Translation: Not Available

PROGRAM

10:00-10:10	Welcoming Address Chair, ICH Project Committee, JPMA	Dr. Hironobu Saito
10:10-10:25	Introduction Q-IWG Topic Leader, JPMA	Dr. Fusashi Ishikawa
10:25-10:50	Criticality of Quality Attributes and Process Parameters MHLW (NIHS)	Dr. Yukio Hiyama
10:50-11:30	Control Strategy Q-IWG Deputy Topic Leader, JPMA	Mr. Tetsuhito Takarada
11:30-11:55	Level of Documentation in Enhanced (QbD) Regulatory Submissions MHLW (PMDA)	Dr. Yoshihiro Matsuda
11:55-13:00	Lunch Break	
13:00-13:30	Role of Models in Quality by Design (QbD) Q-IWG Topic Leader, JPMA	Dr. Fusashi Ishikawa
13:30-14:00	Design Space Q-IWG Expert, JPMA	Mr. Kazuhiro Okochi
14:00-14:30	Process Validation / Continuous Process Verification MHLW (PMDA)	Mr. Masatoshi Morisue
14:30-15:10	Background and Issues about Revised Enforcement Notice on Good Manufacturing Products MHLW (PMDA)	Mr. Masatoshi Morisue
15:10-15:30	Coffee Breaks	
15:30-16:00	Consideration of the Case Study for Sakuramil MHLW (PMDA/NIHS)	Dr. Kazunori Takagi
16:00-17:00	Panel Discussion Moderator: Dr. Haruhiro Okuda Mr. Kiyotoshi Matsumura Panelist: All Speakers	Q11 Expert, JPMA MHLW (NIHS)
17:00-17:05	Closing Remarks Director, Global Scientific and Regulatory Affairs, JPMA	Dr. Kurajiro Kishi

For further information, please contact JPMA ICH Coordinator:

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