

Integrated Implementation Training Workshops for ICH Q8, Q9, Q10: Follow-up

Program

April 25, 2011
Tower Hall Funabori, Tokyo, Japan

Organized by

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

ICH Project Committee, Japan Pharmaceutical Manufacturers
Association (JPMA)

Sponsored by

Federation of Pharmaceutical Manufacturers' Associations of
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Osaka Pharmaceutical Manufacturers Association

Japan Pharmaceutical Association

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10:00 **Welcome Remarks:**
 Tadao Terao (Chairperson, PMRJ)

Session A:

10:05 **Integrated Implementation Training Workshops for ICH Q8, Q9, Q10
Guidelines, Oct 25-27, 2010 in Tokyo: Objectives, Outcomes and Future**
 Yukio Hiyama (NIHS), Q-IWG

Session B: How Q8, Q9, Q10 guidelines work in life cycle approach

10:35 **Case Study: Product Development**
 Kazuhiro Okochi (Takeda Pharmaceutical Co., Ltd.), Q-IWG

11:15 **Case Study: Regulatory Assessment**
 Yoshihiro Matsuda (PMDA), Q-IWG

11:55 Lunch

12:55 **Case study: Implementation and Pharmaceutical Quality System
considerations**
 Shigeki Tamura (Astellas Pharma Inc.), Q-IWG

13:35 **Case study: Inspections at Manufacturing Site**
 Masatoshi Morisue (PMDA), Q-IWG

14:15 Coffee Break

Session C: Report from breakout session, Integrated Implementation Workshops for ICH Q8, Q9, Q10 Guidelines, Oct 25-27, 2010 in Tokyo

14:35 **General Update:**
 Fusashi Ishikawa (Dainippon Sumitomo Pharma Co., Ltd.), Q-IWG

15:00 **Track: Design Space**
 Kimiya Okazaki (Pfizer Japan Inc.)

15:15 **Track: Control Strategy**
 Takeshi Hamaura (Daiichi Sankyo Co., Ltd)

15:30 **Track: Pharmaceutical Quality Systems**
 Tomonori Nakagawa (Otsuka Pharmaceutical Co., Ltd.)

15:45 **Track D: Quality Risk Managements**
 Kazunori Takagi (PMDA)

Session D: Closing panel discussion

16:00 **Open Q&A from Floor**
 Moderator:
 Yukio Hiyama (NIHS), Q-IWG
 Fusashi Ishikawa (Dainippon Sumitomo Pharma Co., Ltd.), Q-IWG
 Kazuhiro Okochi (Takeda Pharmaceutical Co., Ltd.), Q-IWG
 Yoshihiro Matsuda (PMDA), Q-IWG
 Shigeki Tamura (Astellas Pharma Inc.), Q-IWG
 Masatoshi Morisue (PMDA), Q-IWG
 Kimiya Okazaki (Pfizer Japan Inc.)
 Takeshi Hamaura (Daiichi Sankyo Co., Ltd)
 Tomonori Nakagawa (Otsuka Pharmaceutical Co., Ltd.)
 Kazunori Takagi (PMDA)

17:00 **Closing Remarks**
 Kurajiro Kishi (JPMA)

17:05 End of Workshop