

Integrated Implementation Training Workshops for ICH Q8, Q9, Q10

Program

October 25—27, 2010
Tower Hall Funabori, Tokyo, Japan

Organized by

Pharmaceutical and Medical Device Regulatory Science Society
of Japan

ICH Project Committee, Japan Pharmaceutical Manufacturers
Association (JPMA)

Sponsored by

Ministry of Health, Labour and Welfare (MHLW)

Federation of Pharmaceutical Manufacturers' Associations of
JAPAN

Pharmaceutical Manufacturers' Association of Tokyo

Osaka Pharmaceutical Manufacturers Association

Japan Pharmaceutical Association

Monday, 25 October 2010

Conference Start 13:00

Moderator:

Fusashi Ishikawa (Dainippon Sumitomo Pharma Co., Ltd.), Q-IWG

Session A: Introduction

- 13:00 **Welcome Remarks & Introductions:**
Kohei Wada (Chairperson, ICH Project Committee, JPMA)
- 13:20 **How ICH Q8, Q9, Q10 Guidelines are Working Together Throughout the Product Life Cycle**
Yukio Hiyama (NIHS) , Q-IWG

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

- 13:40 **Case Study: Product Development**
Kazuhiro Okochi (Takeda Pharmaceutical Co., Ltd.), Q-IWG
- 14:30 **Case Study: Regulatory Assessment**
Yoshihiro Matsuda (PMDA), Q-IWG
- 15:20 Coffee Break
- 15:50 **Case study - Implementation and PQS Considerations**
Tetsuhito Takarada (Mochida Pharmaceutical Co., Ltd.), Q-IWG
- 16:40 **Case study- Inspections at Manufacturing Site**
Masatoshi Morisue (PMDA), Q-IWG
- 17:30 **Panel Discussion and Planning for Next Day Breakouts**
Clarifying question only related the four presentation topics
Moderator: Fusashi Ishikawa (Dainippon Sumitomo Pharma Co., Ltd.), Q-IWG
All speakers
- 18:00 End of Day 1

Tuesday, 26 October 2010

Conference Start 09:30

Session C: Break out

4 groups (Team A, Team B, Team C, Team D) are rotating

Track: Design Space

Leader: Motoaki Mitsuki (PMDA), Q-IWG

Kazuhiro Okochi (Takeda Pharmaceutical Co., Ltd.), Q-IWG

Track: Control Strategy

Leader: Yoshihiro Matsuda (PMDA), Q-IWG

Fusashi Ishikawa (Dainippon Sumitomo Pharma Co., Ltd.), Q-IWG

Track: Pharmaceutical Quality System

Leader: Masatoshi Morisue (PMDA), Q-IWG

Shigeki Tamura (Astellas Pharma Inc.), Q-IWG

Track: Quality Risk Management

Leader: Yukio Hiyama (NIHS), Q-IWG

Tetsuhito Takarada (Mochida Pharmaceutical Co., Ltd.), Q-IWG

	Track: Design Space	Track: Control Strategy	Track: Pharmaceutical Quality System	Track: Quality Risk Management
09:30 – 11:30	Team A	Team B	Team C	Team D
12:30 – 14:30	Team B	Team C	Team D	Team A
14:50 – 16:50	Team C	Team D	Team A	Team B
17:10 – 19:10	Team D	Team A	Team B	Team C

End of Day 2

Wednesday, 27 October 2010

Conference Start 09:30

Moderator:
Akira Kusai (JPMA), Q-IWG

Session D: Presentation to report on Q-IWG activities

09:30 **Q-IWG Status and Update**
Fusashi Ishikawa (Dainippon Sumitomo Pharma Co., Ltd.), Q-IWG

Session E: Report from each workshop including addressing Q&A

10:00 **Track: Design Space**
Motoaki Mitsuki (PMDA) , Q-IWG
Kazuhiro Okochi (Takeda Pharmaceutical Co., Ltd.), Q-IWG

10:30 **Track: Control Strategy**
Yoshihiro Matsuda (PMDA), Q-IWG
Fusashi Ishikawa (Dainippon Sumitomo Pharma Co., Ltd.), Q-IWG

11:00 **Track: Pharmaceutical Quality Systems**
Masatoshi Morisue (PMDA), Q-IWG
Shigeki Tamura (Astellas Pharma Inc.), Q-IWG

11:30 Coffee Break

12:30 **Track D: Quality Risk Managements**
Yukio Hiyama (NIHS), Q-IWG
Tetsuhito Takarada (Mochida Pharmaceutical Co., Ltd.), Q-IWG

Session F: Closing panel discussion

13:00 **Open Q&A from Floor**
Moderator: Yukio Hiyama (NIHS), Q-IWG
Yoshihiro Matsuda (PMDA), Q-IWG
Motoaki Mitsuki (PMDA), Q-IWG
Fusashi Ishikawa (Dainippon Sumitomo Pharma Co., Ltd.), Q-IWG
Tetsuhito Takarada (Mochida Pharmaceutical Co., Ltd.), Q-IWG
Shigeki Tamura (Astellas Pharma Inc.), Q-IWG
Kazuhiro Okochi (Takeda Pharmaceutical Co., Ltd.), Q-IWG

13:55 **Workshop Conclusions and Next Steps**
Kurajiro Kishi (JPMA)

14:00 End of Conference