The Fifth Pharmaceutical Quality Forum Symposium—Co-Sponsored by ISPE

Friday 9th June 2006 Yokohama Municipal Education Hall

0830 - 0900 Registration
0900 - 0905 Welcome Charles Holberg ISPE
0905 - 0915 Opening Remarks Akira Kawahara, Director, Evaluation and Licensing Division, MHLW

Session I (John Berridge, Haruhiro Okuda, co-chairs)
Intended Deliverable: Information on latest Q8 thinking and how it can be incorporated into regulatory submissions

08:15 - 09:45 ICH Q-8 Update:
Incorporating Design Space thinking into a submission – authorities’ views and case studies
Fritz Erni –EFPIA (ICH Q8 Rapporteur)

09:45 - 10:15 MHLW Reviewer’s view
Tamiji Nakanishi (PMDA)

10:15 - 10:45 EU’s view
Jean-Louis Robert (EU)

10:45 - 11:00 Break

11:00 - 11:30 FDA’s view
Chi-Wen Chen (FDA)

11:30 - 12:00 Design Space case study I
Kazuhiro Okouchi (JPMA)

12:00 - 12:30 Opportunity and Challenge from the International-based Companies Perspective
Kimiya Okazaki (JPMA)

12:30 - 13:00 Questions and Answers

13:00 - 14:00 Lunch

Session II (Jean-Louis Robert, Shigeru Matsuki, co-chairs)
Intended Deliverable: Greater understanding of the issues, challenges and opportunities for revising and harmonizing a comprehensive Qo(S) (Quality overall Summary) / Quality Gaiyo

14:00 - 14:30 Why was revision of the QOS proposed? Key elements from the concept paper
Procusal: Jean-Louis Robert (EU and CTD-Q Rapporteur)

The QOS as a submission and review document. Historical perspectives and future opportunities.

14:30 - 14:45 MHLW Reviewer’s Experience
Mayumi Shikano (PMDA)

14:45 - 15:00 Canadian Experience
Sultan Ghani (Health Canada)

15:00 - 15:30 Japanese Experience—Benefits of Quality Gaiyo
Nobukazu Igoichi (JPMA)

15:30 - 15:45 Break

15:45 - 16:15 US Regulators’ perspective
Moheb Nasr (FDA)

16:15 - 16:45 US Industry perspective
Bob Baum (PhRMA)

16:45 - 17:15 EU Industry perspective
John Berridge (EFPIA)

17:15 - 17:45 Panel discussion of key elements to be included in the revised QOS

17:45 Closing Remarks Director General of JPMA

http://www.nihs.go.jp/drug/PhForum/program060609.html

2006/06/01