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

(v530)

Friday 9th June 2006 Yokohama Municipal Education Hall

0830 - 0900	Registration	
0900 - 0905	Welcome	Charles Hoiberg 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

09:15 - 09:45	ICH Q-8 Update:	Fritz Erni -EFPIA (ICH Q8 Rapporteur)
	Incorporating Design Space thinking into a submission - authorities' views and case studies	
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-Wan Chen (FDA)
11:30 - 12:00	Design Space case study I	Kazuhiro Ohkouchi(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 QoS(Quality overall Summary) /Quality Gaiyo

14:00 - 14:30 Why was revision of the QOS proposed? Key elements from the concept paper Proposal: 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 Igoshi (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

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