

WORKSHOP AGENDA
OCT 4-5, 2011
GRAND HILTON HOTEL, SEOUL, REPUBLIC OF KOREA

Day 1

OCT 4, 2011 (TUESDAY)				
07:30 - 08:00	Registration			
08:00 - 08:10	Welcoming Remarks & Introduction Jean-Louis Robert (Rapporteur of ICH Q-IWG Department of Quality Control of Medicine, Luxembourg)			
08:10 - 08:40	How ICH Q8, Q9, Q10 guidelines are working together throughout the product lifecycle Moheb Nasr (FDA, CDER, USA, Q-IWG)			
08:40 - 08:50	Opening Ceremony			
Session A: How Q8 / Q9 / Q10 work in a life cycle approach				
08:50 - 09:40	Case Study – Product Development Jean Wyvratt (Merck & Co., USA, Q-IWG)			
09:40 - 10:25	Case Study – Regulatory Assessment Elaine Morefield (FDA, CDER, USA, Q-IWG (tbc))			
10:25 - 10:45	Coffee/Tea Break			
10:45 - 11:30	Case Study – Implementation and PQS considerations Swroop Sahota (Merck Inc., US, or Georges France, Pfizer, Q-IWG)			
11:30 - 12:15	Case Study – Inspections at a manufacturing site Jacques Morénas (AFSSAPS, France, Q-IWG)			
12:15 - 12:45	Panel discussion relating to today's presentations and planning for breakouts <i>Moderators</i> Jean-Louis Robert (Department of Quality Control of Medicine, Luxembourg, Q-IWG) Moheb Nasr (FDA, CDER, USA, Q-IWG)			
12:45 - 02:00	Lunch Break			
Session B: Breakout Discussions Four tracks and teams (Blue, Red, Green, Brown)				
	Design Space	Control Strategy	Pharmaceutical Quality System	Quality Risk Management
02:00 - 04:00	Team 1	Team 2	Team 3	Team 4
04:00 - 06:00	Team 2	Team 3	Team 4	Team 1
※ All teams will attend the four topics. ※ Considering the number of attendees, the host will divide the participants in a lump.				
Track A: Design Space				
<i>Leaders</i> Moheb Nasr (FDA, CDER, USA, Q-IWG)				

Georges France
(Pfizer, UK, Q-IWG)

Track B: Control Strategy

Leaders

Bob Baum
(Pfizer, USA)

Jean-Louis Robert
(Department of Quality Control of Medicine, Luxembourg)

Track C: Pharmaceutical Quality System

Leaders

Jacques Morénas
(AFSSAPS, France, Q-IWG)

Swroop Sahota
(Merck Inc., US, Q-IWG)

Track D: Quality Risk Management

Leaders

Stephan Rönninger
(F. Hoffmann-La Roche, Ltd., Switzerland, Q-IWG (tbc))

Teams to stay in the same room – Facilitators will be rotating

Blue team - Grandball room A in Grand Hilton Hotel Seoul

Red team - Grandball room C

Green team - Emerald Hall A

Brown team - Emerald Hall B

Day 2

OCT 5, 2011 (WEDNESDAY) *Rotation Continues				
	Design Space	Control Strategy	Pharmaceutical Quality System	Quality Risk Management
08:00 - 10:00	Team 3	Team 4	Team 1	Team 2
10:00 - 12:00	Team 4	Team 1	Team 2	Team 3
	※ All teams will attend the four topics. ※ Considering the number of attendees, the host will divide the participants in a lump.			
12:00 - 01:30	Lunch Break			
	Session C: Report from each workshop including addressing Q&A <i>Moderator</i> Stephan Rönninger (F. Hoffmann-La Roche, Ltd., Switzerland, Q-IWG (tbc))			
01:30 - 01:50	Track A: Design Space Moheb Nasr (FDA, CDER, USA, Q-IWG) Georges France (Pfizer, UK, Q-IWG)			
01:50 - 02:10	Track B: Control Strategy Bob Baum (Pfizer, USA, Q-IWG) Jean-Louis Robert (Department of Quality Control of Medicine, Luxembourg, Q-IWG)			
02:10 - 02:30	Track C – Pharmaceutical Quality Systems Jacques Morénas (AFSSAPS, France, Q-IWG) Swroop Sahota (Merck Inc., US, Q-IWG)			
02:30 - 02:50	Track D – Quality Risk Management Stephan Rönninger (F. Hoffmann-La Roche, Ltd., Switzerland, Q-IWG (tbc))			
02:50 - 03:20	Coffee/Tea Break			
	Session D: Panel Discussion Q & A <i>Moderator</i> Jean-Louis Robert (Department of Quality Control of Medicine, Luxembourg, Q-IWG)			
03:20 - 04:20	Open Q&A from floor Jacques Morenas (AFSSAPS), France Moheb Nasr (FDA, CDER, USA), Georges France (Pfizer, UK), Bob Baum (Pfizer, USA), (tbn) (MHLW/PMDA), (tbn) (JPMA)			
04:20 - 04:30	Workshop Conclusions and Next Steps Jean-Louis Robert Rapporteur of ICH Q-IWG Department of Quality Control of Medicine, Luxembourg			
04:30 - 04:40	Closing Remarks and Group Photo Session APEC Harmonization Center			
04:40	End of the conference workshop			