Workshop Agenda

※List of speakers and other details are subject to change

Day 1 『Understanding and implementation of GHTF guidance on clinical evidence for premarket conformity assessment』

November 15, 2010 (Monday)	
08:30 – 09:00	**Registration**
09:00 – 09:20	Opening Ceremony **Opening Remarks** by Dr. Seung Hee Kim **Welcoming Address** by Dr. Yun Hong Noh **Congratulatory Remarks** by Dr. Bup Wan Kim
09:20 – 09:50	**Keynote Speech** *Speaker* Eun-Sook Jhon (Director, Medical Device Safety Bureau, KFDA)
09:50 – 10:30	**Differences between Medical Devices and other Health Products** *Speaker* TBC
10:30 – 11:10	**Overview of GHTF Regulatory Model** *Speaker* Michael Gropp (GHTF Steering Committee)
11:10 – 11:30	**Break**
11:30 – 12:20	**Clinical Evidence Key Definitions and Concepts** *Speaker* GHTF Speaker
12:20 – 14:00	**Lunch**
14:00 – 14:50	**Focus on Clinical Evaluation** *Speaker* GHTF Speaker
14:50 – 15:40	**Focus on Clinical Evaluation (continue)** *Speaker* Kathy Harris (Regulatory Director for Asia-Pacific, Johnson & Johnson)
15:40 – 16:00	**Break**
16:00 – 16:50	**Focus on Clinical Investigations** *Speaker* Herbert Lerner (US FDA)
16:50 – 17:40	**Post-Marketing Clinical Follow-up** *Speaker* GHTF Speaker

Day 2 『Understanding the infrastructure needed in supporting clinical trial which is designed and conducted ethically and scientifically when it is required for premarket conformity assessment, building confidence on clinical data generated in other jurisdictions』

November 16, 2010 (Tuesday)	
08:50 – 09:20	**Registration**
09:20 – 09:30	Recap of the 1st day
09:30 – 12:00	**Clinical Investigation Policies in major countries** *Speaker* Japan - Mami Ho (PMDA) (09:30 – 10:00) Korea - Hea-Young Cho (KFDA) (10:00 – 10:30) Chinese Taipei – Chinese Taipei FDA Speaker (10:30 – 11:00) United States - Carole Carey (USFDA) (11:00 – 11:30) Asia Pacific -Tran Quan (AHWP SG5 Co Chair) (11:30 – 12:00)
12:00 – 13:30	**Lunch**
13:30 – 14:20	**Clinical trial design in medical device clinical trial to meet regulatory requirements on premarket conformity assessment** *Speaker* Stephen Rhodes (BCG / FDAAA)
14:20 – 15:10	**Focus on Good Clinical Practices for Medical Device Clinical Investigations** *Speaker* Neal Fearnot (Cook Medical)
15:10 – 15:30	**Break**
15:30 – 16:20	**Multiregional clinical trial corporation: opportunity and challenges** *Speaker* Carole Carey (USFDA)
16:20 – 17:00	**Panel Discussion and Q&A**
17:00 –	Closing