Programme of Workshop on 5th November 2009

(Theme: Medical Device Regulatory Requirements, Compliance and Harmonization)

Time	Speakers	Tentative Presentation Topics
Session 1 (Moderator: Dr. Jorge Garcia)		
8:30	Dr. Rohan Hammett	*The Future of Medical Device Regulation in a Globalised Marketplace*
9:00	Mr. Bill Sutton	*USFDA's Centre for Devices and Radiological Health*
9:30	Mr. Kentarou Azuma	*Medical Device Regulation in Japan*
10:00	*Tea Break*	
Session 2 (Moderator: Mr. Michael Gropp)		
10:20	Dr. Joel Nobel	*Essential Elements of an Effective and Efficient Medical Device Regulatory Framework*
10:50	Dr. Jorge Garcia	*Managing a Post-Market Surveillance System*
11:20	Prof. Tony Chan	*Total Life Cycle Risk Management of Medical Devices*
11:50	Mr. Alfred Kwek	*Paving Way for Harmonization*
12:20	Arrangements of the lunch and the visit to the Hong Kong International Medical Devices and Supplies Fair	
12:30	*Lunch Break*	
14:00	**Visit to the Hong Kong International Medical Devices and Supplies Fair**	
15:30	*Tea Break*	
Session 3 (Moderator: Prof. Tony Chan)		
15:50	Ms. Carolyn Albertson	*Medical Device Regulatory Requirements: Classification*
16:10	Mr. Leighton Hansel	*Unique Device Identification Systems (UDI) and their Implications to the Industry*
16:30	Ms. Sumati Randeo	*Update on ASEAN Regulatory Frameworks and Way Forward for AHWP (a View from Industry)*
16:50	Mr. Michael Gropp	*Regulatory Harmonization and Medical Technology Innovation*
17:20	Dr. Phillip Auclair	*Realizing Medical Device Technologies into Marketable Products*
17:50	*End of Workshop*	
18:00	**AHWP Cocktail Reception**	