



Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

15TH AHWP TC MEETING and Workshop
Manila, THE PHILIPPINES
5 – 7 June 2012

PROPOSED WORKSHOP PROGRAM and MEETING AGENDA

Day 1 – Workshop (5 June 2012)

Time	Activity	Lecturer
8:00 – 9:00	Registration	
9:00 – 9:15	Short Opening Ceremony	
9:15 – 10:15	“Determination and Classification of Healthcare Products: If it not a drug, it does not mean that it is a medical device!”	Mr. Alfred Kwek Director, Regulatory Affairs, ASEAN, GE Healthcare
10:15 – 10:30	Coffee Break	
10:30 – 11:30	Regulation of Combination Products	Mr. Tim Missios Director, Intercontinental and Asia Pacific Regulatory Affairs Boston Scientific
11:30 – 12:15	Case Study on Combination Products	Mr. Toni Joergensen Straumann
12:15 – 13:15	Lunch Break	
13:15 – 14:15	Regulation of IVDs – Regulator’s View	Dr. Lakshmid devi Balakrishnan HSA, Singapore
14:15 – 15:15	Regulation of Orthopedic Products	Ms. Marianne Yap & Mr Cai Yiting Zimmer
15:15 – 15:30	Coffee Break	
15:30 – 16:15	IAF Initiative for Accredited Certification to ISO 13485 – Medical Devices	Mr. Grant Ramaley Convener, ISO13485 Working Group, IAF
16:15 – 16:45	Understanding the Philippine Medical Device Regulatory System	Ms. Maria Cecilia C. Matienzo Division Chief, Center for Device Regulation, Radiation Health and Research FDA, DOH, Philippines
16:45 – 17:00	Updates on the 17th AHWP Annual Meeting in Chinese Taipei, 2–6 November 2012	Mr. Jeffrey Chern Industrial Technology Research Institute
17:00 – 18:00	AHWP Strategic Framework (<i>Close Meeting for: Chairs, Vice-chairs, Co-chairs of AHWP, AHWP TC, and WGs & STG</i>)	Dr. Saleh S. Al-Tayyar Vice Executive President, Medical Devices Sector, SFDA Saudi Arabia
Adjourn at 18:00		



Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

15TH AHWP TC MEETING and Workshop
Manila, THE PHILIPPINES
5 – 7 June 2012

PROPOSED WORKSHOP PROGRAM and MEETING AGENDA

Day 2 – TC Meeting (6 June 2012)

Time	Session	Name
9:00 – 10:30	AHWP Working Group (WG) PRE-MEETING	
10:30 – 11:00	Registration	
11:00 – 11:30	Official Opening Ceremony Welcome Address by BHDT	
11:30 – 11:50	Opening Address by AHWP Chair, Dr. Saleh S. Al-Tayyar	Dr. Saleh S. Al-Tayyar
11:50 – 12:00	Group Photography Session	
12:00 – 13:00	~ Lunch ~	
13:00 – 14:30	<ul style="list-style-type: none">• Roll-call• Adoption of Agenda and AHWP TC 3 years roadmap• Updates on AHWP TC Leaders Meeting in Singapore with AHWP Chair (1 – 2 Mar 2012)• Update on GHTF, IMDRF, WHO & APEC	AHWP TC secretariat Ms. Joanna Koh Ms. Joanna Koh Mr. Ali M. Al-Dalaan
14:30 – 15:00	~ Coffee Break ~	
15:00 – 15:45	<ul style="list-style-type: none">• Updates by WG1 (Pre-Market Submission)<ul style="list-style-type: none">- Update 3 years WG1 plans- Update of Achieved work items	WG Chair / Co-Chair
15:45 – 16:30	<ul style="list-style-type: none">• Updates by WG1a (In-vitro Diagnostic Device)<ul style="list-style-type: none">- Update 3 years WG1a plans- Update of Achieved work items	WG Chair / Co-Chair
Adjourn at 16:30		



Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

15TH AHWP TC MEETING and Workshop
Manila, THE PHILIPPINES
5 – 7 June 2012

PROPOSED WORKSHOP PROGRAM and MEETING AGENDA

Day 3 – TC Meeting (7 June 2012)

Time	Session	Name
9:00 – 9:45	<ul style="list-style-type: none">• Updates by WG2 (Post-Market Surveillance and Vigilance)<ul style="list-style-type: none">- Update 3 years WG2 plans- Update of Achieved work items	WG Chair / Co-Chair
9:45 – 10:30	<ul style="list-style-type: none">• Updates by WG3 (Quality Management System)<ul style="list-style-type: none">- Update 3 years WG3 plans- Update of Achieved work items	WG Chair / Co-Chair
10:30 – 10:45	~ Coffee Break ~	
10:45 – 11:30	<ul style="list-style-type: none">• Updates by WG4 (Quality System Audit)<ul style="list-style-type: none">- Update 3 years WG4 plans- Update of Achieved work items	WG Chair / Co-Chair
11:30 – 12:15	<ul style="list-style-type: none">• Updates by WG5 (Clinical Evidence Requirements)<ul style="list-style-type: none">- Update 3 years WG5 plans- Update of Achieved work items	WG Chair / Co-Chair
12:15 – 13:15	~ Lunch ~	
13:15 – 14:00	<ul style="list-style-type: none">• Updates by WG6 (Capacity Building and Regulatory Training)<ul style="list-style-type: none">- Update 3 years WG6 plans- Update of Achieved work items	WG Chair / Co-Chair
14:00 – 14:45	<ul style="list-style-type: none">• Updates by STG (N) (Medical Device Nomenclature)<ul style="list-style-type: none">- Update 3 years STG plans- Update of Achieved work items	STG Chair / Co-Chair
14:45 – 15:15	~ Coffee Break ~	
15:15 – 16:30	Discussion on the invitation of TC Advisors	Ms. Joanna Koh
Adjourn at 16:30		