



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

Time	Activity	Lecturer
8:00 – 9:00	Registration	
9:00 – 9:30	Short Opening Ceremony	
9:30 – 10:30	“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
10:30 – 11:00	Coffee Break	
11:00 – 12:00	Regulation of Combination Products	TBA – Boston Scientific
12:00 – 13:00	Regulation of IVDs – Regulator’s View	TBA – HSA, Singapore
13:00 – 13:30	Lunch Break	
13:30 – 14:30	Regulation of Orthopaedic Products	TBA - Zimmer
14:30 – 15:30	IAF Initiative for Accredited Certification to ISO 13485 –Medical Devices	Mr. Grant Ramaley Convener ISO 13485 Working Group, IAF
15:30 – 15:45	Coffee Break	
15:45 – 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	Open Forum	
17:00 – 18:00	AHWP strategy framework <i>(Close Meeting for: AHWP Chairs, AHWP TC chairs, and WG /STG chairs)</i>	N/A
Adjourn at 18:00		



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Day 2 & 3 – TC Meeting

Time	Session	Name
Day 2 – 6 June 2012		
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 Joanna Koh Joanna Koh 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		



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Day 2 & 3 – TC Meeting (Cont.)

Time	Session	Name
Day 3 – 7 June 2012		
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	Joanna Koh
Adjourn at 16:30		