



Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

**13TH ASIAN HARMONIZATION WORKING PARTY TECHNICAL COMMITTEE MEETING
(13TH AHWP TC MEETING)
5 – 7 July 2011, SEOUL, SOUTH KOREA
PROPOSED MEETING AGENDA**

Tuesday, 5 July 2011

Welcome dinner, hosted by KFDA Commissioner, for AHWP TC registered participants.

Wednesday, 6 July 2011

Time	Session	Name
09:00 – 11:00	TC PRE-MEETING Agenda: <ul style="list-style-type: none">• Directions of AHWP TC• Review of AHWP work targets for 2009 to 2011• Nominations for TC elections	TC comm.: Chair, Co-Chairs, WG Chair / Co-Chair Secretariat (Jack)
11:00 – 11:30	~ Refreshment Interlude ~	Ground Support Team (Rachel)
11:30 – 12:00	Registration	
Afternoon Session		
12:00 – 12:15	Official Opening Ceremony Welcome Address	Dr. Seung Hee Kim, Director of APEC Harmonization Center and Director General of NiFDS (National Institute of Food and Drug Safety Evaluation)
12:15 – 12:30	Opening Address by AHWP TC Chair	Mrs Joanna Koh
12:30 – 13:00	Group Photography Session	(arranged by Rachel)
13:00 – 14:00	~ Lunch ~	Ground Support Team (Rachel)
14:00 – 15:00	<ul style="list-style-type: none">• Roll-call• Adoption of Agenda• Update on AHWP Secretariat Meeting with	Mr Jack Wong Mrs Joanna Koh Mr Jack Wong



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	AHWP Chair (10 – 11 Mar 2011)	
15:00 – 15:20	<ul style="list-style-type: none">• Updates by WG1 (Pre-Market Submission and CSDT)<ul style="list-style-type: none">- Itemised of present work, including work to be closed by Nov 2011 (Bali meeting)- Update of outstanding work items to be carried forward to 2012	WG Chair / Co-Chair
15:20 – 15:40	<ul style="list-style-type: none">• Updates by WG1a (In-vitro Diagnostic Device)<ul style="list-style-type: none">- Itemised of present work, including work to be closed by Nov 2011 (Bali meeting)- Update of outstanding work items to be carried forward to 2012	WG Chair / Co-Chair
15:40 – 16:00	~ Refreshment Interlude ~	
16:00 – 16:20	<ul style="list-style-type: none">• Updates by WG2 (Post-Market Surveillance and Vigilance)<ul style="list-style-type: none">- Itemised of present work, including work to be closed by Nov 2011 (Bali meeting)- Update of outstanding work items to be carried forward to 2012	WG Chair / Co-Chair
16:20 – 16:40	<ul style="list-style-type: none">• Updates by WG3 (Quality Management System)<ul style="list-style-type: none">- Itemised of present work, including work to be closed by Nov 2011 (Bali meeting)- Update of outstanding work items to be carried forward to 2012	WG Chair / Co-Chair
16:40 – 17:00	<ul style="list-style-type: none">• Updates by WG4 (Quality System Audit)<ul style="list-style-type: none">- Itemised of present work, including work to be closed by Nov 2011 (Bali meeting)- Update of outstanding work items to be carried forward to 2012	WG Chair / Co-Chair
~ End of Day 1 Meeting Programme ~		



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Thursday, 7 July 2011

Time	Session	Name
Morning Session		
09:00 – 09:20	<ul style="list-style-type: none">• Updates by WG5 (Clinical Evidence Requirements)<ul style="list-style-type: none">- Itemised of present work, including work to be closed by Nov 2011 (Bali meeting)- Update of outstanding work items to be carried forward to 2012	WG Chair / Co-Chair
09:20 – 09:40	<ul style="list-style-type: none">• Updates by WG6 (Capacity Building and Regulatory Training)<ul style="list-style-type: none">- Itemised of present work, including work to be closed by Nov 2011 (Bali meeting)- Update of outstanding work items to be carried forward to 2012	WG Chair / Co-Chair
09:40 – 10:00	<ul style="list-style-type: none">• Updates by STG (Legal Entity)<ul style="list-style-type: none">- Itemised of present work, including work to be closed by Nov 2011 (Bali meeting)- Update of outstanding work items to be carried forward to 2012	STG Chair / Co-Chair
10:00 – 10:30	~ Refreshment Interlude ~	
10:30 – 10:50	<ul style="list-style-type: none">• Updates by STG (Medical Device Nomenclature)<ul style="list-style-type: none">- Itemised of present work, including work to be closed by Nov 2011 (Bali meeting)- Update of outstanding work items to be carried forward to 2012	STG Chair / Co-Chair
10:50 – 11:25	<ul style="list-style-type: none">• Update on GMDN	GMDN Representative
11:25 – 12:00	<ul style="list-style-type: none">• Update on UMDN	UMDN Representative
12:00 – 13:30	~ Lunch ~	
Afternoon Session		



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13:30 – 14:00	“Good Regulatory Practice” initiatives with APEC LSIF	Director Li Ling Liu MD&C, Chinese Taipei FDA
14:00 – 15:00	Report on GHTF Steering Committee meeting (May 2011, Brisbane) <ul style="list-style-type: none">- Outcome from pre-meeting discussion on this topic (subject to agreement by TC comm.)- Discussion on impact of GHTF new structure	GHTF representative Joanna
15:00 – 15:30	~ Refreshment Interlude ~	
15:30 – 16:30	Elections: Discussion on nominations <ul style="list-style-type: none">- Positions for election- Procedure- Nominations as of today	To be discussed at pre-meeting