

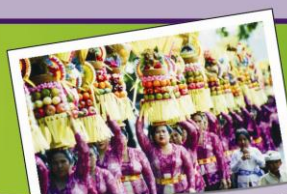
# The 16<sup>th</sup> Asian Harmonization Working Party Meeting

## The 14<sup>th</sup> Asian Harmonization Technical Committee and Workshop

Organized by:



Grand Hyatt Hotel, Bali - Indonesia  
November 8<sup>th</sup> - 12<sup>th</sup>, 2011



Day 1 (Tuesday, 8 <sup>th</sup> Nov 2011)		Speaker and Moderator
AHWP Technical Committee Meeting		
08:30 - 08:40	Welcome Speech by Directorate General of Pharmaceutical and Medical Device Service	Indonesia MOH
08:40 - 08:50	Opening Speech	Mr Wang Baoting
	Chairman, AHWP	
08:50 - 09:35	Report and Overview of Seoul (July 2011) TC Meeting	Ms Joanna Koh
09:35 - 09:45	Announcement of the Election Arrangement for Office Bearers of AHWP	Mr Bryan SO
09:45 - 10:00	Tea Break - Distribution of Election Form	
10:00 - 10:10	Adoption of TC Meeting Agenda	Ms Joanna Koh
		Mr Ali M. Al -Dalaan
		Ms Daphne Yeh
10:10 - 12:10 (TC Meeting - 30mins each)	WG1 Pre-market Submission	WG Chair
	WG1A Pre-market Submission IVD	WG Chair
	WG2 Post-market Surveillance & Vigilance	WG Chair
	WG3 Quality Management System	WG Chair
12:10 - 13:30	Lunch & Prayers	-
13:30 - 15:00 (TC Meeting - 30mins each)	WG4 Quality System Audit	WG Chair
	WG5 Clinical Safety/Performance	WG Chair
	WG6 Capacity Building & Regulatory Training	WG Chair
15:00 - 15:20	Tea Break	
15:20 - 16:00	STG: Legal Entity	STG Chair
	STG: Nomenclature	STG Chair
16:00 - 16:40	Report on the Formation of AHWP Administration Services Limited	Mr Ali M. Al -Dalaan
16:40 - 17:00	Preparation for Dinner	
17:00 - 21:00	WELCOME DINNER	
Day 2 (Wednesday, 9 <sup>th</sup> Nov 2011)		Speaker and Moderator
Technical Committee Training		
08:45 - 09:15	GHTF UPDATE (i) Rationale and Impetus for Change in Direction of GHTF (ii) Future Strategic Directions of GHTF	Speaker: Dr. Azuma Kentaro - Deputy Director Office of Medical Devices Evaluation Pharmaceutical and Food Safety Bureau Ministry of Health, Labour and Welfare Japan
09:15 - 10:00	The EU DIRECTIVE - Overview of the Medical Device Directives recast, new changes in (i) Risk classification rules (ii) New approach to accreditation of notified body (iii) New controls on implants	Speaker: Laurent Selles - Deputy Head of Unit Cosmetics and Medical Devices European Commission, DG Health Consumers Belgium
10:00 - 10:40	Proposed changes to the 510(k) program and the potential impact of the changes on Medical Device industry	Speaker : Janet Trunzo - Executive Vice President Technology & Regulatory Affairs Advanced Medical Technology Association (AdvaMed)
10:40 - 10:55	Tea break	
10:55 - 11:30	Key point to evaluate Clinical Data	Speaker: Danielle Giroud - World Medical Device Organization (WMDO) SA Switzerland Moderator 1: Dr Petra Kaars-Wiele
11:30 - 12:00	Panel Discussion and Q&A	
12:00 - 12:55	Lunch	
12:55 - 13:15	Global PMS implementation program part of corporate quality manual roll out	Speaker: Mr. Matthias Bürger - Corporate Vice President, Global Quality Assurance-Zimmer
13:15 - 13:35	Importance of Trending Post Market information in protecting Patient Safety	Speaker : Mr. Atsushi Tamura - PMDA Japan
13:35 - 14:05	Product Localization and Global Harmonization - a Medical Device Industry's Perspective	Speaker : Yang Chen- Sidley Austin Beijing
14:05 - 15:35	Tools for Harmonization - Common Dossiers and Grouping of Medical Devices	Speaker: Alfred Kwek - Regulatory Affairs Director, ASEAN GE Pacific Pte Ltd - Singapore
15:35 - 15:50	Tea Break	

15:50 - 16:20	Panel Discussion and Q&A	Moderator 2 : Mr Michael Gropp
16:20 - 16:50	ASEAN Update	Speaker: Bahdar T Hamid - Ministry of Health, Republic of Indonesia
16:50 - 17:50	Country Update by Indonesia, Malaysia, South Korea, Yemen, Vietnam, and Chinese Taipei	Speaker: all country updates
17:50 - 18:20	Panel Discussion and Q&A	Moderator 3 : Mr. Budi Prasetyo (GAKESLAB/ Indonesia Medical Device Association)
18:20	Free time	
<b>Day 3 (Thursday, 10<sup>th</sup> Nov 2011)</b>		<b>Speaker and Moderator</b>
<b>AHWP WORKSHOP</b>		
<b>Theme: THE MEDICAL DEVICE HORIZON IN EMERGING MARKETS</b>		
08:00 - 08:45	Registration	--
08:45 - 09:25	Benefits of Implementing a Global Quality Management System to Enhance Patient Safety	Speaker: Ms. Liz Blackwood, Senior Executive Quality Assurance, GE Healthcare
09:25 - 10:05	Medical Device's Industry Role in Patient Safety Topic:- Managing Risk in Patient Safety	Speaker : Mr. Harald Weiss -Head of Global Regulatory Affairs B. Braun Melsungen AG. Germany
10:05- 10:20	Tea break	
10:20 - 11:00	Patient Safety in relation to Electrical Safety	Speaker: Dr. John Garnet Abbott, Phd Director, Global Standards Philips Healthcare
11:00 - 11:40	A local manufacturer's perspectives	Speaker: Mr. Jemmy Hartanto - Director OneMed Indonesia
11:40 - 12:10	Panel Discussion and Q&A	Moderator 1: Dr. Aran Maree (J&J)
12:10 - 13:10	Lunch	
13:10 - 13:50	Personalize medicine - The concept and the reality	Speaker: Karen S Long - Divisional Vice President, Medical Regulatory and Clinical Affairs - Abbot US
13:50 - 14:30	Aspects of consideration in the development of a combination product	Speaker : Brad Hosack- VP Regulatory Affairs International, Boston Scientific Corp USA
14:30 - 14:45	Teabreak	
14:45 - 15:25	Regulatory harmonization - the why, what and how	Speaker: Laurent Selles - Deputy Head of Unit Cosmetics and Medical Devices European Commission, DG Health Consumers Belgium
15:25 - 15:55	Panel Discussion and Q&A	Moderator 2: Tran Quan Executive - QARA, Asia Pacific
15:55 - 16:35	Ride to Dinner Venue	
16:35 - 17:35	COCKTAIL	-
17:35 - 21:00	GALA DINNER	
<b>Day 4 (Friday, 11<sup>th</sup> Nov 2011)</b>		<b>Speaker and Moderator</b>
<b>AHWP Meeting (Opening Ceremony &amp; Election)</b>		
08:00 - 08:30	Registration for Delegates	-
08:30 - 08:40	Arrival of Guest of Honour	Ministry of Health of Indonesia
		Mr Wang Baoting
		Ms Joanna Koh
08:40 - 09:00	Welcome Dance	
09:00 - 09:10	Welcome Speech from Indonesian DG	Directore General
09:10 - 09:20	Opening Speech - AHWP Chair	Mr Wang Baoting
	Indonesian MoH Profile	
09:20 - 09:25	AHWP Slide Show	
09:25 - 09:30	Indonesia Medical Device regulatory and Industry environment Video	
09:30 - 09:45	Key Note Address by Guest of Honor of Indonesia	Indonesian Ministry of Health
09:45 - 10:00	Presentation of Souvenirs by Wang Baoting to:-	AHWP Secretariat
	i. Guest of Honor (flower and souvenir) - Indonesia Ministry of Health	
	ii. Souvenir and flower for Diamond Sponsor	
10:00 - 10:15	Tea Break	
10:15 - 10:30	Adoption of Meeting Agenda	Mr Wang Baoting
	i. Roll Call (Only Official Members)	
	ii. Admission of New Members (if any)	
10:30 - 10:50	Confirmation of Minutes of 15 <sup>th</sup> AHWP Meeting held in Kingdom of Saudi Arabia from 27 Nov – 1 Dec 2010	Mr Wang Baoting AHWP Secretariat
10:50 - 11:35	Report by AHWP Secretariat	AHWP Secretariat
	i. Report by AHWP Secretariat from 2009 to 2011	
	ii. Report on Financial Statement for 2010/2011	
	iii. Proposal for Budget 2011/2012	
11:35 - 12:00	Photography Session	EO

12:00 - 13:30	Lunch & Prayers	
13:30 - 13:45	Announcement of AHWP Administration Services Limited	Mr Ali M. Al -Dalaan
13:45 - 14:00	Summary of TC's work 2009 - 2011 by TC Chair	Joanna Koh
14:00 - 14:15	Summary of AHWP's work 2009 - 2011 by AHWP Chair	Mr Wang Baoting
14:15 - 14:35	Recognition of staff contribution to AHWP's work	Mr Wang Baoting
14:35 - 14:50	Tea Break	
14:50 - 15:05	Briefing on Election Rules and List of Candidates	AHWP Secretariat
15:05 - 16:30	Election of Office Bearers	Note:
	i. AHWP Main Committee	i. To circulate Terms of Reference for all delegates
		ii. To issue notice of nomination for Election to all Member States
	- Position of Chair, AHWP (Regulator)	
	- Position of Co-Chair, AHWP (Regulator)	
	- Position of Co-Chair, AHWP (Industry)	
	ii. AHWP Technical Committee	
	- Position of Chair, AHWP TC	
	- Position of Co-Chair, AHWP TC (Regulator)	
	- Position of Co-Chair, AHWP TC (Industry)	
	- Working Group Chair and Co chair	
16:30 - 16:40	Speech by Newly Elected Chair, AHWP	Newly Elected Chair, AHWP
16:40 - 16:50	Closing of Meeting by OUT GOING Chair, AHWP	Mr Wang Baoting
17:00 - 17:30	Depart to Venue	
17:30 - 20:00	Appreciation Dinner the success of former Chair and welcoming the New Chair	
<b>Day 5 (Saturday, 12th Nov 2011) (OPTIONAL DAY)</b>		<b>Organiser: Indonesia MOH</b>
<b>COST OF EVENT NOT INCLUDED IN REGISTRATION FEE</b>		
<b>NETWORKING FORUM</b>		
8.00 - 8.30	Registration	
8.30 - 9.00	Depart to Venue	
9.00 - 10.00	Meeting & Discussion with all Regulators & Industries	
10.00 - 12.30	Lunch & Pray	
12.30 - 14.00	Continue Meeting & Discussion with all Regulators & Industries	
14.00 - 16.00	Back to Hotel	