

The 16th Asian Harmonization Working Party Meeting

The 14th Asian Harmonization Technical Committee and Workshop

Organized by:



Grand Hyatt Hotel, Bali - Indonesia
November 8th - 12th, 2011



Day 1 (Tuesday, 8 th Nov 2011)		Name
AHWP Technical Committee Meeting		
08:30 - 08:40	Welcome Speech by Directorate General of Pharmaceutical and Medical Device Service, Indonesia MOH	Ms. Dra. Sri Indrawaty, Apt, M.Kes.
08:40 - 08:50	Opening Speech by Chairman AHWP	Mr. Wang Baoting
08:50 - 09:30	Report and Overview of Seoul (July 2011) TC Meeting	Ms. Joanna Koh
09:30 - 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 - 20mins 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
	WG4 Quality System Audit	WG Chair
	WG5 Clinical Safety/Performance	WG Chair
12:10 - 13:30	Lunch & Prayers	-
13:30 - 13:50	WG6 Capacity Building & Regulatory Training	WG Chair
13:50 - 14:10	STG: Legal Entity	STG Chair
14:10 - 14:30	STG: Nomenclature	
14:30 - 15:00	Report on the formation of AHWP Administration Services limited	Mr. Ali M. Al -Dalaan
15:00 - 15:15	Tea Break	
15:15 - 16:15	TC Officers Bearers Election	Mr. Bryan SO
16:15 - 17:00	Preparation for Dinner	
17:00 - 21:00	WELCOME DINNER	
Day 2 (Wednesday, 9 th Nov 2011)		Name
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: Azuma Kentaro - Deputy Director Office of Medical Devices Evaluation Pharmaceutical and Food Safety Bureau Ministry of Health, Labor 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 : Mr. Michael Gropp Vice President, Global Regulatory Strategy Medtronic, Inc.
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
11:30 - 12:00	Panel Discussion and Q&A	Moderator 1: Dr. Petra Kaars-Wiele Director International Regulatory Affairs/ Division Labeling Abbott GmbH & Co KG
12:00 - 12:55	Lunch	
12:55 - 13:15	Proactive Post Market Surveillance and Clinical Data	Speaker: Ms. Miang Chadaporn Tanakasemsub - Vice President, Quality Assurance/Regulatory Affairs - Zimmer
13:15 - 13:35	Importance of Trending Post Market information in protecting Patient Safety	Speaker : Dr. 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 - 14:45	Tools for Harmonization - Common Dossiers and Grouping of Medical Devices	Speaker: Alfred Kwek - Regulatory Affairs Director, ASEAN GE Pacific Pte Ltd - Singapore
14:45 - 15:00	Tea Break	
15:00 - 15:30	Panel Discussion and Q&A	Moderator 2 : Mr. Michael Gropp Vice President, Global Regulatory Strategy Medtronic, Inc.
15:30 - 15:50	ASEAN Update	Speaker: Bahdar T Hamid - Ministry of Health, Republic of Indonesia
15:50 - 16:20	Country Update by Indonesia, South Korea, Yemen, Vietnam, and Chinese Taipei	Speaker: all country updates
16:20 - 16:50	Panel Discussion and Q&A	Moderator 3 : Mr. Budi Prasetyo (GAKESLAB/ Indonesia Medical Device Association)
16:50	Free time	

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Day 3 (Thursday, 10th Nov 2011)		Name
AHWP WORKSHOP		
Theme: THE MEDICAL DEVICE HORIZON IN EMERGING MARKETS		
08:00 - 08:45	Registration	--
08:45 - 09:25	Benefits of Implementing a Global Quality Management System to	Speaker: Ms. Liz Blackwood, Senior Executive Quality
09:25 - 10:05	Ensuring Patient's and Health Care Practitioner's Safety- a shared responsibility of all stake holders	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: Prof. Jack Wong Director of Regulatory Affairs Johnson & Johnson Medical
12:10 - 13:10	Lunch	
13:10 - 13:50	Navigating Evolving Regulatory Environments, The dawn of molecular medicine	Speaker: Philippe Auclair, Senior Director, Regulatory Strategy and Advocacy Abbott Quality and Regulatory EMEA, Abbott Vascular Intl - 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	Tea break	
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	
Day 4 (Friday, 11th Nov 2011)		Name
AHWP Meeting (Opening Ceremony & Election)		
08:00 - 08:30	Registration for Delegates	-
08:30 - 08:40	Arrival of Guest of Honor	Ministry of Health of Indonesia Mr. Wang Baoting Ms. Joanna Koh
08:40 - 08:50	National Anthem of Indonesia: Indonesia Raya	
08:50 - 08:55	Welcome Speech by AHWP Chair	Mr. Wang Baoting
08:55 - 09:00	Welcome Remarks by Governor of Bali	Governor of Bali
09:00 - 09:15	Opening Speech & Key Note Address by Guest of Honor of Indonesia	Ministry of Health/Vice Ministry of Health
09:15 - 09:30	Presentation of Flower and Souvenirs by Wang Baoting to:	AHWP Secretariat
	i. Guest of Honor - Indonesia Ministry of Health	
	ii. Diamond Sponsor - GE	
09:30 - 09:35	AHWP Slide Show	AHWP Secretariat
09:35 - 09:40	Congratulation Speech by China SFDA	Ms. Xu Yuojun General Director, Department of International Cooperation, China SFDA
09:40 - 09:50	Indonesia Medical Device regulatory and Industry environment Video	Ministry of Health/Gakeslab
09:50 - 09:55	Address on ASEAN initiatives in the Medical Device Sector	Ms. Shirley V. Ramesh Senior Officer Trade and Facilitation Division ASEAN Economic Community Department, ASEAN Secretariat
09:55 - 10:05	Tea Break	
10:05 - 10:25	Adoption of Meeting Agenda	Mr. Wang Baoting
	i. Roll Call	
	ii. Admission of New Members	
10:25 - 10:45	Confirmation of Minutes of 15 th AHWP Meeting held in Kingdom of Saudi Arabia from 27 Nov – 1 Dec 2010	Mr. Wang Baoting AHWP Secretariat
10:45 - 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	
12:00 - 13:30	Lunch & Prayers	
13:30 - 13:45	Announcement of AHWP Administration Services Limited	Mr. Ali M. Al-Dalaan

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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 AHWP Office Bearers	
	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 AHWP Chair	
	- Position of AHWP Vice-Chair (Regulatory Authority)	
	- Position of AHWP Vice-Chair (Industry)	
	ii. Endorsement of the Newly Elected Office Bearers of AHWP Technical Committee (Chair, Co-Chair(Regulatory Authority, Co-Chair (Industry))	
	iii). Endorsement of the Newly Elected Office Bearers of Work Groups and Special Task Groups (Chair & 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	
Day 5 (Saturday, 12th Nov 2011) (OPTIONAL DAY)		Name
COST OF EVENT NOT INCLUDED IN REGISTRATION FEE		
NETWORKING FORUM		
08:00 - 08:30	Registration	
08:30 - 09:00	Depart to Venue	
09:00 - 11:00	Meeting & Discussion with all Regulators & Industries	
11:00 - 12:30	Lunch & Pray	
12:30 - 14:00	Continue Meeting & Discussion with all Regulators & Industries	
14:00 - 16:00	Back to Hotel	