



## 17th AHWPTC Meeting

Wednesday, December 4th, 2013  
Grand Lagoon Ballroom, Sunway Lagoon Hotel Resort & Spa  
Kuala Lumpur, Malaysia

08:00	Registration	13:30 - 15:30	Updates by WG1 <b>-Ms. Ming Hao Tan</b> HSA, Singapore
08:30 - 09:30	Formal Meeting with AHWP Chair (Close Meeting) <b>-TC Leaders &amp; AHWP Chair</b>		<b>-Mr. Alfred Kwek</b> GE Healthcare, Singapore
09:30 - 10:00	AHWP TC Working Group Pre-Meeting including discussion of TC Advisory recommendation items with TC Advisors (Close Meeting) <b>-WG Chairs/Co-chairs</b>		Updates by WG1a <b>-Ms. Li-Ling Liu</b> TFDA, Chinese Taipei
10:00 - 10:15	Welcome Address <b>Malaysian representative, TBD</b>		<b>-Mr. Jeffrey Chern</b> ITRI, Chinese Taipei
10:15 - 10:30	Opening Speech <b>-Dr. Saleh S. Al-Tayyar</b> Chair, AHWP		Updates by WG2 <b>-Ms. Jennifer Mak</b> DOH, Hong Kong SAR
10:30 - 10:45	Roll-call <b>-AHWP Secretariat</b>		<b>-Dr Kulwant Saini</b> Johnson & Johnson, India
	Adoption of Agenda <b>-Mrs. Joanna Koh</b> Chair, AHWP TC		Updates by WG3 <b>-Mr. Ali M. Al-Dalaan</b> SFDA, Kingdom of Saudi Arabia
	<b>-Mr. Ali M. Al-Dalaan</b> Co-Chair, AHWP TC		<b>-Mr. Ee Bin Liew</b> Philips Healthcare, Singapore
	<b>-Ms. Chadaporn Tanakasemsub</b> Co-Chair, AHWP TC		Updates by WG4 <b>-Mr. Abdullah Al-Rasheed</b> SFDA, Kingdom of Saudi Arabia
10:45 - 11:00	Tea Break		<b>Ms. Eun Hee Cho</b> Abbott Vascular, Korea
11:00 - 11:15	Report and overview of AHWP TC meeting in Taipei & meeting with TC Advisors in Bangkok <b>-Mrs. Joanna Koh</b> Chair, AHWP TC		Updates by WG5 <b>-Ms. Yuwadee Patanawong</b> ThaiFDA, Thailand
11:15 - 12:00	Introduction of TC Advisors  Short speech by TC Advisors Representative  Recommendations made by TC Advisors in TC leaders meeting in Bangkok – some updates <b>-Mrs. Joanna Koh</b> Chair, AHWP TC		<b>-Ms. Sumati Randeo</b> Abbott Laboratories, India
	<b>-Mr. Ali M. Al-Dalaan</b> Co-Chair, AHWP TC		Updates by WG6 <b>-Dr. Rama Sethuraman</b> HSA, Singapore
	<b>-Ms. Chadaporn Tanakasemsub</b> Co-Chair, AHWP TC		<b>-Mr. Jack Wong</b> Terumo BCT (Asia Pacific), Hong Kong
	<b>-Mr. Scott Sardeson</b> TC Advisor, AHWP TC		Updates by STG (N) <b>-Mr. Lian Chun Yang</b> CFDA, China
12:00 - 13:30	Lunch		<b>-Ms. Carol Yan</b> J&J Medical Asia Pacific, China
		15:30 - 15:45	Tea Break
		15:45 - 16:00	Updates from Secretariat <b>-Mr. Bryan So</b> HKPC, Hong Kong SAR
		16:00 - 16:30	AHWP TC Meeting Closing Remarks <b>-Mrs. Joanna Koh</b> HSA, Singapore
		19:45 - 21:30	<b>Gala Dinner</b>

# 18th AHWP Annual Meeting

Thursday, December 5th, 2013

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07:30	Registration		
08:00 - 08:10	Welcome speech <b>-Mr. Zamane Abdul Rahman</b> Chief Executive Medical Device Authority Ministry of Health, Malaysia		<b>Ms. Quan Tran</b> Advisor to Chair, AHWP Vice President, Quality Assurance & Regulatory Affairs, Asia Pacific, GE Healthcare, Singapore
08:10 - 08:20	Opening speech <b>-Dr. Saleh S. Al-Tayyar</b> Chair, AHWP Vice Executive President for Medical Devices, SFDA Kingdom of Saudi Arabia	11:25 - 12:15	Report by AHWP TC <b>-Mrs. Joanna Koh</b> Chair, AHWP TC Director, Medical Device Branch, Health Sciences Authority, Singapore
08:20 - 08:30	Speech by Honorable Guest <b>-Y.B Datuk Seri Dr. S. Subramaniam</b> Minister of Health, Malaysia	12:15 - 13:45	Lunch
08:30 - 08:50	Souvenirs to Host, Honorable Guest and Sponsors <b>-Dr. Saleh S. Al-Tayyar</b> Chair, AHWP Group photo	13:45 - 15:15	Country Update (15' per presentation) • Malaysia • South Korea • India (t.b.c.) • Saudi Arabia (t.b.c.) • Chinese Taipei (t.b.c.) <b>-Country representatives</b>
08:50 - 09:20	Keynote Speech <b>-TBA</b>	15:15 - 15:25	Tea Break
09:20 - 09:40	Tea Break	15:25 - 15:55	Report by Secretariat - Report by AHWP Secretariat from 2012 to 2013 - Report on Financial Statement for 2012/2013 - Proposal for Budget 2013/2014 <b>-Mr. Ali M. Al-Dalaan</b> Secretary General, AHWP Executive Director, Medical Device Sector, SFDA, Kingdom of Saudi Arabia
09:40 - 10:10	IMDRF Status Report <b>-Mr. Laurent Sellés</b> Management Committee member from EU, IMDRF Senior Coordinator for International Relations Health Technology and Cosmetics - DG Health and Consumers, European Commission		<b>-Mr. Bryan So</b> Executive Deputy Secretary General, AHWP Senior Consultant, Hong Kong Productivity Council, Hong Kong SAR
10:10 - 11:25	AHWP Status Report and Strategic Framework including the Summary on 1st AHWP-RAPS Joint Conference - Adoption of Agenda - Roll Call (Only Official Members) - Confirmation on Minutes of 17th AHWP Meeting held in Chinese Taipei, 2-6 Nov 2012 - Discussion on the Final Proposed Document "AHWP Strategic Framework Towards 2020 - The Foreseeable Harmonization Horizon" - Summary on 1st AHWP-RAPS Joint Conference <b>-Dr. Saleh S. Al-Tayyar,</b> Chair, AHWP Vice Executive President for Medical Devices, SFDA Kingdom of Saudi Arabia  <b>Ms. Li-Ling Liu</b> Vice Chair, AHWP Director, Division of Medical Devices and Cosmetics TFDA, Chinese Taipei  <b>Ms. Lindsay Tao</b> Vice Chair, AHWP Corporate Director, Global health Policy, Johnson & Johnson, China	15:55 - 16:25	Resolutions: 1. AHWP leadership: "AHWP Strategic Framework Towards 2020 - The Foreseeable Harmonization Horizon" 2. WG1a: "AHWP Regulatory Framework for IVD Medical Devices" 3. WG1a: "Essential Principles of Safety and Performance of IVD Medical Devices" 4. WG1a: "Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices" 5. WG1a: "Comparison between the GHF Summary Technical Documentation (STED) formats for Medical Devices and In Vitro Diagnostic Medical Devices and the Common Submission Dossier Template (CSDT) format"

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	<p>6. WG2: "Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative" 7. WG3: (t.b.c.) 8. Secretariat: Amendments to the Asian Harmonization Working Party House</p> <p><b>-Dr. Saleh S. Al-Tayyar,</b> <i>Chair, AHWP</i> <i>Vice Executive President for Medical Devices, SFDA Kingdom of Saudi Arabia</i></p>
16:35 - 16:45	<p>Confirmation of Host of the 19th AHWP Meeting</p> <p><b>-Dr. Saleh S. Al-Tayyar,</b> <i>Chair, AHWP</i> <i>Vice Executive President for Medical Devices, SFDA Kingdom of Saudi Arabia</i></p>
16:45 - 16:55	<p>Closing Remarks</p> <p><b>-Mr. Zamane Abdul Rahman</b> <i>MOH, Malaysia</i></p>
16:55 - 18:00	<p><b>2nd AGM of AHWP ASL</b> (Open to Industry and Regulatory Representatives of AHWP Member Economies)</p> <p><b>Agenda</b></p> <ul style="list-style-type: none"> <li>- Adoption of Agenda</li> <li>- Introduction of ASL</li> <li>- Admission of New ASL Members</li> <li>- Resolution: Application for tax-exempt charitable status for AHWP ASL under Section 88 of Inland Revenue Ordinance in Hong Kong</li> <li>- Election of New Directors of the Board</li> </ul> <p><b>-Mr. Ali M. Al-Dalaan</b> <i>President, AHWP ASL</i> <i>Secretary General, AHWP</i> <i>Executive Director, Medical Device Sector, SFDA, Kingdom of Saudi Arabia</i></p>
18:00	<p><b>End of the 18th AHWP Annual Meeting</b></p>