

18th AHWP Annual Meeting (Main Meeting)

Thursday, December 5, 2013

Venue: Grand Lagoon Ballroom, Sunway Lagoon Resort & Spa, Kuala Lumpur, Malaysia

Time	Session	Speaker/Moderator
08:00 – 08:10	Welcome Speech	Mr. Zamane Abdul Rahman Chief Executive Medical Device Authority Ministry of Health Malaysia
08:10 – 08:20	Opening Speech	Dr. Saleh S. Al-Tayyar Chair, AHWP Director General, Medical Devices Sector SFDA, Kingdom of Saudi Arabia
08:20 – 08:50	Keynote Speech	Dr. Sherry Keramidas Executive Director Regulatory Affairs Professional Society
08:50– 09:00	Speech by Honorable Guest	Y.B Datuk Seri Dr. Hilmi Bin Haji Yahya Deputy Minister of Health Malaysia
09:00 – 09:20	Souvenirs to Host, Honorable Guest and Sponsors	Dr. Saleh S. Al-Tayyar Chair, AHWP Director General, Medical Devices Sector SFDA, Kingdom of Saudi Arabia
09:20 – 09:40	GROUP PHOTO	
09:40 – 10:10	Tea Break	
10:10 – 11:25	AHWP Status Report and Strategic Framework including the Summary on 1 st AHWP-RAPS Joint Conference - Adoption of Agenda - Roll Call (Only Official Members) - Confirmation on Minutes of 17 th 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"	Dr. Saleh S. Al-Tayyar Chair, AHWP Director General, Medical Devices Sector SFDA, Kingdom of Saudi Arabia Ms. Li-Ling Liu Vice Chair, AHWP Director, Division of Medical Devices and Cosmetics TFDA, Chinese Taipei Ms. Lindsay Tao Vice Chair, AHWP Corporate Director, Global health Policy Johnson & Johnson, China

	- Summary on 1st AHWP-RAPS Joint Conference	Ms. Quan Tran Advisor to Chair, AHWP Vice President, Quality Assurance & Regulatory Affairs Asia Pacific GE Healthcare, Singapore
11:25 – 12:15	Report by AHWP TC	Mrs. Joanna Koh Chair, AHWP TC Director, Medical Device Branch Health Sciences Authority, Singapore
12:15 – 13:45	Lunch	
13:45 – 15:15	Country Update <ul style="list-style-type: none"> • Malaysia • Republic of Korea • Kingdom of Saudi Arabia • Chinese Taipei 	Country representatives
15:15 – 15:25	Tea Break	
15:25 – 15:55	Report by Secretariat <ul style="list-style-type: none"> - Report by AHWP Secretariat from 2012 to 2013 - Report on Financial Statement for 2012/2013 - Proposal for Budget 2013/2014 	Mr. Ali M. Al-Dalaan Secretary General, AHWP Executive Director, Medical Device Sector SFDA, Kingdom of Saudi Arabia Mr. Bryan So Executive Deputy Secretary General, AHWP Senior Consultant, Hong Kong Productivity Council Hong Kong SAR

<p>15:55 – 16:25</p>	<p>ROPOSED FINAL documents for resolutions:</p> <ol style="list-style-type: none"> 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 GHTF Summary Technical Documentation (STED) formats for Medical Devices and In Vitro Diagnostic Medical Devices and the Common Submission Dossier Template (CSDT) format" 6 ∙ WG2: "Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative" 7 ∙ WG3: "Quality management system – Medical devices – Nonconformity Grading System for Regulatory Purposes and Information Exchange" 8 ∙ Secretariat: "Amendment 1 to the GUIDANCE for Member Economy Hosting the Meetings of AHWP or its Technical Committees" 9 ∙ Secretariat: "Amendment 2 to the Asian Harmonization Working Party House Rules" 10. Secretariat: "Amendment 3 to the Asian Harmonization Working Party House Rules" 	<p>Dr. Saleh S. Al-Tayyar Chair, AHWP Director General, Medical Devices Sector SFDA, Kingdom of Saudi Arabia</p>
<p>16:25 – 16:35</p>	<p style="text-align: center;">Tea Break</p>	

16:35 – 16:45	Confirmation of Host of the 19 th AHWP Meeting	Dr. Saleh S. Al-Tayyar Chair, AHWP Director General, Medical Devices Sector SFDA, Kingdom of Saudi Arabia
16:45 – 16:55	Closing Remarks	Mr. Zamane Abdul Rahman Chief Executive Medical Device Authority Ministry of Health Malaysia
16:55 – 18:00	<p>2nd AGM of AHWP ASL (Open to Industry and Regulatory Representatives of AHWP Member Economies)</p> <ul style="list-style-type: none"> - Adoption of Agenda - Admission of New ASL Members - Resolution: Application for tax-exempt charitable status for AHWP ASL under Section 88 of Inland Revenue Ordinance in Hong Kong. - Election of New Directors of the Board 	Mr. Ali M. Al-Dalaan President, AHWP ASL Secretary General, AHWP Executive Director, Medical Device Sector SFDA, Kingdom of Saudi Arabia
18:00	End of the 18th AHWP Main Meeting	