



# Progress Report on the Preparation for the 17th AHWP Annual Conference

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AHWP Secretariat Meeting, Riyadh, KSA



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# Program at a glance

	<b>Friday Nov 2, 2012 W Taipei</b>	<b>Saturday Nov 3, 2012 W Taipei</b>	<b>Sunday Nov 4, 2012 TICC</b>	<b>Monday Nov 5, 2012 TICC</b>	<b>Tuesday Nov 6, 2012</b>	
08:00 AM	AHWP TC WG Meetings (AHWP TC Members Only)	AHWP TC Training Workshop with Parallel Sessions (Open session)	APEC-AHC-HWP-Joint Workshop on Medical Devices Combination Products (Open session)	17th AHWP Annual Meeting (Open session)	Networking Activities, e.g., Visit to Clinical Investigation Center, etc. (Open session)	Networking Activities, e.g., Visit to Building 101, etc. (Open session)
09:00 AM						
10:00 AM						
11:00 AM	AHWP TC Pre-Meeting (AHWP TC Members Only)					
12:00 AM						
13:00 PM	AHWP TC Meeting (Open session)	Networking Activities, e.g., Visit to Palace Museum (Open session)				
14:00 PM						
15:00 PM						
16:00 PM						
17:00 PM	1st AGM of ASL (Open to All representatives from AHWP Member Economies)					
18:00 PM		Welcome Dinner	Gala Dinner			

# 1. Program of Events

Date	Time	Meeting	Activity	Venue	No. participants
11/2 (Fri)	08:00-10:00	AHWP TC WG Breakout Meetings	/	W Taipei (Venue confirmed)	~50 (AHWP TC)
	10:00-12:00	AHWP TC Pre-Meeting			~50 (AHWP TC)
	12:00-13:00	AHWP TC Leaders Working Lunch			~50 (AHWP TC)
	13:00-16:30	AHWP TC Meeting			~50 (AHWP TC) ~150 (Observers)
11/3 (Sat)	08:00-16:30	AHWP TC Training Workshop with 2 Parallel Sessions	/	W Taipei (Venue confirmed)	~400 (~200/session)
	18:30-21:00				Welcome Dinner

# 1. Program of Events (Continued)

Date	Time	Meeting	Activity	Venue	No. participants
11/4 (Sun)	08:30- 18:10	APEC-AHC-AHWP Joint Workshop on Medical Devices Combination Products		TICC (Venue confirmed)	~400
11/5 (Mon)	08:00- 17:00	17th AHWP Annual Meeting		TICC (Venue confirmed)	~400
	17:00- 18:00	1st AGM of ASL		TICC (Venue confirmed)	~100
	18:30- 21:00		Gala Dinner	TICC (Venue confirmed)	~400
11/6 (Tue)	10:00- 12:00		Visit to Clinical Trial Center or Visit to	TBD	TBD
	13:30- 16:30		Visit to National Palace Museum	National Palace Museum	~100



## 2. Agenda

Nov 2 (Fri), AHWP TC Meeting

Time	Session
Morning (08:00-10:00)	AHWP TC WG Meeting
Morning (10:00-12:00)	AHWP TC Pre-Meeting
Noon (12:00-13:00)	AHWP TC Leaders Working Lunch
Afternoon (13:00-16:30)	AHWP TC Meeting Welcome address by Dr. Shioh-Ing Wu Deputy Director-General, TFDA, DOH, Chinese Taipei (awaiting confirmation)



## 2. Agenda

### Nov 3 AHWP TC Training Workshop

Time	Session	Speaker
08:00 – 08:10	Opening Speech	Mrs. Joanna Koh, Chair, AHWP Technical Committee (confirmed)
08:10 – 08:20	Welcome Address	Dr. Shioh-Ing Wu Deputy Director-General, TFDA, DOH, Chinese Taipei (awaiting confirmation)
08:20 – 08:30	Souvenirs to Speakers & Photo Taking	Dr. Shioh-Ing Wu Deputy Director-General, TFDA, DOH, Chinese Taipei (awaiting confirmation)

## Nov 3 AHWP TC Training Workshop (Continued)

	Parallel Session 1			Parallel Session 2		
Time	Session	Speaker	Moderator/Facilitator	Session	Speaker	Moderator/Facilitator
08:30 - 10:00	QMS/Good Distribution Practice a) Implementing GHTF Guidance on Medical Devices QMS	Mr. Grant Ramaley, IAF (confirmed) Mr. Egan Cobbold, Health Canada (Chair of GHTF SG3) (awaiting decision)	Mr. Y. S. Kuo, Chairman, TMBIA, Chinese Taipei (awaiting confirmation)	How medical software are currently regulated in US and EU?	Mr. Bakul Patel, FDA, USA (awaiting confirmation) Dr. Laurent Selles, EU Commission (Confirmed)	Dr. Yio-Wha Shau, General Director, BDL, ITRI, Chinese Taipei (awaiting confirmation)
10:00 - 10:30	Tea break					
10:30 - 12:00	QMS/Good Distribution Practice (Continued)	Ms. Jan Welch, FDA, USA (Chair of GHTF SG4) (awaiting decision) Mr. Jeffrey Gren, Department of Commerce, USA (declined)	Mr. Y. S. Kuo, Chairman, TMBIA, Chinese Taipei (awaiting confirmation)	Latest Development on Medical Software in China Status on Standards Development for Medical Software	Ms. Gao Li, SFDA, China (awaiting confirmation) Mr. Peter Linders (Chair of CENELEC TC62) (awaiting confirmation)	Dr. Yio-Wha Shau, General Director, BDL, ITRI, Chinese Taipei (awaiting confirmation)
12:00 - 13:00	Lunch					



## Nov 3 AHWP TC Training Workshop (Continued)

	Parallel Session 1			Parallel Session 2		
Time	Session	Speaker	Moderator/Facilitator	Session	Speaker	Moderator/Facilitator
13:00 - 14:00	Enhancement of Post-market Surveillance Experiences in EU The Use of NCAR and SADS in Reporting	Dr. Laurent Selles, EU Commission <b>(confirmed)</b>	Dr. Jau-Min Wong, National Taiwan University <b>(awaiting confirmation)</b>	Affordable and Accessible IVD	Dr. Rosanna Peeling, LSHTM, UK <b>(awaiting confirmation)</b>	Dr. Chin-Yuan Tzen, Chairman, TSMM, Chinese Taipei <b>(awaiting confirmation)</b>
14:00 - 15:00		Ms. Isabelle Demade, EU Commission (Chair of GHTF SG2) <b>(awaiting decision)</b>		Clinical rationale (basis) of Medical Devices and Medical Technology advances in Medical Device	Dr. Mitchell Krucoff, Duke University, USA <b>(declined)</b>	
15:00-15:30	<b>Tea break</b>					
15:30 - 16:30	Successful elements of post-market surveillance system a) Benchmark b) Best Practice •Experiences in Chinese Taipei •Experience Sharing by Australian Industry	Ms. Tina Wu, TFDA, DOH, Chinese Taipei  Zimmer Representative, USA <b>(Confirmed)</b>	Dr. Jau-Min Wong, National Taiwan University. <b>(awaiting confirmation)</b>	Clinical rationale (basis) of Medical Devices and Medical Technology advances in Medical Device (Continued)	Dr. Krishnan Ranga, Duke University, USA <b>(awaiting decision)</b>  Dr. Herb Lerner, FDA, USA <b>(Declined)</b>	Dr. Rong-Sen Yang, Dept. Orthopedics Surgery, NTUH <b>(awaiting confirmation)</b>
16:30	<b>End of AHWP Training Workshop</b>					

## 2. Agenda

### Nov 5 The 17th AHWP Annual Meeting

Time	Session	Speaker / Moderator
08:00-08:15	Welcome Address	Dr. Jaw-Jou, Kang, Director-General, TFDA, Department of Health, Chinese Taipei (awaiting confirmation)
08:15-08:25	Opening Speech	Dr. Saleh Al-Tayyar, AHWP Chair, SFDA, KSA (confirmed)
08:25-08:55	Souvenirs to Host, Keynote Speakers and Diamond sponsor & Photo Taking	Dr. Saleh Al-Tayyar, AHWP Chair, SFDA, KSA (confirmed)
08:55-09:25	<b>Keynote Speech</b> Regulations Update and Medical Devices and Biotech Development in Chinese Taipei	Mr. Hui-Hua Jiang, Executive Secretary, Board of Science and Technology, Executive Yuan, Chinese Taipei (confirmed)
09:25-09:45	Tea Break	
09:45-10:15	GHTF Status Report	Mr. Kazunari Asanuma MHLW, Japan (confirmed)
10:15-10:45	IMDRF Status Report	IMDRF Representative
10:45-12:00	AHWP Status Report and Strategic Framework Including announcement of the AHWP Conference - Adoption of Agenda - Admission of New AHWP Members - Roll Call (Only Official Members)	Dr. Saleh Al-Tayyar, AHWP Chair, SFDA, KSA (confirmed)
12:00-13:00	Lunch	

## Nov 5 The 17th AHWP Annual Meeting (Continued)

Time	Session	Speaker / Moderator
13:00-14:20	Country Update I)China II)Thailand III)Indonesia IV)Brazil V)Chile	Country representatives  Chile: Ms. Maria Lopez (confirmed)
14:20-14:40	Tea Break	
14:40-15:20	Report by AHWP TC	Mrs. Joanna KOH TC Chair, HSA, SG (confirmed)
15:20-15:50	Report by Secretariat	Mr. Ali M. Al-Dalaan Secretary General, AHWP, SFDA, KSA (confirmed) & Mr. Bryan SO Executive Deputy Secretary General, AHWP, HKPC, HK (confirmed)
15:50-16:10	Tea Break	

## Nov 5 The 17th AHWP Annual Meeting (Continued)

Time	Session	Speaker/Moderator
16:10-16:40	<ul style="list-style-type: none"> <li>- Resolution 1: Adoption of the Proposed AHWP Strategic Plan (by Lindsay TAO)</li> <li>- Resolution 2: Adoption of the Updated AHWP TOR on Liaison Membership (by Bryan SO)</li> <li>- Resolution 3: Advisor to AHWP</li> <li>- More Resolutions TBC</li> </ul>	Dr. Saleh Al-Tayyar, AHWP Chair, SFDA, KSA (confirmed)
16:40-16:50	Confirmation of Host of the 18th AHWP Meeting	Dr. Saleh Al-Tayyar, AHWP Chair, SFDA, KSA (confirmed)
16:50-17:00	Closing Remarks	Ms. Li-Ling Liu AHWP Vice-Chair Director, Division of Medical Devices and Cosmetics, FDA, Department of Health, Chinese Taipei (confirmed)
17:00-18:00	1 <sup>st</sup> AGM of AHWP ASL (Open to All Participants from AHWP Member Economies) <ul style="list-style-type: none"> <li>- Adoption of Agenda</li> <li>- Introduction of ASL</li> <li>- Admission of New ASL Members</li> <li>- Election of Lindsay TAO as Director of the Board</li> <li>- ASL House Rules (by Mr. Bryan So)</li> </ul>	Mr. Ali M. Al-Dalaan Secretary General, AHWP, SFDA, KSA (confirmed)
18:30-21:00	End of 17th AHWP Annual Meeting	
18:30-21:00	Gala Dinner	

## 2. Budget

Expenditure	
Nov 2 (Fri), AHWP TC Meeting	USD 23,450
Nov 3 AHWP TC Training Workshop	USD 79,200
Nov 5 The 17th AHWP Annual Meeting	USD 60,680
Net Working & Local Event Agent	USD 69,790
VIP and Speakers (Assuming 20, exact number to be provided by OC)	USD 50,200
<b>Total</b>	<b>USD 283,320</b>

Income (estimated)	
Local SME participants registration	USD 68,400
Local Multinational Corporation & Overseas participants registration	USD 66,500
Local Sponsorship	USD 16,400 (sponsored by TFDA)
Overseas Sponsorship	USD 75,000
ASL Sponsorship	USD 40,000
<b>Total</b>	<b>USD 266,300</b>

## 4. Venues

- Nov 2 (Fri) & Nov 3 (Sat): W Hotel , Taipei, 10, Zhongxiao East Road, Sec. 5, Xinyi District, Taipei City, 100 Taiwan (capacity 400p )
- Nov 4 (Sun) & Nov 5 (Mon): Taipei International Convention Center (TICC), 1, Xinyi Road, Section 5, Taipei City, 100 Taiwan (capacity 400p )



W Hotel



(TICC)



## 5. Announcement & Registration

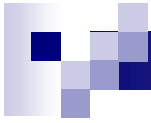
- 2012/3/12: AHWP Meeting Website 1<sup>st</sup> Announcement
- 2012/3/31: AHWP Meeting overall program and budget proposal (submit to AHWP Secretariat)
- 2012/8/27 : AHWP Meeting Website 2<sup>nd</sup> Announcement
- 2012/9/07 : Registration started (51 registrants by far)
  - Local SME participants registration: 37
  - Local Multinational Corporation & Overseas participants registration: 14



## 6. Support from AHWP Members & Secretariat

- Budget Approval
- Speakers Invitation
- Active Promotion of Registration (See [AHWP web](#))
- Overseas Sponsorship





See You in Taipei!

