

**Second
Announcement**

The 17th Asian Harmonization Working Party (AHWP) Annual Meeting, AHWP Technical Committee Meeting and Training Workshop



- **W Hotel TAIPEI, Chinese Taipei
November 2 - 3, 2012**
- **Taipei International Convention
Center, Chinese Taipei
November 4 - 5, 2012**



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA



FDA 食品藥物管理局
Food and Drug Administration

AHWP and its Roles and Responsibilities

Asian Harmonization Working Party (AHWP) is established as a non-profit organization. Its goals are to study and recommend ways to harmonize medical device regulations in the Asian and other regions and to work in coordination with the Global Harmonization Task Force, APEC and other related international organizations aiming at establishing harmonized requirements, procedures and standards. The Working Party is a group of experts from the medical device regulatory authorities and the medical device industry. Membership is open to those representatives from the Asian and other regions that support the above stated goals.

Asian Harmonization Working Party Technical Committee (AHWP TC) is the executive arm of AHWP. It performs the following roles and responsibilities to support the Working Party:

- Execute the Working Party's decisions and resolutions;
- Make recommendations to the AHWP Meetings;
- Provide expert opinions and advices;
- Develop technical documents and policy papers;
- Plan and organize meetings, training, seminars, workshops and experience sharing sessions;
- Work with related organizations and participate in their activities; and
- Report on the progress of its activities to the AHWP Meetings.

Overview of the Meetings

The 17th AHWP Annual Meeting, AHWP TC Meeting and AHWP Training Workshop will be held in Chinese Taipei from November 2-5. The AHWP Annual Meeting and AHWP TC Meeting will focus on the progress of recent technical activities in the harmonization of medical devices regulations. The AHWP TC Training Workshop will serve as a training platform on various regulatory issues, such as clinical performance evaluation, quality management system, postmarket surveillance, software verification and validation, etc. Participants may interact with the delegates from regulatory authorities as well as industry throughout the world.

The following is the program of events and tentative agenda of the meetings.

Program at a glance

	Friday Nov 2, 2012 W Taipei	Saturday Nov 3, 2012 W Taipei	Sunday Nov 4, 2012 TICC	Monday Nov 5, 2012 TICC	Tuesday Nov 6, 2012
07:00 AM					
08:00 AM	AHWP TC WG Meetings and	AHWP TC Training Workshop with Parallel Sessions (Open session)	AHWP-APEC Medical Devices Combination Products Conference (Open session)	17th AHWP Annual Meeting (Open session)	Networking Activities, e.g., Visit to Clinical Investigation Center, etc. (Open session)
09:00 AM	TC Pre-Meeting (AHWP TC Members Only)				
10:00 AM	AHWP TC Meeting (Open session)				
11:00 AM					
12:00 AM					
13:00 PM					
14:00 PM					
15:00 PM					
16:00 PM					
17:00 PM				1st AGM of ASL (Open to All participants from AHWP Member Economies)	
18:00 PM				Gala Dinner	

AHWP TC WG Meeting, TC Pre-Meeting & AHWP TC Meeting, Nov 2, 2012

Time	Session
Morning (08:00-10:00)	AHWP TC WG Meeting and TC Pre-Meeting
Afternoon (10:00-16:30)	AHWP TC Meeting Welcome address by Dr. Shioh-Ing Wu Deputy Director-General, TFDA, DOH, Chinese Taipei

AHWP TC Training Workshop, Nov 3, 2012 (Tentative agenda)

Time	Session			Speaker		
08:00 – 08:10	Opening Speech			Mrs. Joanna Koh, Chair, AHWP Technical Committee		
08:10 – 08:20	Welcome Address			Dr. Shioh-Ing Wu Deputy Director-General, TFDA, DOH, Chinese Taipei		
08:20 – 08:30	Souvenirs to Speakers & Photo Taking			Dr. Shioh-Ing Wu Deputy Director-General, TFDA, DOH, Chinese Taipei		
	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	Local Industry Representative, Chinese Taipei	Towards a global vision on medical software	DITTA Representative	BDL Representative, ITRI, Chinese Taipei
10:00 – 10:30	Tea break					
10:30 – 12:00	QMS/Good Distribution Practice (Continued)	Mr. Grant Ramaley, IAF	Local Industry Representative, Chinese Taipei	Towards a global vision on medical software (Continued)	DITTA Representative	BDL Representative, ITRI, Chinese Taipei
12:00 – 13:00	Lunch					

13:00 - 14:00	Elements of a successful registry in the post-market surveillance system	Ms. Tina Wu, TFDA, DOH, Chinese Taipei	Local Industry Representative, Chinese Taipei	Affordable and Accessible IVD	Clinical Epidemiologist, LSHTM, UK	Molecular Medicine Clinician, Chinese Taipei
14:00 - 15:00	a) Benchmark b) Best Practice <ul style="list-style-type: none"> Experiences in Chinese Taipei Experience Sharing by Australian Industry 	Zimmer Representative, USA		Clinical rationale (basis) of Medical Devices and Medical Technology advances in Medical Device	Clinician	Medical Devices Advisory Committee Representative, TFDA, Chinese Taipei
15:00 - 15:30	Tea break					
15:30 - 16:30	Enhancement of Post-market Surveillance <ul style="list-style-type: none"> Experiences in EU 	Dr. Laurent Selles, EU	National Taiwan University Representative, Chinese Taipei	Clinical rationale (basis) of Medical Devices and Medical Technology advances in Medical Device (Continued)	Clinician	Local Industry Representative, Chinese Taipei
16:30	End of AHWP Training Workshop					

AHWP-APEC Joint Workshop on Medical Device Combination Products, Nov 4, 2012

(Tentative agenda)

Time	Session	Speaker	Moderator/Facilitator
08:50-09:00	Opening Speech (include photo taking)	Dr. Jaw Jou Kang Director-General, TFDA, DOH, Chinese Taipei	
09:00-09:30	Keynote 1: Updates on APEC	Mr. Mike Ward, APEC	
09:30-10:00	Keynote 2: GHTF's View on Regulations for Combination Products (CP)	GHTF Representative	
10:00-10:30	Keynote 3: US FDA Updates on Combination Products	US FDA Representative, USA	
10:30-11:00	Tea Break		
11:00-12:00	Safety and Performance Evaluation for Combination Products in USA	US FDA Representative, USA	Representative from Science and Technology Advisory Group of Executive Yuan, Chinese Taipei
12:00-13:00	Lunch		
13:00-13:15	Combination product survey report	Dr. Hsienyi Lin, TFDA, Chinese Taipei	National Yang Ming University Representative, Chinese Taipei
13:15-14:00	Current Challenges and Needs : From regulator perspective From Industry Perspective	AHC Representative AdvaMed Representative	
14:00-15:00	Safety and Performance Evaluation for Combination Products in UK	MHRA Representative, UK	National Yang Ming University Representative, Chinese Taipei
15:00-15:30	Tea Break		
15:30-16:30	Safety and Performance Evaluation for Combination Products in Japan	Mr. Kentaro Azuma, MHLW, Japan	McKay Medical College Representative, Chinese Taipei
16:30-18:00	Panel Discussion <ul style="list-style-type: none"> • Definition • Clinical Investigation (IDE) • Premarket Review (PMA) • GMP • Post Market Surveillance • International Cooperation 	All Speakers	Representative from SFDA, China
18:00-18:10	Closing Remark	Li-Ling Liu AHWP vice-chair Director, TFDA, DOH, Chinese Taipei	
18:10	End of AHWP-APEC Joint Workshop		

17th AHWP Annual Meeting, Nov 5, 2012 (Tentative agenda)

Time	Session	Speaker/Moderator
08:00-08:15	Welcome Address	Dr. Jaw-Jou, Kang, Director-General, TFDA, Department of Health, Chinese Taipei
08:15-08:25	Opening Speech	Dr. Saleh Al-Tayyar, AHWP Chair, SFDA, KSA
08:25-08:55	Souvenirs to Host, Keynote Speakers and Diamond sponsor & Photo Taking	Dr. Saleh Al-Tayyar, AHWP Chair, SFDA, KSA
08:55-09:25	Keynote Speech 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
09:25-09:45	Tea Break	
09:45-10:15	GHTF Status Report	Mr. Kentaro Azuma, MHLW, Japan
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
12:00-13:00	Lunch	
13:00-14:20	Country Update i) China ii) Thailand iii) Indonesia iv) Brazil v) Chile	Country representatives
14:20-14:40	Tea Break	
14:40-15:20	Report by AHWP TC	Mrs. Joanna KOH TC Chair, HSA, SG
15:20-15:50	Report by Secretariat	Mr. Ali M. Al-Dalaan

		Secretary General, AHWP, SFDA, KSA & Mr. Bryan SO Executive Deputy Secretary General, AHWP, HKPC, HK
15:50-16:10	Tea Break	
16:10-16:40	<ul style="list-style-type: none"> - Resolution 1: Adoption of the Proposed AHWP Strategic Plan (by Lindsay TAO) - Resolution 2: Adoption of the Updated AHWP TOR on Liaison Membership (by Bryan SO) - Resolution 3: Advisor to AHWP - More Resolutions TBC 	Dr. Saleh Al-Tayyar, AHWP Chair, SFDA, KSA
16:40-16:50	Confirmation of Host of the 18th AHWP Meeting	Dr. Saleh Al-Tayyar, AHWP Chair, SFDA, KSA
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
17:00-18:00	<p>1st AGM of AHWP ASL (Open to All Participants from AHWP Member Economies)</p> <ul style="list-style-type: none"> - Adoption of Agenda - Introduction of ASL - Admission of New ASL Members - Election of Lindsay TAO as Director of the Board - ASL House Rules (by Mr. Bryan So) 	Mr. Ali M. Al-Dalaan Secretary General, AHWP, SFDA, KSA
18:30-21:00	End of 17th AHWP Annual Meeting	
18:30-21:00	Gala Dinner	

TRAVEL TIPS

Accommodation

In addition to the venue hotel, W Taipei, at a special discount rate, there are a number of hotels in vicinity:

- Grand Hyatt Taipei Hotel
2, SongShou Road, Xinyi Dist., Taipei, Taiwan 11051 +886-2-2720-1234
<http://taipei.grand.hyatt.com/hyatt/hotels-taipei-grand/index.jsp?null>
- Le meridien Taipei
No.38, Songren Rd., Xinyi Dist., Taipei City 110, Taiwan (R.O.C.)
+886-2-6622-8000
<http://www.lemeridien-taipei.com/>
- The Tango Hotels
297, ZhongXiao East Road, Section 5, Xinyi Dist., Taipei 110, Taiwan
+886-2-2528-8000
<http://www.tango-hotels.com/>
- Pacific Business Hotel
11F, No.495, Guang-Fu S. Rd. Xinyi Dist., Taipei, 11074, Taiwan
+886-2-8780-8000
<http://www.businesscenter.com.tw/>
- AT Boutique Hotel
No. 468, Section 4, Xinyi Road, Xinyi District Taipei City, Taiwan 110
+886-2-2345-9777
<http://www.at-boutique-hotel.com/at-boutique/index.jsp>

Transportation

Downtown Taipei is at a distance of approximately 50 km (60 minutes drive approximately) from Taoyuan International Airport. Prepaid taxis, rental cars, buses and hotel shuttle buses are available at the airport. For more information, please visit the following web site:

<http://www.taoyuan-airport.com/english/Publish.jsp?cnid=1208>

Weather

October and November are great months to visit Taipei from the weather perspective. The average temperature in November is around 68°F (20°C). It is not too hot, and you can go out during the day or night to enjoy the sights and attractions.

Electricity

Electricity in Chinese Taipei is 110 V, alternating at 60 cycles per second. If you travel with a device that does not accept 110 V at 60 Hz, you will need a voltage converter.

Visa

For related information, please visit the following web sites of the Bureau of Consular Affairs, Ministry of Foreign Affairs, Taiwan, R.O.C. and National Immigration Agency:

- <http://www.boca.gov.tw/mp?mp=2>
- <http://www.immigration.gov.tw/mp.asp?mp=2>

Other Enquiries

For enquiries (e.g. assistance in getting an invitation letter, having difficulties during visa application, etc.) and further details, please contact:

- Mr. Jeffrey Chern, Email: jfchern@itri.org.tw, Tel: +886-3-574-3730;
Fax: +886-3-5734092
- Dr. Christopher Chan, Email: cchan@itri.org.tw, Tel: +886-3-574-3836;
Fax: +886-3-5732299



Registration Form for the 17th AHWP Annual Meeting, AHWP TC Meeting & AHWP TC Training Workshop, 2-6/11/2012, Chinese Taipei

1. Registration Details

Please complete the following contact information. All fields with an asterisk (*) are required to be filled. (Check where appropriate.)

Title*: Dr. Mr. Mrs. Ms. Sex: Male Female

First Name*: _____ Last Name *: _____

Affiliation*: _____

Address: _____

City: _____ State/Province: _____ Country*: _____

Zip/Postal Code: _____ E-mail*: _____

Telephone*: () Fax *: () Cell phone: _____

2. I would like to participate: (Check where appropriate.)

Nov 2 (Fri) Afternoon	<input type="checkbox"/> AHWP TC Meeting
Nov 3 (Sat)	<input type="checkbox"/> AHWP TC Training Workshop with Two Parallel Sessions
Nov 4 (Sun)	<input type="checkbox"/> APEC-AHWP Joint Workshop on Medical Devices Combination Products
Nov 5 (Mon)	<input type="checkbox"/> AHWP Annual Meeting
	<input type="checkbox"/> 1 st AGM of ASL (Note: Open to industry and regulatory representatives of AHWP Member Economies only.)
	<input type="checkbox"/> Gala Dinner
Nov 6 (Tue)	<input type="checkbox"/> Networking Forum

Food Preference: Regular Vegetarian Other, please specify: _____

3. Registration Fee

I would like to register as*: Regulator Industry /Trader

The current exchange rate is approximately US\$1 = NT\$30

Category	Local Small to Medium Enterprises	Local Multinational Corporation	Overseas Participants
<input type="checkbox"/> Industry / Trader	US\$400 (NT\$12,000)	US\$700 (NT\$21,000)	US\$700 (US\$21,000)
<input type="checkbox"/> Regulators	-	-	Complimentary for 2 delegation of each member economy

§ Please submit a registration form for each participant.

§§ Confirmation of successful registration will be sent after clearance of payment.

4. Accommodation

Accommodation is available at the meeting venue, W Taipei at the following discounted rates.

Room Type	Rate
Wonderful Room	NT\$8,500 (US\$283)
Fabulous Room	NT\$9,500 (US\$317)

Please mention "17th AHWP Annual Meeting" when you are making the reservation. For bookings, please contact:

Ms. Jamie Yen, Sales Manager / W TAIPEI

10 Zhongxiao East Road, Sec. 5, Xinyi District, Taipei, Taiwan 110
T +886 2 7703 8864 / F +886 2 7703 8897

Please email or fax the completed registration form with the proof of payment no later than Oct 19, 2012 to:

Dr. Christopher Chan
Fax: +886-3-5732299
Email: cchan@itri.org.tw

OR

Mr. Jeffrey Chern
Fax: +886-3-5734092
Email: jfchern@itri.org.tw

5. Payment (Check where appropriate.)

By Cheque/Bank Draft (Payable to "Industrial Technology Research Institute")

Name of Bank: _____

Cheque/Bank Draft No. _____

Amount: US\$/NT\$ _____

- Please submit the completed registration form together with the cheque or bank draft to Industrial Technology Research Institute
- If pay by US\$ bank draft or cheque, please note that the bank draft or cheque must be drawn on a bank in Chinese Taipei or the United States.
- Please state clearly on cheque/bank draft that the payment is for "17th AHWP Annual Meeting"

By Credit Card VISA MASTER American Express

Card No. : _____

Expiry Date: _____

Charge amount: US\$/NT\$ _____

Signature: _____

- Please submit the completed registration form and the Credit Card Authorization Form (Pg.7) to Industrial Technology Research Institute

By Telegraphic Transfer

Remittance should be made to the following:

Bank Name: Mega International Commercial Bank, Hsinchu Branch

Bank Address: 69 Tung Chien Street, Hsinchu, Taiwan, Republic of China

Swift Code: ICBCTWTP203

Account Number: 203-53-00029-0

Account Name: Industrial Technology Research Institute

Remitting Bank Name: _____

Date: _____

Amount: US\$/NT\$ _____

- All banking charges, if any, are to be borne by the delegates
- Please note the "17th AHWP Annual Meeting" in the remittance document as the remittance message for our verification.
- Please submit the completed registration form together with the copy of remittance document to Industrial Technology Research Institute



The 17th AHWP Annual Meeting, AHWP TC Meeting & Training Workshop Credit Card Authorization Form

I authorize Industrial Technology Research Institute (ITRI) to charge the total payment fee indicated on this form to my credit card.

Date of Purchase	___/___/____ (mm/dd/yyyy)		
Card Type	<input type="checkbox"/> VISA <input type="checkbox"/> MasterCard <input type="checkbox"/> JCB <input type="checkbox"/> American Express		
Card Holder Name	(First Name)		(Last Name)
Telephone Number		Email	
Card Number	____-____-____-____		
Expiry Date	___/___ (mm/yy)		
Verification Code	____ (For Visa/Master/JCB, this is the last 3 digits on the back of card on signature panel)		
	____ (For American Express, this is the 4 digits on front of card above the credit card number)		
Total Payment	NT\$		
Signature	(Same as the signature on credit card)		

Please fax or email the completed authorization form to:

Dr. Christopher Chan
Fax: +886-3-5732299
Email: cchan@itri.org.tw

OR

Mr. Jeffrey Chern
Fax: +886-3-5734092
Email: jfchern@itri.org.tw