

11TH ASIAN HARMONIZATION WORKING PARTY TECHNICAL COMMITTEE MEETING 6th-7th September 2010



CONFERENCE ON THE GLOBAL HARMONIZATION OF MEDICAL DEVICE REGULATION 8th-9th September 2010



Organizer & Host:

Asian Harmonization Working Party (AHWP)

Taiwan Food & Drug Administration,
Department of Health (TFDA, DOH), Chinese Taipei

Co-organizer :

Industrial Technology Research Institute (ITRI)

With support and participation of:

Global Harmonization Task Force (GHTF)
American Chamber of Commerce in Taipei
European Chamber of Commerce in Taipei
Electronics Testing Center, Taiwan

Metal Industries Research and Development Center
Plastic Industry Development Center
Medical and Pharmaceutical Industry Technology
and Development Center
Taiwan Medical and Biotech Industry Association



Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA



FDA

食品藥物管理局
Food and Drug Administration

AHWP TC and its Roles and Responsibilities

Asian Harmonization Working Party Technical Committee (AHWP TC) is the executive arm of Asian Harmonization Working Party (AHWP), a non-profit organization dedicated to the harmonization of medical device regulations in the Asian and other regions. AHWP TC 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.

AHWP TC collaborates with the Global Harmonization Task Force (GHTF), APEC and other related international organizations aiming at establishing harmonized requirements, procedures and standards.

Overview of the Meeting

The 11th AHWP TC meeting will be held in Chinese Taipei, from 6th September to 7th September. The meeting will focus on the technical activities in the recent collaborative efforts with the GHTF Study Groups such as harmonization of medical device nomenclature system, STED-CSDT mapping as well as harmonization of adverse event reporting system.

Due to limited seats, reservation will be made on a first-come-first-serve basis. The number of participants from each company will also be limited. Seize the opportunity and register NOW!

6th – 7th September 2010

FAR EASTERN PLAZA HOTEL, Taipei City 10675, Taiwan

Tentative Agenda

Date	6 th Sep. 2010 (Monday)	7 th Sep. 2010 (Tuesday)
Time	11 th AHWP TC Pre-meeting	11 th AHWP TC Meeting
08:30		Registration
09:00		Welcome Address & Photo Taking
10:30		Tea Break
10:50		AHWP TC Meeting (Session 1)
12:30		Lunch Break
13:30	Registration and AHWP TC Pre-meeting (Session 1)	AHWP TC Meeting (Session 2)
15:30	Tea Break	
15:50	AHWP TC Pre-meeting (Session 2)	AHWP TC Meeting (Session 3)
17:00	End of Meeting	End of Meeting



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CONFERENCE ON THE GLOBAL HARMONIZATION OF MEDICAL DEVICE REGULATION

8th – 9th September 2010

FAR EASTERN PLAZA HOTEL, Taipei City 10675, Taiwan

Overview of the Conference

The conference will be held from 8th September to 9th September, wherein GHTF delegates will speak about various issues related to global harmonization of medical device regulations from premarket through postmarket. The conference serves as an information exchange forum where participants could interact with the representatives of medical device industries and regulatory authorities from all over the world.

Tentative Agenda

Date	8 th Sep. 2010 (Wednesday)	9 th Sep. 2010 (Thursday)	
Time	Conference on the Global Harmonization of Medical Device Regulation		
08:30	Registration		
09:00	Welcome Address & Keynote Speech 1 (Dr. Kang Jaw-Jou, TFDA)	09:00	Keynote Speech 3 (Medical Technology Development) (Speaker to be confirmed)
09:45	Keynote Speech 2 (GHTF)	09:45	SG4- Auditing (Speaker to be confirmed)
10:30	Tea Break		
11:00	SG1- Premarket Evaluation (Speaker to be confirmed)	11:00	Tea Break
12:30	Lunch Break	11:20	SG5 –Clinical Safety/Performance Dr. Susanne Ludgate, MHRA, UK
13:30	SG2- Post Market Surveillance/ Vigilance Ms. Isabelle Demade, EC	12:30	Meeting Adjourn
15:00	Tea Break	14:00	Regulators Meeting (hosted by TFDA)
15:30	SG3- Quality Systems (Speaker to be confirmed)		
17:00	End of Day 1		

Due to limited seats, reservation will be made on a first-come-first-serve basis. The number of participants from each company will also be limited. Seize the opportunity and register NOW!



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11TH ASIAN HARMONIZATION WORKING PARTY TECHNICAL COMMITTEE MEETING and
CONFERENCE ON THE GLOBAL HARMONIZATION OF MEDICAL DEVICE REGULATION

6th – 9th September 2010

FAR EASTERN PLAZA HOTEL, Taipei City 10675, Taiwan

Registration Form

1. I would like to participate [Please tick the appropriate box(es)] :

<input type="checkbox"/> 6th September (Monday) AHWP TC Pre-meeting (For AHWP TC members only)	<input type="checkbox"/> AHWP Nominated Representative <input type="checkbox"/> AHWP TC office bearer, please specify: _____ <input type="checkbox"/> AHWP WG/STG, please specify: _____
<input type="checkbox"/> 7th September (Tuesday) AHWP TC Meeting	
<input type="checkbox"/> 8th - 9th September (Wednesday & Thursday) Conference on the Global Harmonization of Medical Device Regulation	

Remark: Seats are limited and will be reserved on a first-come-first-serve basis. The number of participants from each company may also be limited.

2. Registration details:

Name: Ms. / Mr. / Dr. _____

Organization/Company: _____

Full Address: _____

_____ Postal Code: _____

Telephone: (Country code) _____ (Area code) _____ (Number) _____

Facsimile: (Country code) _____ (Area code) _____ (Number) _____

Email: _____

Kindly fill out the form and send it back by email or fax to either of the contact persons below: <ul style="list-style-type: none">● 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
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TRAVEL TIPS

ACCOMMODATION

Accommodation is available at the meeting venue, Far Eastern Plaza Hotel, Taipei (Web page:<http://www.shangri-la.com/en/property/taipei/fareasternplaza>) at specially discounted rate. Please mention “AHWP TC Meeting” when you are making the reservation. For bookings, please contact:

Ms. Teresa Ho, Events Manager

Shangri-La's Far Eastern Plaza Hotel, Taipei

201 Tun Hwa South Road, Section 2, Taipei City 10675 Taiwan.

Tel.: +886-2-2378-8888 #5022

Fax: +886-2-2376-3277

Email: teresa.ho@shangri-la.com

More options:

- *The Grand Hotel*
No.1, Sec. 4, Zhongshan N. Rd., Zhongshan Dist., Taipei City 10461, Taiwan
Tel : +886-2-2886-8888 Fax : +886-2-2885-2885
<http://www.grand-hotel.org/main/default.aspx?lang=en-us>
- *CAESAR PARK TAIPEI*
38, Chung Hsiao W. Rd., Sec. 1, Taipei, 100, Taiwan
Tel: +886-2-2311-5151 Fax : +886-2-2331-9944
<http://en.taipei.caesarpark.com.tw/>
- *Grand Hyatt Taipei*
2, Song Shou Road, Taipei, Taiwan 11051
Tel: +886-2-2720-1234 Fax: +886-2-2720-1111
<http://taipei.grand.hyatt.com/hyatt/hotels/index.jsp>



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FAR EASTERN PLAZA HOTEL, Taipei City 10675, Taiwan

- *Brother Hotel*
255, Sec. 3, Nanjing East Road, Taipei, Taiwan
Tel: +886-2-2712-3456 Fax: +886-2-2717-3334
<http://www.brotherhotel.com.tw/english/index.htm>
- *Agora Garden*
No. 68, Sung-Kao, Rd., Taipei, 110, Taiwan
Tel :+886-2-8780-5168 Fax:+886-2-8780-5608
http://www.agoragdn.com.tw/en_hotel.htm
- *The Landis Taipei Hotel*
41, Min-Chuan East Road, Sect.2, Taipei, 104, Taiwan
Tel: +886-2-2597-1234 Fax: +886-2-2596-9223
<http://taipei.landishotelsresorts.com/>

TRANSPORT

Far Eastern Plaza Hotel is at a distance of approximately 50 km (60 minutes drive approximately) from Taoyuan International Airport (Formerly known as Chiang Kai Shek International Airport). Prepaid taxis, rental cars, buses and hotel shuttle buses are available at the airport. For more information, please visit the following web pages:

<http://www.taoyuanairport.gov.tw/english/Publish.jsp?cnid=1208>

<http://www.shangri-la.com/en/property/taipei/foreasternplaza/transportation>

WEATHER

September marks the beginning of autumn, the most refreshing season in Chinese Taipei. The sky is high while the air is fresh and cool.

Average temperature: 25 °C / 77 °F.



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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 pages of the Bureau of Consular Affairs, Ministry of Foreign Affairs, Taiwan, R.O.C. and National Immigration Agency:

- <http://www.boca.gov.tw/lp.asp?ctNode=534&CtUnit=77&BaseDSD=7&mp=2>
- <http://www.immigration.gov.tw/ns/maind.htm>

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

