

**AHWP Technical Committee Meeting and Workshop 2001
Kuala Lumpur, Malaysia**

PROGRAM – Day 1

Date	Time	Program	Speaker
Sep 6	08:00~09:00	R E G I S T R A T I O N	
	AHWP Technical Committee Meeting and Workshop Opening Addresses		
	09:00~09:40	Welcome Address by Vice-Chair, AHWP	Mr Ed Woo (HK)
		Opening Address by Chair, AHWP	Dr Clarence Tan (Singapore)
		Address by Co-Host, Malaysia's MOH and to declare the Meeting and Workshop open	Senior Official, MOH
	09:40~10:00	Keynote Speech: Brief Introduction to GHTF and its perspective	Ms Rita Maclachlan (Chair of GHTF)
	10:00~10:30	B R E A K	
10:30~12:00	Role and activities of AHWP Technical Committee	Mr Albert Li (Chair of AHWP/TC)	
	Proposed changes to the Terms of Reference of AHWP to incorporate functional role of the Technical Committee	Mr Jack Moore (Vice Chair of AHWP/TC)	
		Ms Eishah Abdul Rahman (Vice Chair of AHWP/TC)	
12:00~13:00	L U N C H		

Date	Time	Program	Speaker
Sep 6	Training Workshop I		
	13:00~14:00	Selected GHTF SG1 guidance document: - Essential Principles of Safety and Performance of Medical Devices (Final)	Mr Michael Gropp (GHTF SG 1)
	14:00-15:00	Comments on above GHTF SG1 guidance document	Mr Michael Gropp (GHTF SG 1)
	15:00~15:20	B R E A K	
	AHWP Technical Committee Meeting I		
	15:20~17:00	Review of GHTF SG1 guidance documents: - Essential Principles of Safety and Performance of Medical Devices (Final) - Medical Devices Classification (Working Draft) - Summary Technical Documentation for Demonstrating Conformity to Essential Principles of Safety and Performance of Medical Devices (Working Draft)	Mr Michael Gropp (GHTF SG 1) Technical Committee and Reps from member economies
	17:00	End of Day 1	
	19:00~22:00	Social Program: Buffet Dinner at Melati Room 7, Mezzanine Floor	

**AHWP Technical Committee Meeting and Workshop 2001
Kuala Lumpur, Malaysia**

PROGRAM – Day 2

Date	Time	Program	Speaker
Sep 7	Training Workshop II		
	09:00~11:00	Selected GHTF SG3 and 4 guidance documents: - Guidance for Regulatory Auditing of Quality Systems of Medical Device Manufacturers (Final) - Training Requirements for Auditors (Final) - Process Validation Guidance for Medical Device Manufacturers (Final)	Ms Christine Nelson (FDA) Ms Judy Strojny (FDA)
	11:00~11:20	B R E A K	
	11:20~12:20	Comments on above GHTF SG3 and 4 guidance documents	Ms Christine Nelson (FDA) Ms Judy Strojny (FDA)
	12:20~13:30	L U N C H	

Date	Time	Program	Speaker
Sep 7	AHWP Technical Committee Meeting II		
	13:30~14:30	Review of above GHTF SG3 and 4 guidance documents	Ms Christine Nelson (FDA) Ms Judy Strojny (FDA) Technical Committee and Reps from member economies
	14:30~15:00	B R E A K	
	AHWP Technical Committee Closing Meeting		
	15:00~17:00	Proposed process for review and raising Technical Committee comment on working draft GHTF SG guidance documents to the AHWP for recommendation to GHTF; Proposed process to facilitate and assist in the training, deployment and integration of the final GHTF SG guidance documents into the regulatory framework of the AHWP member economies	Mr Albert Li (Chair of AHWP/TC) Mr Jack Moore (Vice Chair of AHWP/TC) Ms Eishah Abdul Rahman (Vice Chair of AHWP/TC) Reps from member economies
	17:00	End of AHWP Technical Committee Meeting and Workshop	

Note:

1. The proposed changes to Terms of Reference of AHWP to incorporate functional role of the Technical Committee have been distributed to the participants before the meeting.
2. GHTF Study Group guidance documents are available at <http://www.ghtf.org>. Comments on GHTF SG1, SG3 and SG4 guidance documents will focus on, but not limited to, the selected documents.



1st AHWP Technical Committee Meeting and Workshop 2001

6 - 7 September 2001

Kuala Lumpur, Malaysia

AHWP is an important Asian regional forum for both regulator and industry to develop a globally harmonised regulatory system for medical devices. Its meetings have been attended by government regulators and industry representatives from member economies in Asia with either established or developing regulatory systems.

This coming 2-day event is planned with opportunities for training sessions and open dialogue. AHWP Technical Committee Meeting is intended to provide a forum for participants to discuss pertinent issues and regional commitment towards greater harmonization of medical device regulations. The Workshop will provide training for participants to have a good understanding of the various GHTF (Global Harmonization Task Force) guidance documents on medical device regulation and it will be led by invited resource persons from the GHTF's Study Groups (SGs).

Invited GHTF SGs Speakers: Christine Nelson and Judy Strojny from US FDA and Michael Gropp (Guidant) and Fred Halverson (Medtronic) from the industry.

Who should attend AHWP Technical Committee Meeting and Workshop 2001?

Representatives from:

- Member economies developing medical device regulatory systems
- Regulatory affair professionals of medical device industry, foreign and local

The AHWP Technical Committee Meeting and Workshop 2001 program objectives:

- The Technical Committee (TC) Meeting to discuss its role and activities and ratify the Terms of Reference
- Establishment of the working processes for TC and its linkage to AHWP and GHTF SGs
- Training Sessions on GHTF SG's guidance documents by invited resource experts: Essential Principles of Safety and Performance of Medical Devices; Medical Devices Classification; Summary Technical File for Pre-market Documentation of Conformity; Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers; and Training Requirements for Auditors
- Regional group discussion to exchange ideas on ways to apply guidance documents to local systems in order to facilitate harmonization

Organising Committee:

Albert Li (Industrial Technology Research Institute, Chinese Taipei), **Eishah Abdul Rahman** (National Pharmaceutical Control Bureau, Malaysia), **Jack Moore** (Boston Scientific, Singapore), **Ed Woo** (Medtronic, HK), **Wong Yew Sin** (Health Sciences Authority, Singapore), **Khoo Teng Chuan** (J&J Medical, Singapore), **George Azoury** (Bausch & Lomb, Australia), **Ginnie Chao** (Guidant, Singapore), **Jacqueline Monteiro** (BD, Singapore) and hosts, **Ministry of Health, Malaysia** and **Association of Malaysian Medical Industries**

**1st Asian Harmonization Working Party
Technical Committee Meeting and Workshop 2001
6-7 September 2001**

*Venue: Sheraton Subang Hotel and Towers, Subang Jaya
Kuala Lumpur, Malaysia*

REPLY RESPONSE (Please photocopy for more delegates)

To register for the Meeting & Workshop, mail or fax this whole page to:

“Secretariat, AHWP Technical Committee Meeting & Workshop 2001”
Association of Malaysian Medical Industries
c/o Key Associates
10A Jalan BM 1/2 Taman Bukit Mayang Emas
47301 Petaling Jaya
Selangor, Malaysia
Fax: (60) 3-703 0753

Tel: (60) 3-704 7636
Email: keyassoc@tm.net.my

Please complete sections A to C

A. Delegate's Particulars

Dr Mr Miss Ms Mrs Mdm

Last Name / Surname	First Name
Organisation / Company	Designation
Address	
Tel	Fax
Email	Meal Request <input type="checkbox"/> Vegetarian <input type="checkbox"/> Non-Vegetarian
I will be attending the social event evening and dinner on 6 September	<input type="checkbox"/> Yes <input type="checkbox"/> No

B. Payment Details

REGISTRATION FEE per person	Amount Due
<input type="checkbox"/> RM 1,200 for Industry participants	RM
<input type="checkbox"/> RM 400 for participants from Regulatory bodies	RM

C. Payment Method

- Payment in Ringgit Malaysia (RM) by telegraphic transfer (TT) only and into Maybank Corporate Current Account No: 514208142132.
- Bank draft/money order in Ringgit Malaysia only must be crossed and made payable to “Association of Malaysian Medical Industries” and on the reverse side of the draft/order, please indicate “AHWP TC Meeting & Workshop 2001”. Mail the draft/order together with the Registration Form to the Secretariat.

Please furnish details of

Bank and Branch:	Draft/Order/TT No:	Amount:
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D. Secretariat Use Only

Date Received:	Date Acknowledged:
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REGISTRATION

All participants must pay registration fees in advance. Registration will only be confirmed upon receipt of payment. The registration fee includes refreshments and lunch during the TC Meeting and Workshop and workshop materials. It also covers for a dinner to be arranged as a social evening event on the first day.

Registration is on first-come-first-serve basis. The cut off date for registration is 17 August 2001. There is a limited capacity for participants at the TC Meeting and Workshop. Walk-in delegates with payment will only be admitted on the basis of space availability.

CANCELLATIONS AND TRANSFERS

If you are unable to attend, a substitute delegate is welcome at no extra charge. Please provide the name and the title of the substitute delegate to the Secretariat at least two days prior to the TC Meeting & Workshop. In the event of cancellation of registration, 50% of the registration fee will be refunded if the cancellation notice was received by 20 August 2001. No refund will be made if the cancellation notice was received after 20 August 2001.

VENUE AND ACCOMMODATION INFORMATION

Sheraton Subang Hotel and Towers, Subang Jaya
 1 Jalan SS12/1, Subang Jaya 47500, Selangor, Malaysia
 Tel: (60) 3 50316060
 Fax: (60) 3 50319624
 Email: Subang.Reservations@sheraton.com
 Attention: Ms Zurena, Room Reservation Dept

Enquiry about hotel:

*Email: hairul.maharis@sheraton.com
 Attention: Mr Hairul Maharis*

The hotel is easily accessible from Kuala Lumpur International Airport (less than 30 minutes by taxi). Ambient temperature in Subang Jaya, a suburb of Kuala Lumpur, ranges from 25°C to 32°C.

For reservation, please make your bookings directly with the hotel. To enjoy the special room rates (at Malaysian Ringgit 230 Nett per room per night, including a breakfast), please quote Asian Harmonization Working Party/National Pharmaceutical Control Bureau (AHWP/NPCB). Hotel bills are to be settled by delegates directly with the hotel. Hotel reservations and travel arrangements are the responsibility of the registrant. Rooms are available on a first-come-first-serve basis.

ABOUT THE MEETING AND WORKSHOP (Tentative Agenda)

6 Sep	0800-0900	Registration
	0900-1000	Keynote Speech, Brief on GHTF and perspectives
	1000-1015	Welcome Address, AHWP and perspectives
	1015-1035	Break
	1035-1200	Role and activities of AHWP/TC
	1200-1300	Lunch
	1300-1500	Training Workshop Session I
	1500-1520	Break
7 Sep	1520-1700	Group Discussion, Session I
	0900-1100	Training Workshop Session II
	1100-1120	Break
	1120-1220	Group Discussion, Session II
	1220-1330	Lunch
	1330-1430	Group Discussion, Session II (continued)
	1430-1500	Break
	1500-1700	TC deliberation on working processes and its linkage to AHWP & GHTF

The Terms of Reference of AHWP will be distributed to the participants for their pre-study before the meeting. Various GHTF documents can be found at <http://www.ghtf.org> and will be included in the training workshop materials. The training workshop on SG 1 and SG 4 documents will focus on, but are not limited to, the selected documents.