



Asian Harmonization Working Party Technical Committee

Update

Topics

- Review of 10th AHWP TC Meeting, Singapore
 - Progress of AHWP TC Work Groups
 - Areas of collaborations with GHTF
- Status of 11th AHWP TC Meeting, Chinese Taipei

Review of 10th AHWP TC Meeting

Revenue from 10th AHWP TC Meeting

Balance as per Bank Statement -5/7/2010	49,074.85
Less Ping Healthcare - PCO Fee & Conference Expenses (not by this Bank a/c)	(27,722.95)
<u>Cheque issued on 5th July not taken in yet</u>	
cheque no. 000105 - Four Season Catering Pte Ltd -Debrief meeting	(1,077.49)
000106 - Lim Lin Teck - Refund of Registration Fee	(200.00)
'000107 -Ping Healthcare Pte ltd - DVD & Postage	(214.58)
TT to Medical Technology (in process by HAS) Entertainment Fee for Dinner - Claim by Ms Yen	(1,200.00)
Theng	(2,600.00)
Earned Interest	(3.65)
Less - Output Tax - Registration Fee for TC Meeting & Workshop	(2,453.27)
Add - Pfizer's 2 Delegates Registration Fee - Pymt not recvd	400.00
Balance in bank	S\$ <u>14,002.91</u>

Review of 10th AHWP TC Meeting

Main points:-

- Propose TC recruitment process
 - Procedure for acceptance of new WG members
 - Procedure for appointment of TC Chair/Co-chair
 - Procedure for nomination of AHWP TC Reps
- TC Work groups
 - Membership criteria
- All WGs reported their project progress and future developments
 - Future developments are focused on collaborations with GHTF Study Groups

Review of 10th AHWP TC Meeting

- Propose TC recruitment process
 - Member: Apply to WG Chair, who endorse and send to TC chair for approval.

Review of 10th AHWP TC Meeting

TC WGs:

- New Members based in AHWP member State e.g Australian consultant. – 2 views
 - 1) to consider on merit shown in CV
 - 2) accept only as observers if approved by their country TC representative
- Multiple memberships
 - To allow a maximum of 2 WG , as even on 1, some don't participate
- Minimum attendance at meetings – Clear requirements to be proposed.
- Procedure to formalise the decisions

Review of 10th AHWP TC Meeting

- Prioritization – Areas of Collaborations with GHTF

S/N	Initiative	Enablers	Timeline	Priority	Decision Rationale
1	MD Nomenclature system	STG- Nomenclature Joanna Koh Mark Lau	AHWP final position by Nov AHWP meeting in Saudi Arabia	1	Enable use of same nomenclature system globally
2	1. Map STED with CSDT 2. Comparison of STED and CSDT 3. Promote CSDT in AHWP ⇒ Harmonization of CSDT and STED - SG1 to help mapping, and verifying the comparison report of CSDT and STED	WG1	CSDT part by Aug 10 STED part TBC	1	

Review of 10th AHWP TC Meeting

- Prioritization – Areas of Collaborations with GHTF

S/N	Initiative	Enablers	Timeline	Priority	Decision Rationale
3	<p>Harmonized AE report -Create a common form with help of GHTF</p> <p>Building regulatory capacity in post-market areas</p> <p>Sharing of non-confidential information -Request GHTF to share the information to AHWP</p> <p>Merge NCAR/SADS: Exchange the non-confidential safety information - Need NCAR training & mentoring support from GHTF</p>	WG 02	By end 2010	1	

Review of 10th AHWP TC Meeting

- Prioritization – Areas of Collaborations with GHTF

S/N	Initiative	Enablers	Timeline	Priority	Decision Rationale
4	Training on SG05 guidance document and get GHTF advise on AHWP Regulatory development - GHTF support to develop Advisory & Expert Panel	WG05	2011	1	
5	Develop Regulatory training certificate together with AHWP and GHTF - GHTF need to agree and support the joint certificate program - Build syllabus and training material together	WG06	End May – comment from GHTF 2011 – Launch	1	

Status of 11th AHWP TC Meeting

- Focus of the Meeting
 - Status of priority work items for collaborations
 - Current status on work items
 - Response from GHTF Study Groups
 - Steps forward
 - Progress of other work items
 - Sharing on progress of AHWP Meeting in Riyadh, Saudi Arabia

Status of 11th AHWP TC Meeting

Organizing Committee
Chairperson
<i>Dr. Jaw-Jou, Kang, Director General, Food and Drug Administration, Department of Health, Executive Yuan</i>
Vice Chairperson
<i>Ms. Li-Ling, Liu, Director, Division of Medical Devices and Cosmetics, Food and Drug Administration, Department of Health, Executive Yuan</i>
Committee Members
<i>Dr. Chiareiy, Liu, Director, Division of Planning and Research Development, Food and Drug Administration, Department of Health, Executive Yuan</i>
<i>Ms. Pei-Weng, Tu, Senior Technical Specialist, Division of Medical Devices and Cosmetics, Food and Drug Administration, Department of Health, Executive Yuan</i>
<i>Dr. Hsiau-Wen, Huang, Senior Researcher, Food and Drug Administration, Department of Health, Executive Yuan</i>
<i>Mr. Li-Shin, Wang, Chairman, J & J Taiwan, American Chamber of Commerce In Taipei Medical Devices Committee</i>
<i>Ms. Yi-Chen, Lin, European Chamber of Commerce Taipei</i>
<i>Ben, Chen, Chairman, Taiwan Medical And Biotech Industry Association</i>
<i>Mr. Albert Li, Manager, Industrial Technology Research Insititute / Center for Measurement Standards</i>

Status of 11th AHWP TC Meeting

Speakers and Topics

Section	Speaker	Tentative topic	Status
Keynote Speech 1 by TFDA (45mins)	Dr. Jaw-Jou, Kang, Director-General, TFDA	<ul style="list-style-type: none">●Medical device technology development in Taiwan or●The role and development of TFDA (To be confirmed)	Confirmed
Keynote Speech 2 by GHTF (45mins)	Mr. Michael Gropp or Mr. Hiroshi Ishikawa	To be confirmed	Both have confirmed their willingness to attend
Keynote 3 by medical device technology key opinion leader (45mins)	Dr. Sheng-Mau, Hou, Former Minister of Department of Health	To be confirmed	To be confirmed
SG1 Premarket (90mins)	Ms. Shelly Tang, TGA (As recommended by Ms. Nancy Shadeed, Chair of SG1)	To be confirmed	Awaiting response from Shelly

Status of 11th AHWP TC Meeting

Speakers and Topics

Section	Speaker	Tentative topic	Status
SG2 Postmarket (90mins)	Mr. Phillippe Auclair (As recommended by Ms. Isabelle Demade, Chair of SG2)	To be confirmed	Confirmed
SG3 QMS (90mins)	To be confirmed	To be confirmed	Awaiting recommendation from Mr. Egan Cobbold, Chair of SG3
SG4 Audit (75mins)	Mr. Roger Snaith (As recommended by Ms. Jan Welch, Chair of SG4)	To be confirmed	Awaiting response from Mr. Snaith
SG5 Clinical (70mins)	Mr. Greg LeBlanc, Cook Medical (As recommended by Dr. Susanne Ludgate, Chair of SG5)	To be confirmed	Awaiting response from Mr. LeBlanc

Status of 11th AHWP TC Meeting

Preparation of the Conference

Item	Status	Remark
Promotion	<ul style="list-style-type: none">•AHWP website (since early Jul 2)•Domestic websites (since Jul 19)•GHTF website (once the speaker and topics are confirmed)	<ul style="list-style-type: none">•Versions of flyer (English, Traditional Chinese, Simplified Chinese) have been drafted•Need to collaborate with SFDA and CAMDI to promote
Conference Logistics	<ul style="list-style-type: none">•All venues in Far Eastern Plaza Hotel are reserved•Real-time interpretation has been arranged (~200 people)•Food and drinks•Sponsorship	Sponsorship confirmed by: <ul style="list-style-type: none">•J & J Taiwan•PITDC•TMBIA
Registration	Ongoing (will strengthen public announcement to have more registrants)	17 non-regulatory registrants by far

THANK YOU