

# The 17<sup>th</sup> Asian Harmonization Working Party (AHWP) Annual Conference

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*Taipei* Nov 2-6, 2012

[www.ahwp.info/index](http://www.ahwp.info/index) Organized by :



Reported at the 18<sup>th</sup> AHWP Annual Meeting  
by Ms. Li-Ling Liu, TFDA, Chinese Taipei  
*Dec 5, 2013*

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## Organizing Committee for 17th AHWP Meeting November 5-6, 2011, Taipei, Chinese Taipei

Position	Name	Title & Affiliation
Advisor	Dr. Jaw-Jou Kang	Director-General, FDA, Department of Health, Chinese Taipei
Chair	Ms. Li-Ling Liu	Division Director, FDA, Department of Health, Chinese Taipei; AHWP Vice Chair
Vice-Chair	Ms. Lindsay Tao	Johnson & Johnson, China; AHWP Vice Chair
Chief Executive	Mr. Ali M. al-Dalaan	Saudi Food and Drug Administration, Kingdom of Saudi Arabia; AHWP TC Cochair
Local Host Secretary I	Mr. Albert Li	CMS, ITRI, Chinese Taipei; (AHWP Nominated Representative)
Local Host Secretary II	Mr. Jeffrey Chern	CMS, ITRI, Chinese Taipei; WG1a Cochair
Members	Mr. Yeow-Wah Shau	BDL, ITRI, Chinese Taipei
	Ms. Joanna Koh	Health Sciences Authority, Singapore; AHWP TC Chair
	Ms. Tran Quan	GE Healthcare, Singapore; Advisor to AHWP Chair
	Ms. Meang Tanakasemsub	Zimmer Medical, Asia Pacific, Singapore; AHWP TC Vice Chair
	Mr. Bryan So	Hong Kong Productivity Council; Hong Kong SAR; AHWP Secretariat
	Prof. Jack Wong	Johnson & Johnson, Singapore; AHWP Secretariat
	Mr. Yih-Sung Kuo	President, Taiwan Medical and Biotech Industry Association
	Mr. Lung-Sheng Hwang	Chair, Taiwan Federation of Medical Devices Commercial Associations
	Ms. Emily Chiang	Medical Devices Committee, American Chamber of Commerce in Taiwan

## Sponsors

Sponsorship Packages	Sponsors	Amount (USD)	Amount (NTD)
<b>Diamond</b>	<b>UOC(Taiwan)</b>	<b>50,000</b>	<b>1,450,000</b>
<b>Gold</b>	<b>Medtronic</b>	<b>35,000</b>	<b>1,015,000</b>
<b>Silver</b>	<b>Abbott</b>	<b>25,000</b>	<b>725,000</b>
<b>Bronze</b>	DITTA	15,000	435,000
	Edward Lifesciences	15,000	435,000
	ITRI(Taiwan)	15,000	435,000
	Terumo(Taiwan)	15,000	435,000
<b>Other</b>	<b>Roche Diagnostics (Taiwan)</b>	<b>3,000</b>	<b>87,000</b>
<b>Total Sponsorship Amount</b>		<b>173,000</b>	<b>5,017,000</b>



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**Asian Harmonization Working Party**  
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

**REPORT OF THE 17<sup>th</sup> MEETING OF THE  
ASIAN HARMONIZATION WORKING PARTY (AHWP)**  
Taipei International Convention Center (TICC)  
Chinese Taipei  
2-6 November 2012

## INTRODUCTION

(1) The 17<sup>th</sup> Meeting of the Asian Harmonization Working Party (AHWP) was held on 2-6 Nov 2012 at Taipei International Convention Center, Chinese Taipei. The Meeting was chaired by Dr Saleh S. Al-Tayyar, Director General, Medical Devices Sector, Saudi Food and Drug Administration, Kingdom of Saudi Arabia (AHWP Chair), and co-chaired by Ms Li-Ling LIU (AHWP Vice-Chair), Ms Lindsay TAO (AHWP Vice-Chair), Ms Joanna KOH (AHWPTC Chair), Eng. Ali AL DALAAN (AHWPTC Co-Chair) and Ms Chadaporn TANAKASEMSUB [Miang] (AHWPTC Co-Chair).

## WELCOME ADDRESS BY THE CHAIR

(2) Dr Saleh, Chair of AHWP, welcomed and thanked all participants for attending the 17<sup>th</sup> AHWP Meeting. He extended his thanks and gratitude to the TFDA, Department of Health, Chinese Taipei for hosting this Meeting. He also thanked the members of the Organizing Committee and the AHWP Secretariat for all the arrangements of this Meeting.

## AGENDA ITEM 1: ADOPTION OF THE AGENDA

(3) The Agenda of the Meeting as in ANNEX (1) was adopted with applause.

## AGENDA ITEM 2: ROLL CALL

(4) Over 300 participants attended the 17<sup>th</sup> AHWP Meeting, with the list of participants as appended in ANNEX (2).

## AGENDA ITEM 3: CONFIRMATION OF THE 16<sup>th</sup> AHWP MEETING MINUTES

(5) The meeting confirmed the report of the 16<sup>th</sup> AHWP Meeting, held in Bali, Indonesia on 8-12 Nov 2011, as in ANNEX (3) without any amendments.

## AGENDA ITEM 4: DISCUSSION ON THE PROPOSED "AHWP STRATEGIC FRAMEWORK TOWARDS 2020 – THE FORESEEABLE HARMONIZATION HORIZON"

(6) Ms Lindsay TAO, Vice-Chair of AHWP, introduced the background and objective of the strategic framework. Ms TAO invited members to submit their comments via the AHWP



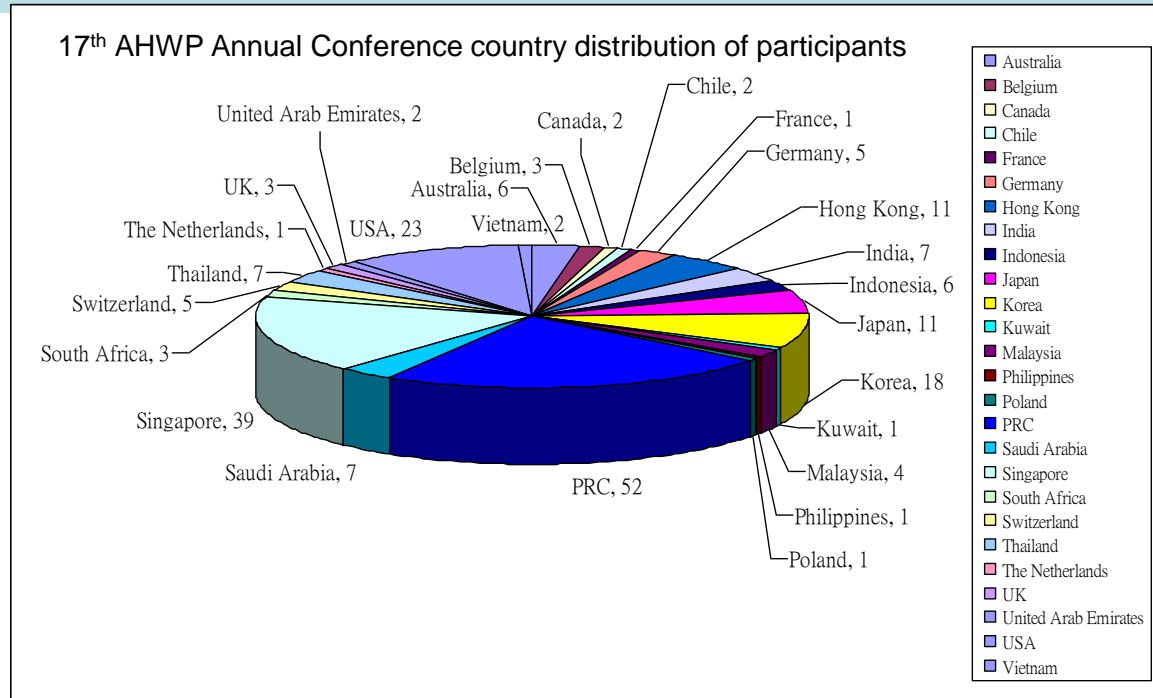
<http://www.ahwp.info/index.php?q=node/312>

## Outline of the 17<sup>th</sup> AHWP Meeting Minutes

- Adoption of the Agenda
- Roll Call (Participants)
- Confirmation of the 16<sup>th</sup> AHWP Meeting Minutes
- Discussion on the Proposed “AHWP Strategic Framework toward 2020 – The Foreseeable Harmonization Horizon”
- Introduction to the 1<sup>st</sup> AHWP-RAPS Joint Conference
- Country Update
- Report by AHWP TC
- Report by Secretariat
- Report of Financial Statement 2011/2012 and Budget for 2012/2013
- Resolution and Endorsement
- Confirmation of Host of the 18th AHWP Meeting
- Closing Remarks
- Acknowledgement

## Roll Call

**350 participants from 26 Countries** attended 17<sup>th</sup> AHWP Annual Conference held in Taiwan (2012)



Speakers	Foreigners	Local
25	212	113
Speakers	Regulators	Industry
25	38	287



Discussion on the Proposed “AHWP Strategic Framework toward 2020 – The Foreseeable Harmonization Horizon”

- The five key elements of the strategic framework where highlighted
  - **Element ONE:** AHWP Membership Expansion
  - **Element TWO:** Training and Capacity Building
  - **Element THREE:** Harmonization in Key Areas based on GHTF Principles and AHWP Guidance
  - **Element FOUR:** Working alongside with APEC and ASEAN to expand beyond regional blocks
  - **Element FIVE:** Enhance AHWP’s Global Presence

# Country Update

- Four representatives updated their countries regulation of medical devices, with presentations on updates of their general administrative framework, current regulations, revision of medical device regulations, future priority plans, e-registration system, etc.
  - Mr Gao Guobiao of **China**
  - Ms Yuwadee Patanawong of **Thailand**
  - Ms Ade Arinata of **Indonesia**
  - Ms Maria Cecilia Lopez of **Chile**



# Report by AHWP TC

- Key achievements and next work items for each WG/STG being highlighted
  - WG1
    - a) Completed and published the mapping of CSDT to STED on AHWP website
    - b) Introduced the software overview in Manila TC meeting and catered for training on software
  - WG1a
    - a) Actively participated and offered inputs in the preparation of GHTF guidance documents on IVD clinical evidence, with the finalized and completed guidance documents to be further proposed to AHWP for endorsement
    - b) Organized conferences on regulatory convergence for IVDs
  - WG2
    - a) Developed the common AE and FSCA forms for use across AHWP member economies
    - b) Posted the proposed documents on AHWP website for comments
  - WG3
    - a) Completed QMS survey and analysis
    - b) Endorsed the adoption of GHTF N17 and N18 at AHWP for further consideration of implementation
    - c) Joined ISO TC210 as a liaison member and provided comments for the proposed new version of ISO13485

# Report by AHWP TC (Cont.)

- Key achievements and next work items for each WG/STG being highlighted.
  - WG4
    - a) Completed the review of GHTF guidance documents on audit and proposed the guidelines for endorsement in AHWP
    - b) Developed new work item for the auditing of importers and distributors
  - WG5
    - a) Mapped the differences between old and new versions of ISO14155
    - b) Provided consolidated comments on new GHTF guidance documents on clinical evidence for IVDs
  - WG6
    - a) Collated and prioritized the training needs of TC workgroups, with some topics also covered in current AHWP meeting
    - b) Posted information and link of external training platforms on AHWP website
  - STG
    - a) Recruited new members and updated membership
    - b) Collaborated and connected with GMDN on the conduction of UDI training
    - c) Carried out pilot study on UDI implementation in China

# Report by Secretariat

- Two secretariat meetings were held in Feb 2012 and Sep 2012 in Singapore and Riyadh respectively
- Key issues discussed during secretariat meetings:
  - The initiation of the strategic framework of AHWP
  - Review of work completed
  - Report on recent collaborations and meetings with other international organizations (IMDRF, GHTF, APEC, ISO, RAPS, etc.)
  - Receipt of the progress report from TFDA on the 17<sup>th</sup> AHWP main meeting and the progress report from AHWP TC
  - Receipt of updates on AHWP Fund from the Secretariat Hong Kong Office
  - Recap on the administrative procedures of preparing official AHWP documents (4-step procedure)

## Report of Financial Statement 2011/2012 and Budget for 2012/2013

- The financial statement of 2011/2012, with a surplus of USD175,460.43 as of 30/09/2012
- The budget for 2012/2013 was presented with estimated income at around USD403,000 and expenditure of around USD280,000
- The financial statement of 2011/2012 and budget of 2012/2013 were agreed and confirmed with applause

# Resolution and Endorsement

## ● Five Documents were endorsed

- Amendment 2 to the Asian Harmonization Working Party (AHWP) & AHWP Technical Committee (AHWPTC) Terms of Reference (TOR)
- Amendment 1 to the Asian Harmonization Working Party House Rules
- Medical Devices Adverse Event (AE) Report Form
- Definition and Classification of Field Corrective Actions, Recalls and Non Safety related Field Corrective Actions
- Guidance for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers

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## Nov 3 AHWP Training Workshop at W Taipei





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## Nov 3 Welcome Dinner at W Taipei





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## Nov 4 APEC-AHC-AHWP Joint Workshop on Medical Device Combination Products at TICC



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## Nov 5 The 17th AHWP Annual Meeting at TICC





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**Nov 5  
Press Conference**





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## Nov 5 Gala Dinner



# The 17<sup>th</sup> Asian Harmonization Working Party (AHWP) Annual Conference

## Nov 6 Conference on Regulatory Convergence in Enabling Innovative & Emerging Technologies for IVD Medical Devices





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**Nov 6**

## **Networking Forum**

Visit to:

- The NTUH National Clinical Trial & Research Center
- The National Palace Museum



**Thank you for your attention!**



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Chinese Taipei Nov 5, 2012