

Report by AHWP Secretariat 2013-2014

19th AHWP Annual Meeting
18-21 Nov 2014, Seoul, Republic of Korea

Mr. Bryan SO
AHWP Secretariat



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Summary of Supports by AHWP Secretariat

- TC Leaders Meeting
- TC Meeting
- WG restructure
- WG papers
- TC Playbook
- WG membership
- WG projects

Support
to
AHWPTC

Support
to
AHWP

- Strategic framework
- New application of AHWP member economy
- Promotion of Global Appearance of AHWP

- Annual General Meeting(s)
- BOD Meeting(s)
- ASL membership
- Management of AHWP Reserve/Fund

Support
to AHWP
ASL

Secretariat

- Secretariat Meeting
- AHWP website
- SADS On-line System (password-based)
- OC and host of AHWP Annual meeting
- Election at the 19th AHWP Meeting

Support the Endorsement of AHWP Strategic Framework

- Supported the **call for comments** and **endorsement** of the **AHWP Strategic Framework (AHWP/OB/F001:2013)**
- Developed by AHWP office bearers
- Firstly discussed at Singapore Secretariat Meeting, 2012
- Further discussed at Saudi Secretariat Meeting, 2012, and Malaysia Secretariat Meeting, 2013
- Call for public comments
- Endorsed by members at the 18th AHWP Malaysia Annual Meeting, 2013

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

Home | Join Us | Historical Development | Meeting Calendar | Contact Us

Section:

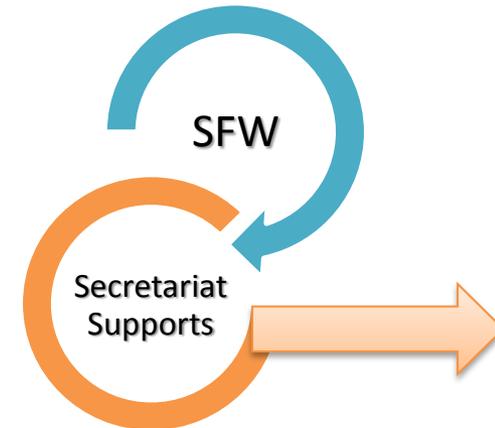
- » Chairman's Message
- » **About AHWP**
 - » Terms of Reference
 - » House Rules
 - » Organization Structure
 - » **Strategic Framework**
 - » Legal Entity (ASE)
 - » Liaison Members of AHWP
 - » Activities
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- » Member Economies

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Asian Harmonization Working Party Strategic Framework Towards 2020 - "The Foreseeable Harmonization Horizon"
Updated: Fri, 05/23/2014 - 10:35

**Asia Harmonization Working Party Strategic Framework Towards 2020
"The Foreseeable Harmonization Horizon"**
(Version SPR 04a)

Introduction
The Asian Harmonization Working Party (AHWP) was established in 1999 as a voluntary group of regulators and industry members whose goal is to promote regulatory harmonization on medical device regulations in Asia and other regions in accordance with GHTF guidance. With the joint efforts of regulators and industry members over the past 12 years, AHWP has built important momentum:



Support to the New Application for Joining AHWP Member Economies

- Received new application: Tanzania
- *Potential applicant: Bangladesh*
- Facilitated collection of required documents:
 - Official Letter by government authority
 - Nominated country representative(s) by Tan-FDA
- Invited representatives from Tanzania to join the 19th AHWP Annual Meeting, Seoul, 2014
- Towards endorsement at the Annual Meeting



Support to the AHWP Training & Capacity Building

Supported the organization of training programme for members:

- AHC-AHWP Joint Workshop, Chinese Taipei, 2012
- 1st AHWP-RAPS Joint Conference, Malaysia, 2013
- Working Group training opportunity, Malaysia, 2013
- AHC-AHWP Joint Workshop, Seoul, 2014
- Working Group training opportunity, Seoul, 2014
- GS1 lunch Training Workshop, Seoul, 2014



Element TWO – Training & Capacity Building

Support to the Harmonization in Key Areas based on GHTF Principles and AHWP Guidance

- Supported the **call for comments** and **endorsement** of AHWP **Guidance documents & Reference documents**, including endorsed Working Group guidance papers in the following areas:
 - Pre-market submission
 - Pre-market submission – IVDD
 - Post-market surveillance
 - Quality management system requirements
 - Quality system audit

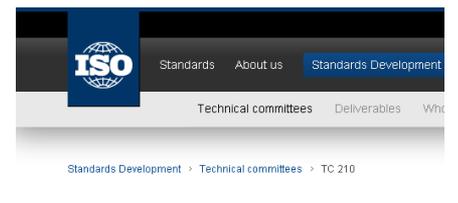


SFW

Element THREE - Harmonization in Key Areas

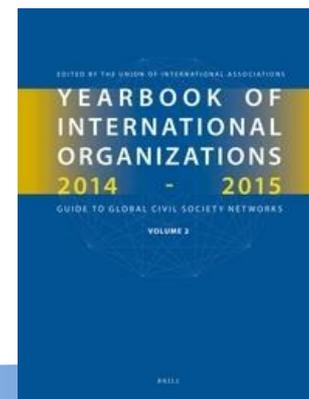
Support to the Enhancement of AHWP's Global Partnership

- AHWP Liaison member: **DITTA**, **GS1**
- TC Working Group collaborations with **ISO**:
 - ISO 13485/TC210 (*QMS*)
 - ISO 14155/TC194 (*Clinical investigation*)
- Leadership's report at **WHO** meetings
- Affiliate Organization to **IMDRF**
- Listed in Year Book by **Union of International Associations**
- Joint conference with **RAPS**
- Joint workshop with **AHC**
- Joint workshop programme with **DITTA**



Organizations in liaison:

[AHWP](#), [DITTA](#), [EDMA](#), [EUCOMED](#), [EUROM](#), [WHO](#)



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Support the Organization of AHWP TC Leaders Meeting

- Supported the organization of **AHWPTC leaders Meeting**, participated by AHWP TC leaders, WG leaders, TC Advisors, AHWP leaders and Secretariat



9 – 10 May 2014, Singapore

Support to the Streamlining of AHWP Working Group Structure

- The **new WG structure** was discussed and agreed during the **AHWP TC Leaders Meeting** in May 2014, Singapore

- Updated the website & membership list** based on the new work group structure

- Added remarks at website** for previously endorsed WG documents to avoid confusion.

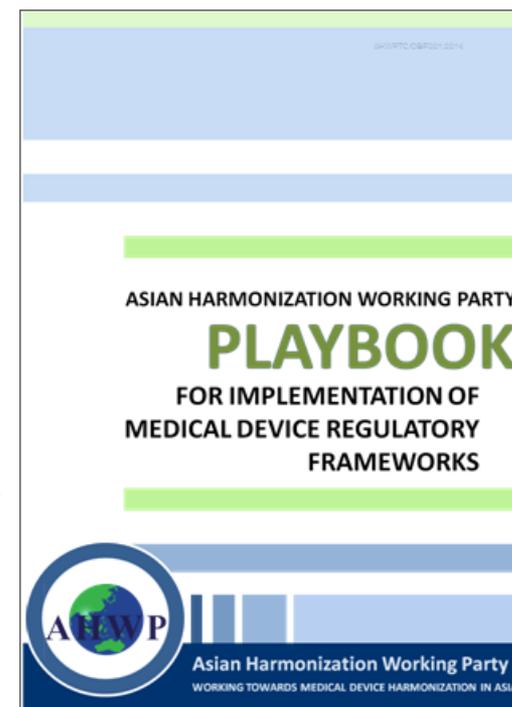
The screenshot shows the AHWP website with a navigation menu at the top: Home | Join Us | Historical Development | Meeting Calendar | Contact Us. A sidebar on the left lists sections: Chairman's Message, About AHWP, Member Economies, Technical Committee (with sub-items: Terms of Reference, Work Group, Background & Objectives, TC Minutes), Events Announcements, and AHWP Newsletter. The main content area displays 'Work Group 1 (WG1) - Pre-market: General MD' with an update date and a list of other work groups: WG2 (Pre-market: IVDD), WG3 (Pre-market: Software as a Medical Device), WG4 (Post-Market), WG5 (Clinical Performance & Safety), WG6 (Quality Management System: Audit & Assessment), WG7 (Quality Management System: Operation & Implementation), WG8 (Standards), WG9 (Training), and STG (U&N) - Special Task Group on UDI & Nomenclature.

This screenshot shows a table of documents. A sidebar on the left lists document types: Documents, Minutes, Reports, Final Documents, Guidance Documents, and Reference Documents. The table has columns for document ID, description, date, and a download link. An orange arrow points from the 'Documents' sidebar to the table. Another orange arrow points to a note in the 'AHWP/WG3/F001:2013' row: '(now restructured to WG7)'. A third orange arrow points from the 'Work Group' section in the top screenshot to this row.

| | | | | |
|-------------|---|--|------------|---|
| » Documents | AHWP/WG3/F001:2013 (now restructured to WG7) | Quality management system – Medical devices – Nonconformity Grading System for Regulatory Purposes and Information Ex- | 6 Dec 2013 | Download file:Final_AHWP_WG3_F001_2013.pdf |
|-------------|---|--|------------|---|

Support to the Preparation of TC Playbook

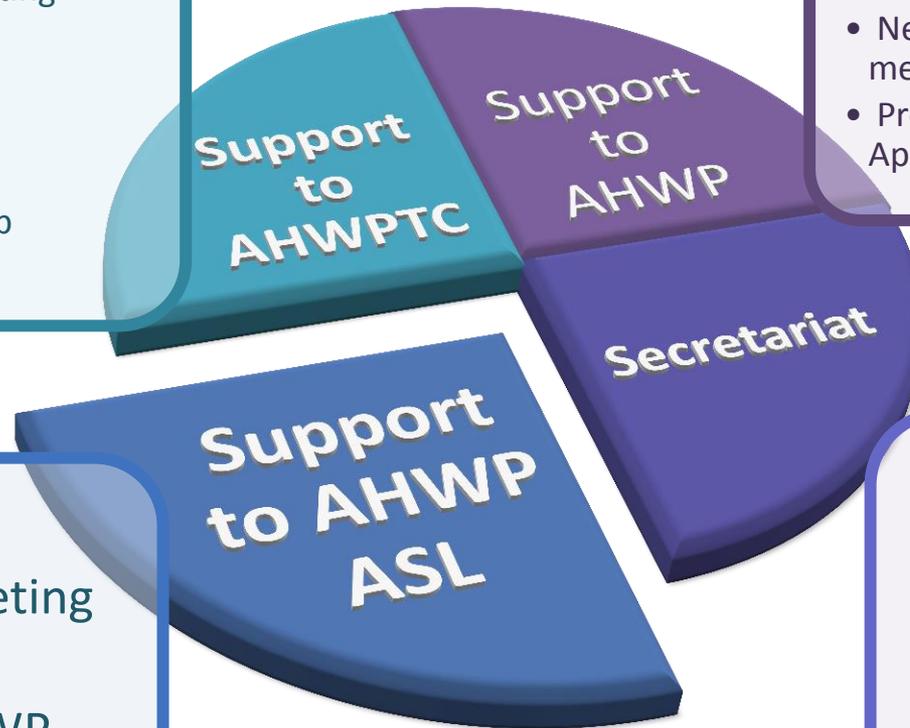
- Supported the **call for comments** and **publication** of **TC Playbook – “Playbook for Implementation of a Medical Device Regulatory Framework”**
- Prepared by AHWP TC office bearers
- Co-prepare/advised by WG1 leaders and TC Advisors
- Firstly discussed at TC Leaders Meeting, 2013
- Further discussed at Malaysia TC Meeting, 2013
- Call for public comments
- To be announced at Seoul TC Meeting, 2014



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Support to AHWP ASL Operations and Meetings

Support to the operation of **AHWP Legal Entity**

– **AHWP Administration Services Limited (ASL)**

- Organization of Board of Directors (**BOD**) **Meetings /Tele-con** for reviewing of AHWP ASL financial position, special resolutions, etc.
- Organization of Annual General Meeting (**AGM**) of AHWP ASL
- Collection & handling of company **sponsorships for AHWP meetings**
- Solicitation & handling of **sponsorships for AHWP official website**
- Work with **professionals** (accountant, auditor, company secretary, legal advisor) to support AHWP ASL daily operations
- Supporting the **review and signatory of legal documents** between AHWP and external organizations
- Processing **new AHWP ASL membership** applications

Management of AHWP Reserve/Fund in AHWP ASL

- The **surplus from AHWP website and AHWP Meetings** were pooled into the AHWP Reserve/Fund under the AHWP ASL Account
- AHWP Reserve/Fund has **facilitated** the round-trip air tickets and hotel accommodations for the **invited speakers** and the **sponsored regulatory representatives** of AHWP member economies **for their attendance to the AHWP Meetings**
- Supported by the professional services providers, including accountants, auditors, company secretary and legal advisor, **ASL financial and statutory documents were prepared** based on the companies ordinance in HKSAR
- **In-progress of application for tax-exemption** under Section 88 of Inland Revenue Ordinance in Hong Kong

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Organization of Secretariat Meetings

- Supported the organization of **AHWP Secretariat Meeting**, participated by AHWP leaders, TC leaders, Secretariat and representatives from 19th AHWP annual meeting local host

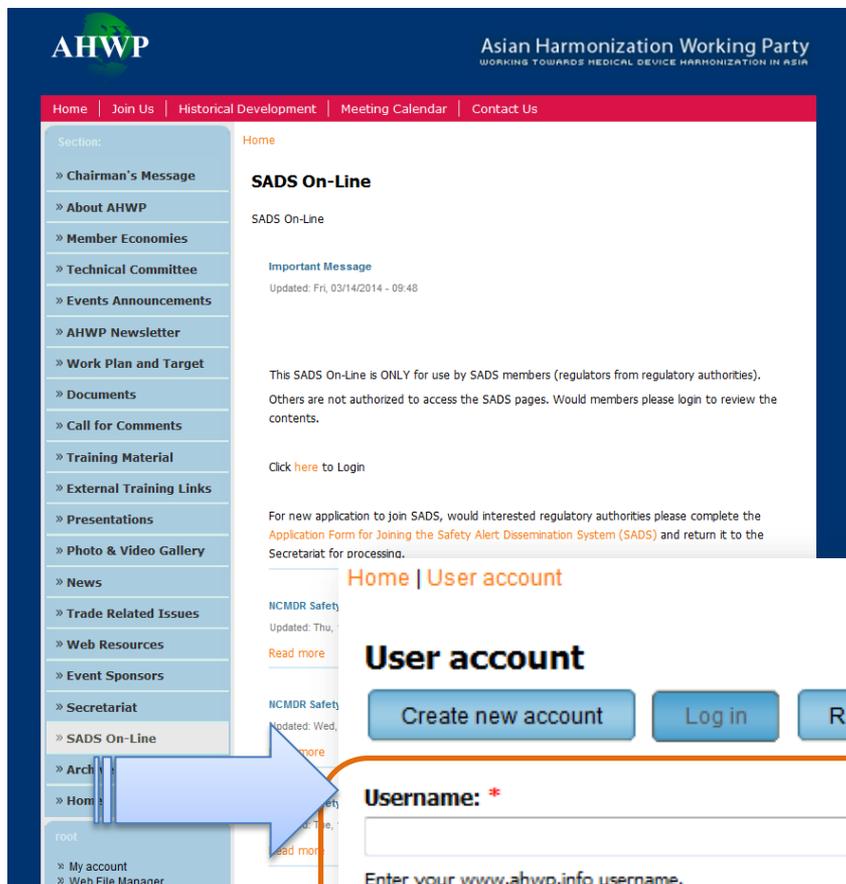


10 May 2014, Singapore

Highlights of Secretariat Meeting in May 2014

- Discussed & confirmed the **updates of AHWP website sponsorship package**
- Reported the **newly launched AHWP SADS On-Line System**
- Reported the **financial summary for the 18th AHWP Annual Meeting and Joint Conference with RAPS on 2-5 Dec 2013**
- Reported the work group documents for endorsement
- Reviewed the updates of AHWP Administration Services Limited (ASL) on **AHWP financial status**
- Received **updates from the Korean host** of the coming 19th annual meeting
- Provided **steering and advice to the organizing committee** of the coming Seoul annual meeting and workshop
- Reported the strategic planning on the **Election** in Nov 2014

AHWP SADS On-Line Weekly Update



- Password-based on-line system **launched** since May 2014
- Collaborated by WG4 (former WG2) and Secretariat
- Replaced the previous email-based update system
- **Subscribed regulators** of AHWP member economies can view the weekly updates by logging in with **password**

Home | **User account**

User account

Create new account Log in Request new password

Username: *

Enter your www.ahwp.info username.

Password: *

Enter the password that accompanies your username.

Log in

Support to OC and Host of AHWP & TC Meetings

- **Formation and participation of Organizing Committee (OC)** of the 19th AHWP annual meeting and 18th AHWP TC meeting
- AHWP Secretariat has **coordinated and supported** the **OC, local host** (MFDS, KMDIA, AIM-Korea) and **collaborating organization** (AHC) to facilitate the successful organization of **AHWP Event 2014**, including the AHC-AHWP Joint Workshop, 18th AHWPTC Meeting and the 19th AHWP Main Meeting in Seoul, 2014, including
 - Website announcements
 - Review of event budget
 - Speaker invitation & delegates supports
 - Development of event programme & collecting presentations materials
 - Development of event sponsorship package
 - Recruitment of participants
 - Venue arrangements and other logistics

Support to the Election at the 19th AHWP Annual Meeting

- According to the Terms of Reference of AHWP & AHWPTC:
 - The term of office of all AHWP office bearers will be **around 3 years** commencing from the date of appointment until next election
 - This year is the **last year** of the 3-year term
- Support facilitating the **nomination** and **election procedures** of all AHWP, TC and WG office bearers (2015-2017):
 - Making **website/email announcement on nomination**
 - Collecting **nomination forms, CV** and **supporting materials** from nominees
 - Preparing **on-site procedures** for election

Supports to AHWP Official Website (www.ahwp.info)

- Supported by **company sponsors**
- Web sponsorship as **income for AHWP**
- Official platform for **information exchange** (e.g. announcements, event news, documents, country updates, etc.)
- **SADS On-line Weekly Updates**
- **Membership Application / Join Us:**
- Countries to join as:
 - Member Economy
- Individuals to join as:
 - Working Group (WG) member
 - ASL (legal entity) member



Contact us: secretariat@ahwp.info

Acknowledgement of AHWP Website Sponsors

Current AHWP website sponsors:

GE Healthcare



SIEMENS

Acknowledgement – AHWP Secretariat Team (2012-2014)

Secretary General:

- Mr. Ali Al Dalaan MBA-IT, SFDA, KSA

Executive Deputy Secretary General:

- Mr. Essam Al Mohandis, SFDA, KSA
- Mr. Bryan SO, HKPC, Hong Kong
- Mr. Jack WONG, Terumo BCT , Singapore

Deputy Secretary General:

- Mr. Abdullah Al Dobaib, SFDA, KSA
- Mr. Abdullah Al Rasheed, SFDA, KSA
- Mr. Sultan Alromayan, SFDA, KSA
- Mr. Fahad Almoammar, Saudi Medical Devices Industry, KSA

Members of Secretariat:

- Mr. Abdullah Alguraibi, SFDA, KSA
- Mr. Abdulah Thabet, SFDA, KSA
- Mr. Nawaf Albarakah, SFDA, KSA
- Mr. Saad Abduljani, SFDA, KSA
- Dr. Khaled Al Haidari, Arabian Medical Marketing Company Ltd, KSA
- Mr. Suhail Algumaizi, Al-Jeel Medical & Trading Co. Ltd, KSA
- Mr. Hattan Gabbani, Covidien AG, KSA
- Mr. Faisal Matbuli, GE, KSA

AHWP Secretariat:

- Ms. Carol LIU, HKPC, Hong Kong
- Ms. Miranda KWOK, HKPC, Hong Kong
- Ms. Emily FUNG, HKPC, Hong Kong
- Ms. Vivian CHOW, HKPC, Hong Kong

» Event Sponsors

» Secretariat

» SADS On-Line

Thank You

AHWP Secretariat Contact:
Mr. Bryan SO / Ms. Carol LIU
[secretariat @ahwp.info](mailto:secretariat@ahwp.info)