



Updates on Medical Device Regulatory Affairs

8 Aug 2014

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About the speaker....



Ir Bryan SO

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With **more than 12 years** of experience in **Advanced Manufacturing Technologies**, **Product Development Technologies**, **Medical Device Development** and the related **Regulatory Affairs** and **Quality Management System**. Provides consultancy services to the medical device industry in **GMP**, **ISO13485** quality system & **ISO14971 risk management system**, **Pre-market notification** (e.g. **USFDA 510(k)**), etc. Supervises the Rapid Prototyping Technology Centre in HKPC to provide **consultancy services** and supports to the industry on new technology development including **CAD/CAM systems**, micro-fabrication technology, **Opto-mechatronics**, micro-laser welding, **3D Printing** & rapid prototyping, as well as industrial design for product development. Investigator of several **government funded development projects** including SME Development Fund project on ISO4971 Risk Management for Medical Devices, **Medical Devices Good Distribution Practice** (MDGDP), PSDAS project on **Biomedical Engineering** and ITF Development Project on **Dental CAD/CAM** system, **Artificial Finger Joint**, Liquid Silicone Rubber (LSR), Device on **Dermoscopy** for Melanoma, etc. Currently the Committee of the Biomedical Division of The Hong Kong Institution of Engineers (**HKIE-Biomedical Division**), the Executive Committee of the IEEE Engineering in Medical and Biological Society Hong Kong- Macau Joint Chapter (**IEEE EMBS**), Deputy Executive Secretary General of the Asian Harmonization Working Party (**AHWP**) on the harmonization of medical device regulatory and currently serving in various panels of the Hong Kong Medical and Healthcare Device Industries Association (**HKMHDIA**).

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Asian Harmonization Working Party

Working Towards Medical Device Harmonization in Asia



23 Member Economies (as of Oct 2014)

Asian Harmonization Working Party

(official website: www.ahwp.info)

Established as a **non-profit** organization formed in 1996-97.

Its goals are to study and recommend ways to harmonize medical device regulations in the Asian and other regions for **establishing harmonized requirements, procedures and standards.**

The Working Party is a group of **experts** from the medical device **regulatory authorities** and the medical device **industry.**

AHWP Organization Structure



*Last updated :
Dec 2013*

The 18th AHWP Annual Meeting was successfully held on 2-5 Dec 2013 at Sunway Hotel, Resort & Spa, Kuala Lumpur, Malaysia.



Local Host:
Medical Device Authority, MOH, Malaysia

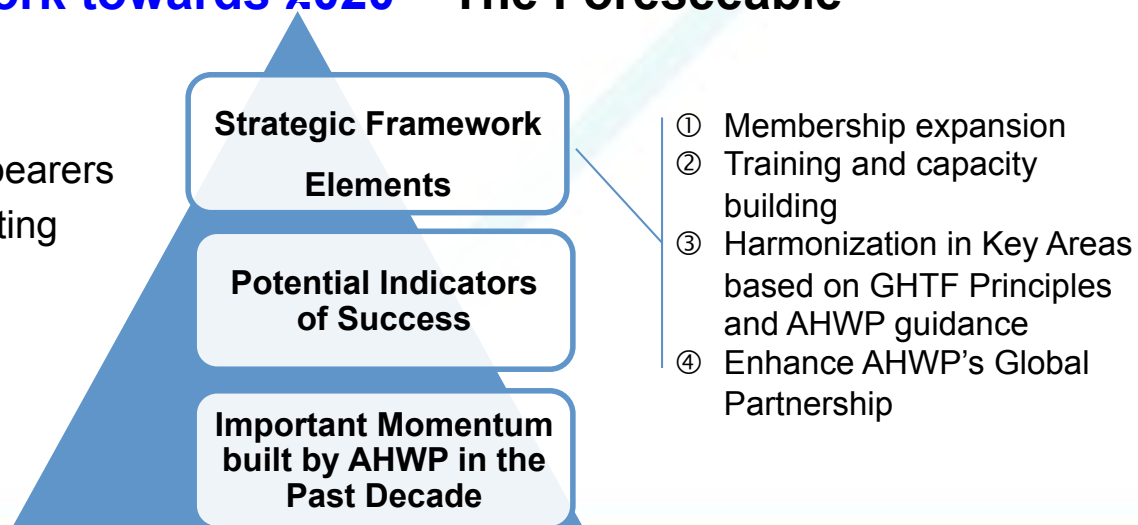
Report on 18th AHWP Annual Meeting (2013)



- **Keynote speech by Dr Sherry Keramidas, ED, Regulatory Affairs Professional Society (RAPS)**
 - Hqt in USA, providing programmes including education and training on medical device regulatory affairs
 - Regulatory Affairs Certification (RAC): post-academic professional credential

- **AHWP Strategic Framework towards 2020 – The Foreseeable Harmonization Horizon**

- AHWP high-level document
- Developed by AHWP officer bearers
- Endorsed at 18th Annual Meeting by AHWP members



Report on 18th AHWP Annual Meeting (2013)



● Highlighted Updates by AHWP Technical Committee (TC)

- AHWP TC Advisory Panel
- **Playbook** for regulatory controls & implementation
- Set up **new Working Group** on **Standards**

No.	Title / Given Name / Surname	Company
1	Dr Philippe Auclair	Abbott Laboratories
2	Mr Michael Gropp	(independent)
3	Dr Eamonn Hoxey	J&J
4	Dr Petra Kaars-Wiele	Abbott
5	Mr Greg Leblanc	Cook Canada
6	Mr Hansel Leighton	(independent)
7	Dr Peter Linders	Philips Healthcare
8	Mr Benny Ons	BD Europe
9	Mr Grant Ramley	Aseptic Inc
10	Mr Scott Sardeson	3M Health Care

Proposal of Playbook

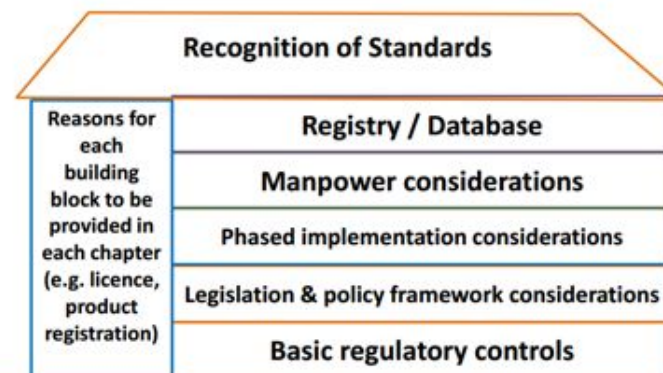
AHWP lays out basic requirements for a harmonized regulatory framework, but many details of the implementation & framework are left to individual countries.

There is need for:

- Predictable regulatory environment for medical devices across Asia
- Unified standards for product registration, distribution and post-market surveillance



Playbook Elements Providing the Framework



Introduction & Rationale for Harmonization

Report on 18th AHWP Annual Meeting (2013)



● Highlighted Updates by TC Working Groups (WGs)

- Gap analysis for pre-market registration for ASEAN
- MD [grouping guidance doc](#) (single registration for ASEAN member states)
- [Medical Software](#) – White paper & Guidance doc
- [Combination Product](#) – Guidance doc
- IVD pre-market registration
- [Affordable and Accessible IVD](#) medical device
- AE Reporting form (available for AHWP MEs)
- [AE Reporting timeline](#)
- SADS on-line system
- Guidance doc on [QMS](#) (application of ISO 13485) for [Importers & distributors](#) (I&D)
- Guidance doc on auditing for I&D
- [Training](#) on auditing guidance doc: developing training module & pilot training
- Training within WGs



Report on 18th AHWP Annual Meeting (2013)



● Highlighted Updates by TC WGs (Cont.)

- [Survey](#) on clinical investigation requirements in AHWP Member Economies
- Collaborating with ISO & Developing guidance doc for clinical trial requirements
- Training on [clinical evaluation plan](#), e.g. monitoring, site audits, data evaluation
- [Priority training areas](#) for WGs
- Developing training modules for AHWP MEs
- Document on [measuring training outcome](#)
- Participating nomenclature work at GMDN, IMDRF, WHO & providing AHWP comments
- GMDN agencies (e.g. GS1, EU DG SANCO) outreach
- [GMDN pilot program](#) in China started & feasibility analysis



Report on 18th AHWP Annual Meeting (2013)



- **Regulatory updates by AHWP Member Economies**

- Malaysia
- Korea
- Saudi Arabia
- Chinese Taipei

- **ME Representatives meeting with TC Leaders and TC Advisors**

(close meeting)

- Different levels of harmonization at AHWP MEs



Report on 18th AHWP Annual Meeting (2013)



● Highlighted Updates by AHWP Secretariat

- Supports to AHWP, TC, WG leaderships
- Updates of Secretariat meetings
- Amendments to AHWP Terms of Reference and House Rules to support enhancement of governance
- AHWP financial status
- Updating on [AHWP website sponsors](#)



● AHWP Liaison Members

- [Liaison membership endorsed](#) at this meeting
- Confirmation of 2 AHWP liaison members: DITTA & GS1



● Endorsed Resolutions

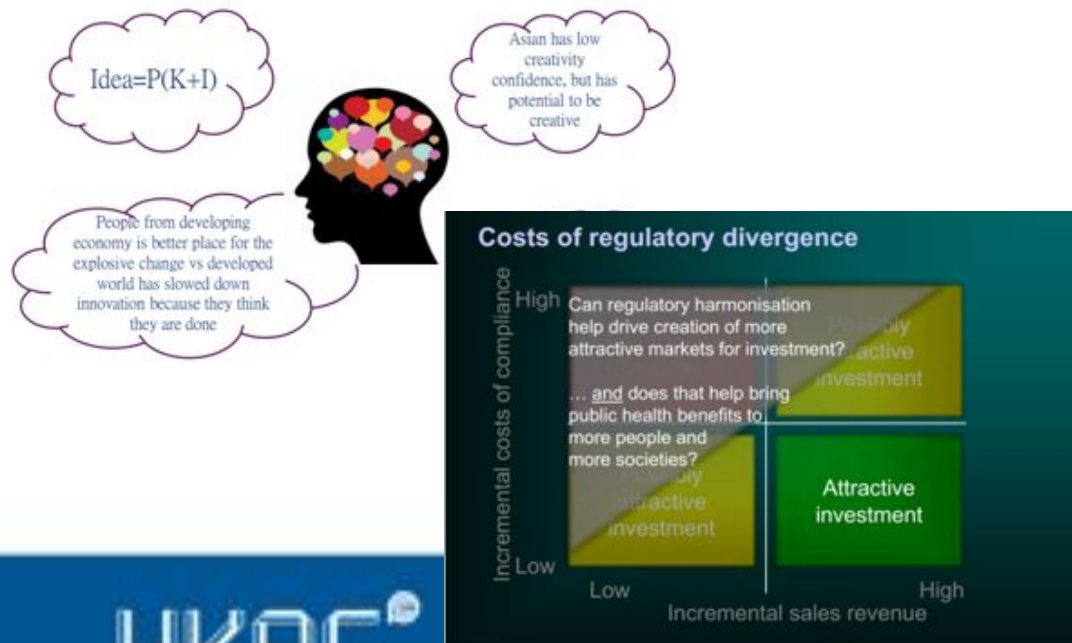
- Strategic Framework
- Guidance documents by WGs
- Amendment to TOR and House Rules



Report on 1st AHWP-RAPS Joint Conference

- 1.5 days conference & exhibition
- 2 opening speeches, 2 plenary presentations, 5 key themes with 12 expert speakers

“Innovation & Global Regulatory Landscape”
by Fredrik Haren



- 327 delegates
- 32 Countries from Asia, Middle East, Africa, USA & Europe regions



Report on AHWP TC Leaders Meeting (9-10 May 2014, Singapore)



- **Work plan & progress updates on Working Groups**
- **Highlighted proposals:**
 - Amendment to House Rules on renewal, nomination, voting of TC advisors
 - Amendment to TOR/House Rules on **adding 1 regulator Co-chair for each WG**, therefore to set up WG leadership as: WG Chair (regulator), Co-chair (regulator) & Co-chair (industry)
 - **Restructure of Working Groups** (towards endorsement at next TC meeting)

Group photo:
AHWP Leaders,
TC Leaders,
TC Advisors
and Secretariat



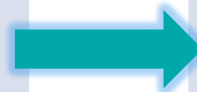
Report on AHWP TC Leaders Meeting (Cont.) (9-10 May 2014, Singapore)



Restructure of Working Groups (towards endorsement at next TC meeting)

Current Structure:

WG1 – Premarket submission and CSDT
WG1a – IVDD
WG2 – Post-Market Surveillance and
Vigilance
WG3 – Quality Management System
WG4 – Quality System Audit
WG5 – Clinical Safety / Performance
WG6 – Capacity Building and Regulatory
Training
WG7 – Standards (new)
STG – Medical Device Nomenclature



Proposed Structure:

WG1 – Premarket, including 3 sub-groups:

- **WG1a – General MD**
- **WG1b – IVDD**
- **WG1c – Medical Software**

WG2 – Post Market
WG3 – Clinical Performance and Safety
WG4 – Quality Management System,
including 2 subgroups:

- **WG4a – Implementation and Operation**
- **WG4b – Audit, Assessment, and
enforcement**

WG5 – Standards
WG6 – Training
STG – UDI/GMDN

(WG names to be further finalized)

Upcoming AHWP Events



AHWP 19th Annual Meeting



Local host: MFDS (former KFDA)



18-21 November 2014
Sheraton Grand Walkerhill Hotel
Seoul, Republic of Korea

AHWP 19th Annual Meeting



18-19 Nov 2014 APEC- AHC-AHWP Joint Workshop

20 Nov 2014 18th AHWP TC Meeting

21 Nov 2014 19th AHWP Meeting

WHAT IS IT ABOUT?

Joint Workshop



- Pre-market submission steps & requirements, industrial highlights
- Global & AHWP ME sharing
- SAP, Medical Software, Refurbishment, etc
- Use of guidance documents

AHWP TC Meeting



- TC Playbook Updates
- WG Progress Updates / Trends
- Election

AHWP Meeting



- IMDRF Updates
- AHWP Country Regulatory Updates
- Resolutions
- Election

Election at 19th Annual Meeting



Dr. Saleh S. Al-Tayyar
Chair of AHWP, 2012-2014

**Current AHWP Chairmanship:
Kingdom of Saudi Arabia (KSA)**

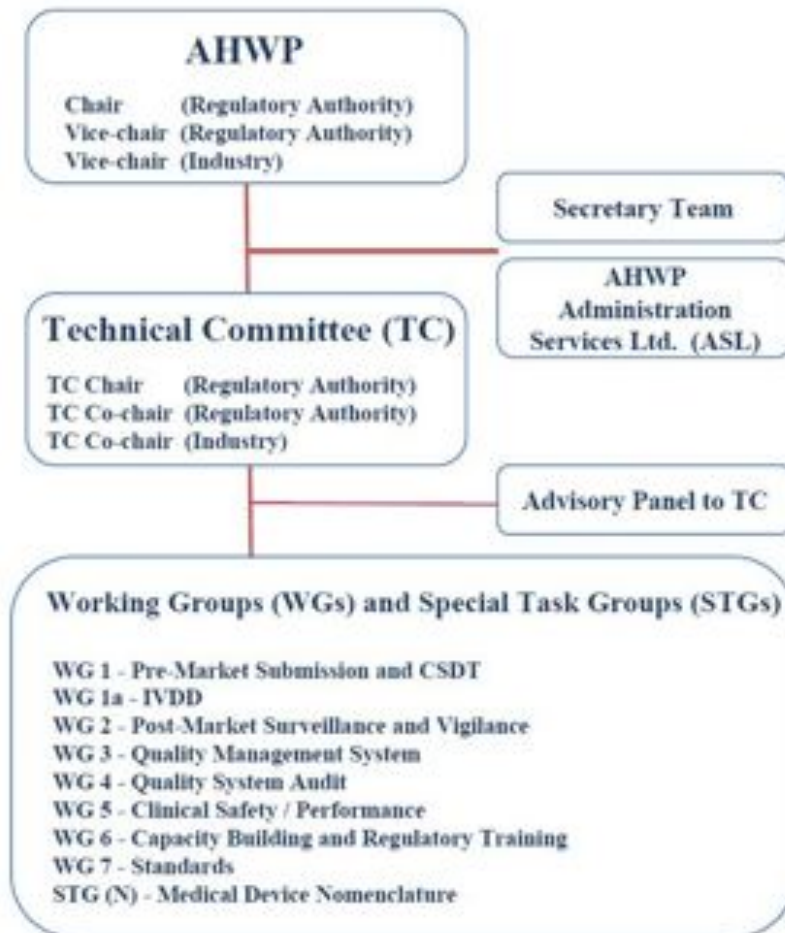
According to the Terms of Reference and House Rules of AHWP:

- 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
- Nomination of office bearers (on-going)
- Election at 19th Annual Meeting, Nov 2014

Election in 19th Annual Meeting



AHWP Organization Structure



Office Bearers to be elected at 19th AHWP Annual Meeting:

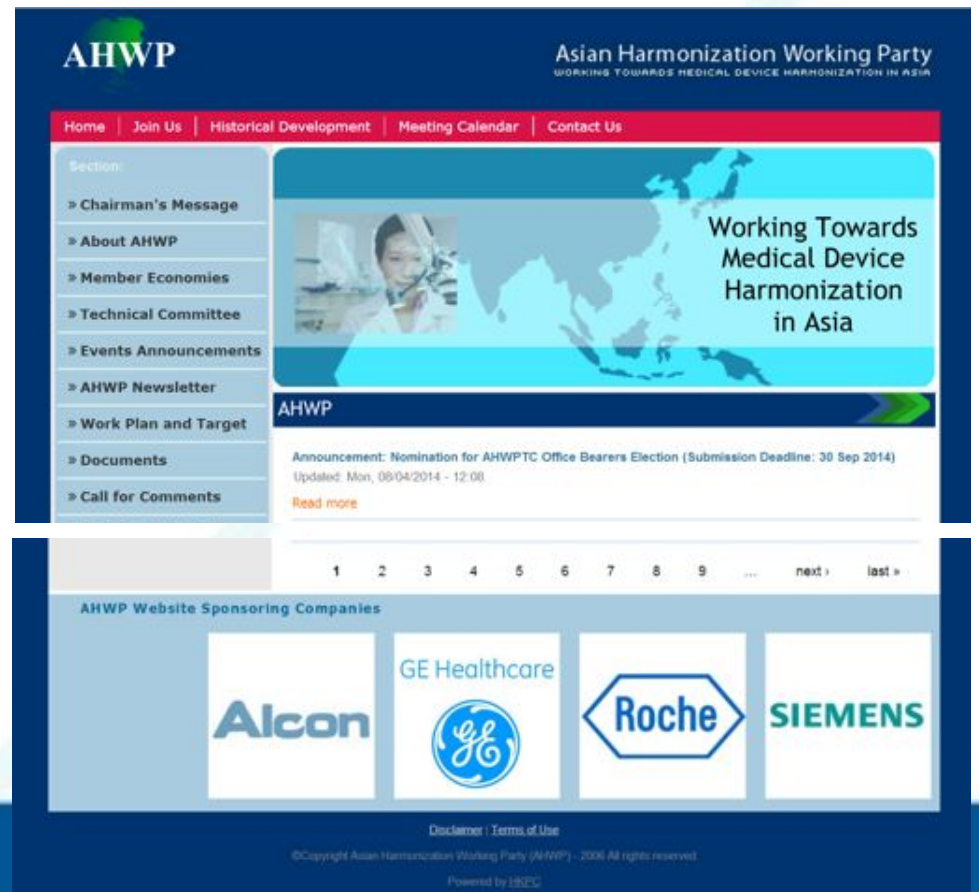
- ◆ AHWP Chair (regulator),
Vice-chair (regulator), Vice-chair (industry)
- ◆ AHWPTC Chair (regulator),
Co-chair (regulator), Co-chair (industry)
- ◆ WGs Chair (regulator),
Co-chair (regulator)*, Co-chair (industry)
- ◆ Secretariat General (regulator)



- Mark your calendar and stay turned on our updates at www.ahwp.info

Sponsor vacancies for Website & Meeting
Grasp this golden opportunity

AHWP Secretariat Contact:
 Mr Bryan SO / Ms Carol LIU
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Q&A

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Other Capacities 其他公職:-

- Guest Lecturer at HKPolyU, CityU, CUHK and VTC on Medical & Biomedical Engineering
香港理工大學, 香港城市大學, 香港中文大學及職業訓練局生物醫學工程學科客席講師
- Executive Deputy Secretary General, Asian Harmonization Working Party (AHWP)
亞洲醫療器械法規協調組織 執行副秘書長
- Committee, Biomedical Division, The Hong Kong Institution of Engineers (HKIE)
香港工程師學會-生物醫學分部 委員
- Executive Committee, Engineering in Medical & Biology Society HK Macau Joint Chapter,
Institute of Electrical & Electronics Engineers (IEEE-EMBS)
電機及電子工程師學會-生物醫學工程學會-香港及澳門分會 委員
- Quality and Regulatory Affairs Panel, Membership Affairs Panel, External Relationships Panel,
Hong Kong Medical and Healthcare Device Industries Association (HKMHDIA)
香港醫療及保健器材行業協會 品質及法規事務部委員, 會員事務部委員, 對外關係部委員