Updates on Medical Device Regulatory Affairs

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Ir Bryan SO
Senior Consultant, Biomedical Engineering Unit, HKPC
Executive Deputy Secretary General, AHWP
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).
Contents

• Background of AHWP
• Report on 18th AHWP Annual Meeting and 1st AHWP-RAPS Joint Conference
• Report on AHWP Technical Committee (TC) Leaders Meeting
• Upcoming Meetings
• Election in the 19th AHWP Annual Meeting
Asian Harmonization Working Party
Working Towards Medical Device Harmonization in Asia

23 Member Economies (as of Oct 2014)
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.
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

- 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

Strategic Framework Elements

Potential Indicators of Success

Important Momentum built by AHWP in the Past Decade

1. Membership expansion
2. Training and capacity building
3. Harmonization in Key Areas based on GHTF Principles and AHWP guidance
4. Enhance AHWP’s Global Partnership

- Highlighted Updates by AHWP Technical Committee (TC)
  - AHWP TC Advisory Panel
  - Playbook for regulatory controls & implementation
  - Set up new Working Group on Standards

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

**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

**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

- 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 18\textsuperscript{th} 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

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

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

<table>
<thead>
<tr>
<th>Current Structure:</th>
<th>Proposed Structure:</th>
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<tbody>
<tr>
<td>WG1 – Premarket submission and CSDT</td>
<td>WG1 – Premarket, including 3 sub-groups:</td>
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<tr>
<td>WG1a – IVDD</td>
<td>• WG1a – General MD</td>
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<tr>
<td>WG2 – Post-Market Surveillance and</td>
<td>• WG1b – IVDD</td>
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<td>Vigilance</td>
<td>• WG1c – Medical Software</td>
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<td>WG3 – Quality Management System</td>
<td>WG2 – Post Market</td>
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<td>WG4 – Quality System Audit</td>
<td>WG3 – Clinical Performance and Safety</td>
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<td>WG5 – Clinical Safety / Performance</td>
<td>WG4 – Quality Management System,</td>
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<td>WG6 – Capacity Building and Regulatory Training</td>
<td>including 2 subgroups:</td>
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<td>WG7 – Standards (new)</td>
<td>• WG4a – Implementation and Operation</td>
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<td>STG – Medical Device Nomenclature</td>
<td>• WG4b – Audit, Assessment, and enforcement</td>
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(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

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

WG's training
Election at 19th Annual Meeting

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

Dr. Saleh S. Al-Tayyar
Chair of AHWP, 2012-2014
Election in 19th Annual Meeting

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](http://www.ahwp.info)

Sponsor vacancies for Website & Meeting
Grasp this golden opportunity

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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-生物醫學分會 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