Highlights of AHWP TC

19th AHWP TC Meeting

5 Nov 2015

By Mr. Ali Aldalaan , AHWP-TC Chair

Dr. Jeong Rim Lee, AHWP TC Co-Chair

Bangkok, Thailand 2-6 Nov 2015

AHWP TC Leaders Meeting

Nov 2015, Bangkok

Contents

- Team Structure
- Capacity Building, Guidelines
- Summary & Conclusion of TC Leaders Meeting
- Proposed Work Items

Asian Harmonization Working Party (AHWP)

24 Member Economies

in Asia, Africa, Middle-East, Latin America

AHWP Organization Structure

AHWP
Chair (Hee-Kyo Jeong, MFDS)
Vice-chair (Zamane B.A. Rahman, MOH)
Vice-chair (Quan Tran, GE)

- Secretariat Team
- Administration Services Ltd. (ASL)
- Advisory Panel to TC

Technical Committee (TC)
TC Chair (Ali M. Al-Daalan, SFDA)
TC Co-chair (Jeong-Rim Lee, MFDS)
TC Co-chair (Alfred Kwek, Samsung)

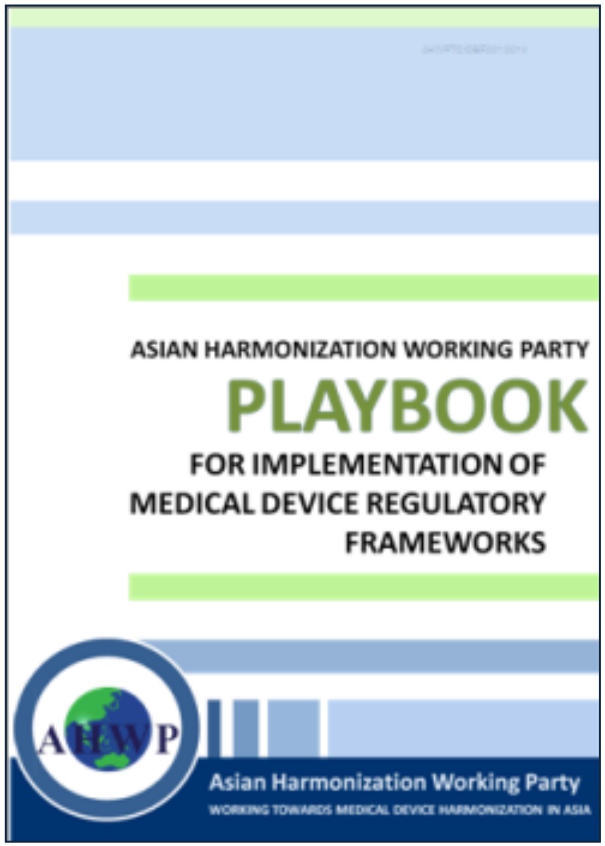
Working Groups (WGs) & Special Task Group (STG)

WG 1 Pre-market: General MD	**WG 2** Pre-market: IVDD	**WG 3** Pre-market: Software as a Medical Device	**WG 4** Post-market	**WG 5** Clinical Performance & Safety
WG 6 Quality Management System: Audit & Assessment	**WG 7** Quality Management System: Operation & Implementation	**WG 8** Standards	**WG 9** Training	**STG** UDI & Nomenclature

TC Teams

TC Office Bearers	Positions
Chair	Mr Ali M Al-Dalaan
Co-Chair	Dr Jeong-Rim Lee
Co-Chair	Mr Aflred Kwek
Secretary	Mr Jack Wong
Work Groups	**Positions**
WG1: Pre-market	Chair - Mr. Essam Mohammed Al Mohandis Co-Chair – Ms Ming Hao Tan
WG2: Pre-market - IVDD	Chair - Mr. Wen-Wei Tsai Co-Chair – Mr. Albert Poon
WG3: Pre-market - Software as a Medical Device	Chair - Dr. Rama Sethuraman Co-Chair - Mr Tony Yip
WG4: Post-market	Chair - Ms. Jennifer Mak Co-Chair – Ms Kitty Mao
WG5: Clinical Performance & Safety	Chair - Ms. Yuwadee Patanawong Co-Chair - Ms. Sumati Randeo
WG6: Quality Management Systems: Audit & Assessment	Chair - Mr. Abdullah Al Rasheed Co-Chair - Ms. Shirley Sum
WG7: Quality Management Systems: Operation & Implementation	Chair - Ms. Aidahwaty M.Olaybal Co-Chair - Mr. Ee Bin Liew
WG8: Standards	Chair - Ms. Maria Cecilia Matienzo Co-Chair – Mr Tony Low
STC: UDI & Nomenclature	Chair - Mr. YANG Lian Chun Co-Chair – Ms Carol Yan

AHWP Training & Capacity Building



- Regulatory Controls
- Legislation and Policy Framework
- Phased Implementation of Regulatory Framework

AHWP Member Economy

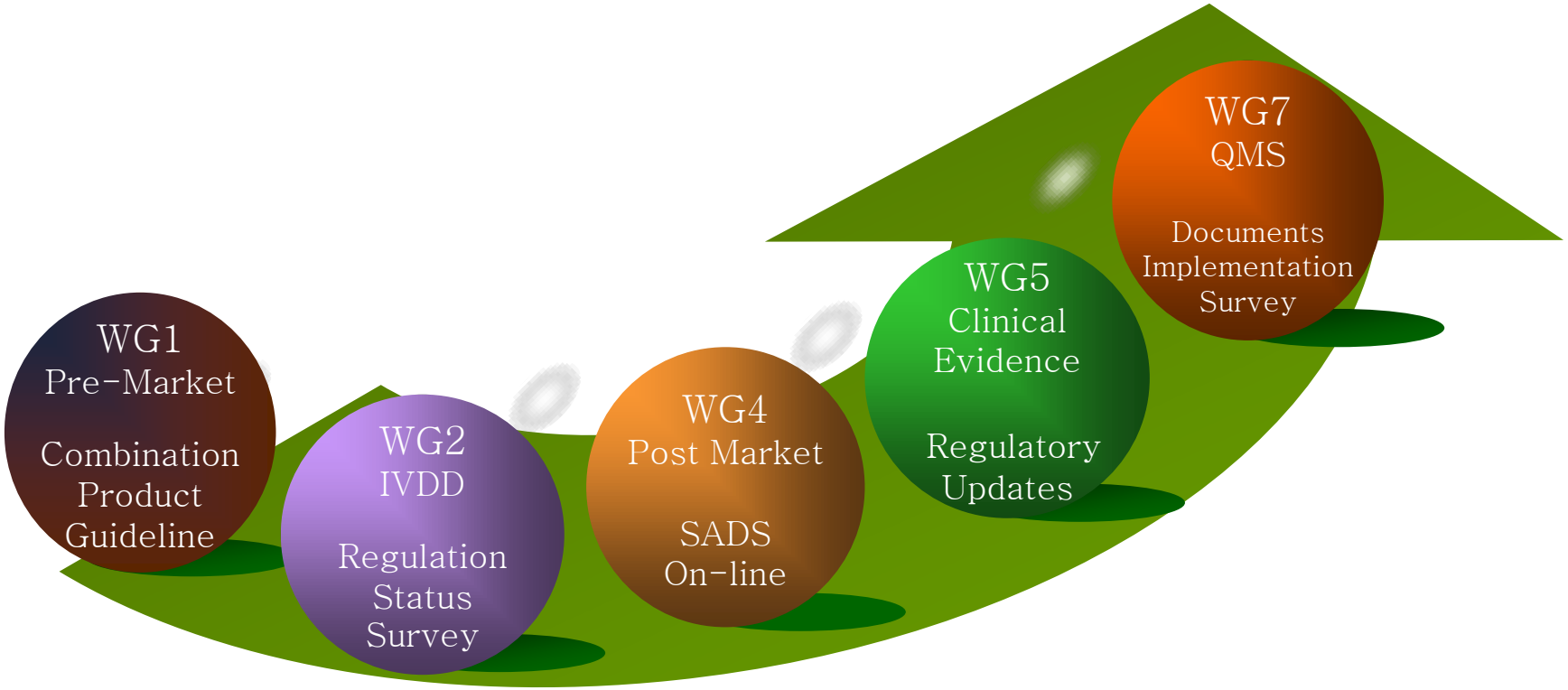
- Training & Capacity Building
- Regulatory Harmonization on Regulations

Global Partnership

- Adopting AHWP guidelines in collaboration with Global Partners
- Participation in development of guideline documents of International Organizations

Development and Implementation of AHWP Guidelines

- More than 10 guideline documents will be endorsed at the 20th AHWP Annual Meeting in November 2015



[AHWP WG Activities]

Summary of
TC Leaders Meeting
on 5 Nov 2015

Bangkok

Summary of Planned Work Items (1)

WG1 (Pre-market) updated by chair Essam Mohammed Al Mohandis and co-chair Ms Ming Hao Tan

Dec 2015:
White paper on summary of combination products guidelines in AHWP and IMDRF jurisdictions
June 2016: Circulation of draft AHWP guidelines for comments
Dec 2017: Finalized guidance for endorsement

For the guidance document for CSDT for General Medical Device Product Expectation is have a harmonized submission format. WG1 will come with CSDT first and then WG2 will use it to develop WG2 CSDT

WG2 (Pre-Market IVDD) updated by chair Mr. Wen-Wei Tsai

Guidance document on Definition of MD/ IVD and Conformity Assessment of IVDs, established IVD WG representation on ISO TC212, survey on IVD regulation was shared

For Guidance document on Definition of MD/ IVD. WG1 will come with CSDT first a nd then WG2 will use it to develop WG2 CSDT

Summary of Planned Work Items (2)

WG3 (Pre-market - Software as a Medical Device) updated by chair Dr. Rama SETHURAMAN

- Aimed to have Guidance document on Medical Device Software – Qualification and Classification endorsed in 2015

This document should be read together with the following AHWP guidance documents

White Paper on Medical Device Software Regulation – Software Qualification and Classification (AHWP/WG1/F001:2014)

WG4 (Post-market) updated by chair Ms Jennifer MAK

- Review and update existing guidelines on Adverse Events (AE) reporting, review report on SADS usage, arranged PMS training
- Update of existing WG4 AE reporting guideline to be endorsed in 2015
- Develop guidelines on AE reporting details for specific devices in 2016/2017
- Currently 15 members in SADS

Summary of Planned Work Items (3)

WG5 (Clinical performance & safety) updated by Chair Ms Yuwadee Patanawong

- Rename WG05 as "**Clinical Evidence for Performance and Safety**"
- 4 documents are proposed for endorsement
  1. Clinical Evidence Definition & Key Concepts MD
  2. Clinical Evidence Definition & Key Concepts IVD
  3. Clinical Evaluation MD
  4. Clinical Evidence - Scientific Validity Determination and Performance evaluation- IVD

WG6 (Quality Management Systems: Audit & assessment) updated by chair Mr Abdullah Rasheed

3 documents to be endorsed

1. Distributor Auditing checklist
2. Guidance on Regulatory Auditing of Quality Management System of Medical Device Distribution
3. Regulatory audit report guidance document

Summary of Planned Work Items (4)

WG7 (Quality Management Systems: Operation & implementation) updated by co-chair Mr. Ee Bin Liew

- Key projects were reviewed: survey on guidance document adaptation, ISO TC 210 involvement, Guidance Document Implementation Training - Malaysia
- Newly added task: TC chair suggested to develop implementation guideline of the importer & distributor guidance document. Malaysia is the pilot, more detail will be shared in next meeting

WG8 (Standards) updated by co-chair Mr. Tony Low

- Key projects were reviewed: Create List of Recognised Standards used in AHWP member economies, Roll out of final list for AHWP member economies with Recognised Standards in place.
- Endorsement of Paper by 20th AHWP TC Meeting (2016)

Summary of Planned Work Items (5)

STG (UDI & Nomenclature) updated by STG chair Mr Yang Lian Chun

- Key projects were reviewed: Monitor GMDN development, Share China draft nomenclature guidance and promote the amendment and adoption of this guidance as STG final guidance
- Medical Device Naming Catalogue and Naming Guidance to be endorsed in 2015

AHWP Playbook Highlights

Survey Feedback & Suggestions

AHWP Playbook workshop survey feedback is shared

Overall assessment (1-not useful,;5- excellent)
1 (0), 2 (7%), 3 (15%), 4 (62%), 5 (15%)

Suggestions
- need for tutorials. Next level training after guidance documents as overviews are not enough
- Wants the details of whole Playbook
- Consider training in every member economies
- Panel discussion interesting and useful
- Have slides before sessions for pre-meeting work
- Good presenters for this workshop e.g. clinical evaluation
- IVD topics should be included in future
- Consider to add practical considerations i.e. case studies

Recommendations from TC Advisors

Suggestions:

- We believe with the right focus and support the work, clarity, and guidance of the AHWP Playbook elements will be a real benefit to many countries
- It is exciting to see it presented at various international meetings such as The 1st MENA MedTech Regulatory Symposium
- **Then to have a 2-day training on key aspects here in Thailand as part of the AHWP Annual meeting**
- The Playbook is a first step in a long journey as we together create better documents and instructions to support the content
- **I would like to highlight the importance of AHWP guidance's to be useful for all parties (regulator and industry).**
- **It seems that the AHWP engine has started and now it is time for AHWP leadership to take us on this journey**
- As TC Advisors we are ready to be there for the adventure, and to see where it takes us

Thank You