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

March 2015, Singapore

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- Team Structure
- Capacity Building, Guidelines
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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)

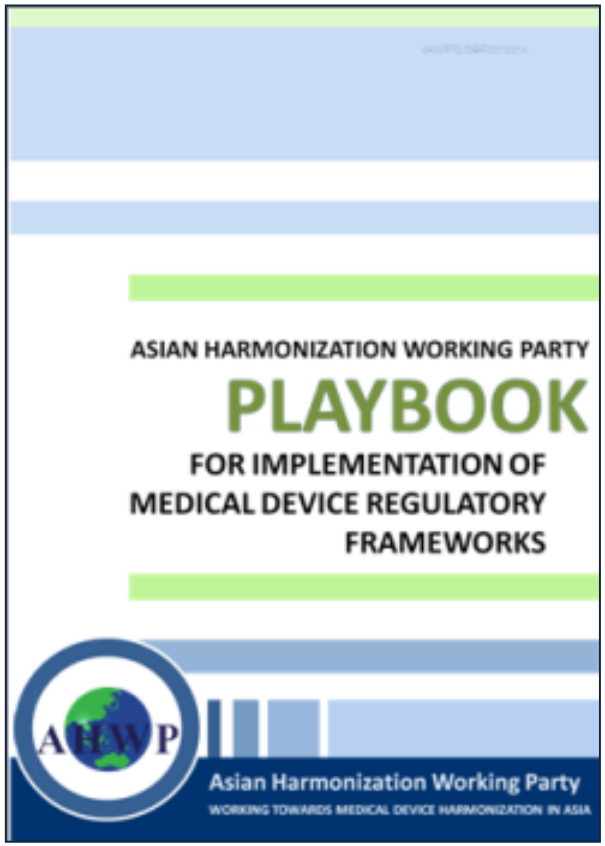
Working Groups (WGs) & Special Task Group (STG)

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

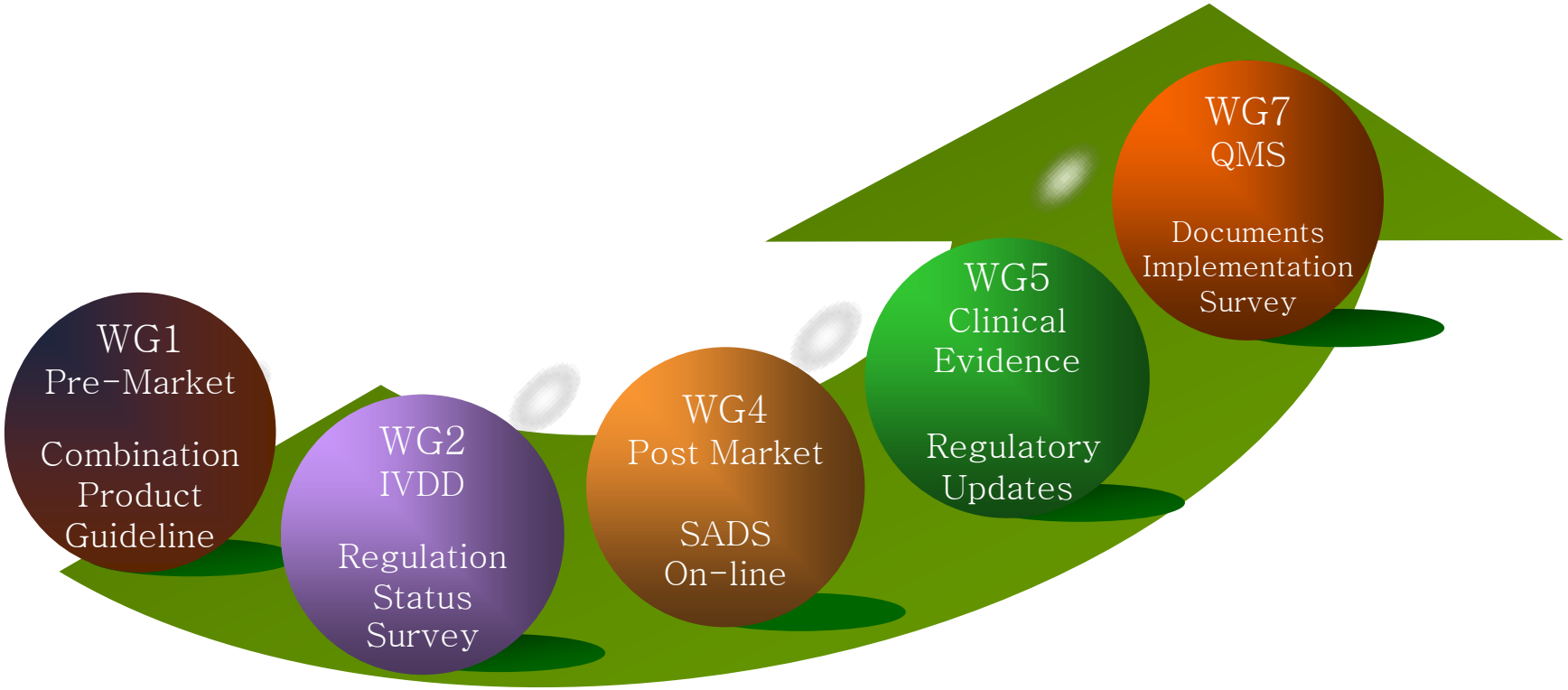
- Training & Capacity Building
- Regulatory Harmonization on Regulations

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 and Conclusion of TC Leaders Meeting in March 2015

Singapore

Summary of Planned Work Items (1)

WG1 (Pre-market) updated by co-chair Ms Ming Hao Tan

- Aimed to finalized CSDT document of AHWP in 2015
- Newly added task: TC chair requested a separate IVD CSDT (lead by WG2 and support by WG1) to be developed by the end 2016

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

- Key projects were reviewed and aimed to complete in 2015
- Guidance document on Definition of MD/ IVD and Conformity Assessment of IVDs, established IVD WG representation on ISO TC212, survey on IVD regulation

Request for all WG chairs:

- ✓ To keep Comment and Feedback practice for guidance document
- ✓ To share draft document to members for comments 3 months (Aug 2015) before annual meeting endorsement/discussion

Summary of Planned Work Items (2)

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

- Key projects were reviewed: Guidance document on medical device software, AHWP document on software classification, white paper on pre-market submission format
- Aimed to have Guidance document on Medical Device Software – Qualification and Classification endorsed in 2015

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

- Key projects were reviewed: Review and update existing guidelines on Adverse Events (AE) reporting, review report on SADS usage, arrange PMS training
- Develop guidelines on AE reporting details for specific devices
- Currently 15 members in SADS

Recommendation:
Follow up with IMDRF on AHWP participation in NCAR system

Summary of Planned Work Items (3)

WG5 (Clinical performance & safety) updated by co-Chair Ms Sumati Randeo

- Suggested to rename WG05 as clinical evidence for performance and safety
- Key projects were reviewed: SWOT analysis of WG5 framework, ISO 14155 TC involvement, guidance documents (clinical evaluation and clinical evidence)

WG6 (Quality Management Systems: Audit & assessment) updated by co-chair Ms Shirley SUM

- Key projects were reviewed: Review IMDRF N8R2 and N24R2 documents, finalize importer & distributor guidance document, training on adopted guidance documents

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, develop feedback mechanism to WG7 work by members
- Newly added task: TC chair suggested to develop implementation guideline of the importer & distributor guidance document

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

- Key projects were reviewed: publish on website list of Common Consensus Standards and existing guideline, awareness presentation of GHTF-SG1-n044 and pilot standard

Summary of Planned Work Items (5)

STG (UDI & Nomenclature) updated by STG secretary Ms Victoria Qu

- 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
- Prepared Guidance for Medical Device Naming Rule

Recommendations from TC Advisors

Suggestions:

- Face to face meeting is more effective for brand new guideline
- Strongly support the review of WG membership and ensure commitment
- Avoid duplication of WG projects
- Avoid multiple database in UDI projects
- Suggest to have WG meeting long enough (1 week instead of 2 days) to get things done

Discussion on Playbook

Things to be considered on Playbooks:

- Diverse regulatory environment in Asia
- Implementation guideline of Playbook is needed as next step
- Member economies to be requestor of help and then we can develop implementation plan that fit the member.

Next steps:

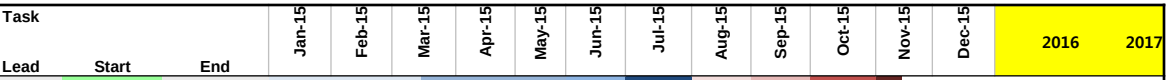
- Playbook is considered as AHWP document and allow to download in AHWP website
- Overview and implementation workshop on Playbook

- panel with representatives from AHWP and TC Advisors & proposal for TC leaders to review

Proposed Work Items for the Future

WG Documents towards Endorsement in 2015

	Tasks	Task Lead	Start	End
1	**Guidance on Common Submission Dossier Template for General Medical Devices**	**WG1**	15/01/2015	15/11/2015
	White paper on summary of combination products guidelines in AHWP and IMDRF jurisdictions	**WG1**		TBC
	White paper on grouping of medical devices for pre-market submission	**WG1**		TBC
2	**Guidance Document on MD/IVDD Definition**	**WG2**	15/01/2015	15/11/2015
	Guidance document on CSDT for IVDD	**WG2**		2016
3	**Guidance document on Medical Device Software – Qualification and Classification**	**WG3**	15/01/2015	15/11/2015
	Guidance document on Medical Device Software – Risk Classification	**WG3**		31/03/2016
	White paper / Position paper on Pre-market requirements and submission format for SaMD	**WG3**		31/12/2016
4	**Revised Guidance document on Adverse Events (AE) Reporting**	**WG4**	15/01/2015	15/11/2015
	Guidelines on Adverse Events (AEs) reporting details for specific devices	**WG4**		2016/2017
	Revised Guidance Documents on Field Safety Correction Actions	**WG4**		2016/2017
	Guidance document for Adverse Event Trending	**WG4**		2016/2017
5	**Guidance Document on clinical definitation & key concepts for MD**	**WG5**	15/01/2015	15/11/2015
6	**Guidance Document on clinical definitation & key concepts for IVDD**	**WG5**	15/01/2015	15/11/2015
7	**Guidance Document on clinical evaluation for MD**	**WG5**	15/01/2015	15/11/2015
8	**Guidance Document on clinical evaluation for IVDD**	**WG5**	15/01/2015	15/11/2015
9	**Guidance Document on clinical evidence for MD**	**WG5**	15/01/2015	15/11/2015
10	**Guidance Document on clinical evidence for IVDD**	**WG5**	15/01/2015	15/11/2015
11	**Guidance document on regulatory auditing for Importer & Distributor**	**WG6**	15/01/2015	15/11/2015
	Adopting IMDRF N11 & N22	**WG6**		31/12/2017
	Adopting IMDRF N3 & N4	**WG6**		31/12/2017
	Adopting IMDRF N5 & N6	**WG6**		31/12/2017
	Guidance document on Pilot Stand (ISO14971 tbc)	**WG8**		2015/2016
	~~Guidance Document on 2nd select Standard (ISO13485 / ISO14969)~~			



Thank You