Report Highlights

Ali Al Dalaan. MBA

Chair, AHWP Technical Committee
Executive Director SFDA Medical Devices

The 21st AHWP and 20th AHWP Technical Committee (TC) Meeting annual meeting.
21- 25th -29th , 2016 . Cebu, Philippines

Content

- Structure of TC
- Work items
  - summary of accomplished work item goals
  - Proposed work items for the future

TC Team

TC Office Bearers	Positions
Chair	Mr Ali M Al-Dalaan
Co-Chair	Dr Jeong-Rim Lee
Co-Chair	Mr Alfred Kwek
Secretary	Ms Miang Tanakasemsub
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 – Ir. Albert POON
WG3: Pre-market - Software as a Medical Device	Chair - Dr. Rama SETHURAMAN Co-Chair - Mr Tony Yip
WG4: Post-market Scope includes post-market aspect of WG 1-3 device categories	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

Collaborating International Organizations & International Associations of Industry


APACMED
APEC
ASEAN
DITTA
WHO
GMTA
PAHWP
AHWP
IEC/ISO
IMDRF
GS1
PAHO
OECD
RAPS

TC Co-operation with International Organizations:

- **Participate in ISO TC 210 , November 15 -20, 2015, review ISO 13485-2016 FD and handbook Seattle, USA**

- IMDFR Meeting March 7 – 11, 2016 Brasilia, Brazil.

  TC CO- Chair presented the report.
- Asia Pacific Health Care Summit 2016, April 7-8 ,2016 Singapore TC Chair speak
- WHO Inter-Country Meeting on Designing & Implementing Regulatory Program For MD, April 11-14, 2016 Hosted by SFDA. Riyadh, KSA.

TC Co-operation with International Organizations

- TC Chair was speaker in RAPS Regulatory Convergence 17-20 Sept 2016 San Jose, USA.

- TC Co-Chair present AHWP in OECD Meeting of International Organizations & Regulatory Policy Committee, April 2016, France

TC Meeting and Activities

- AHWP TC Leaders Meeting, April 2016, Korea
- International Workshop on Regulatory Harmonization of Medical Devices, Feb 2016, Korea
- The 2nd International Medical Device Communication Forum, June 2016, Korea
- Manage and organize AHWP annual meeting activities

Summary of Future Plan and Developed Guidance Documents

WG 1

- Combination Products (Medical Devices) guidelines (target completion Nov 2016)
- Good Review Practice Guidelines (target completion Nov 2016)
- Guideline for custom devices manufactured by the 3D printer (target completion Nov 2016)
- Guideline for reporting minor changes (target completion Nov 2016)
- Grouping for pre-market submission (target completion 2017/2018)

WG2

- Guidance Document for Definition of the Terms ‘Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device’ (target endorsement April 2016)
- Guidance Document for IVD Common Template for a Submission Dossier (target endorsement Nov 2016)
- Guidance Document for Conformity Assessment for IVDs (target endorsement Nov 2016)
- Guidance Document for Classification of IVDs (target endorsement Nov 2017)
- Guidance Document for In Vitro Companion Diagnostic Devices (target endorsement Nov 2017)

WG3

- Risk Categorisation of SaMD (Q2 2016 first draft)White paper / Position paper on Pre-market Submission requirements for SaMD (Q4 2016 first draft)

WG4

- Review and update the existing WG4 guidance documents on Adverse Events (AE) Reporting (endorsed in May 2016)
- Develop guidelines on Adverse Events (AE) reporting for PCI devices (target endorsement Q4 2016)
- Review and update the existing WG4 guidance documents on SADS (target endorsement Q4 2016)

WG5

- Draft guidance document on “General Principles of Clinical Investigation Audit & Inspection” prepared in support with ISO 14155 Technical Committee. Draft circulated for review by WG 5 members target endorsement Q4 2017 .
- Global Clinical Regulatory updates & collaboration with Global forums with regards to developing new guidance documents; following were shared and accomplished
  - ISO 14155 TC Gap Analysis with ICH GCP and ISO 13485:2016
  - APAC New Regulations
  - IMDRF WG updates
  - Following GHTF documents under review by WG 5 they will be compared with latest ISO 13485:2016 and updates from ISO 14155; endorsement deferred to Q4 2017
    - Clinical Investigations
    - Post - Market Clinical Follow Up Studies
- WG 5 has arranged training workshop on Clinical Evaluation guidance in Annual AHWP meeting Nov 22nd 2016 in Cebu, Philippines.

WG6

- Submit the IMDRF documents (N3, N4, N11, N22) for comments as draft proposed documents for AHWP (target endorsement Nov 2017)
- Aligning WG6 documents with WG7 documents

WG7

- Complete Survey for Guidance document Adoption
  Update Guidance on Medical Device Quality Management System - Requirements for Distributors (target endorsement Nov 2016)

WG8

- Create List of Recognised Standards used in AHWP member economies (target for revision in November 2016)

TC WG Work Items
- Proposed work items for endorsement

AHWP WG1 Updates

WG1 – Members Update

- **Chair**: Mr. Essam Al Mohandis from Saudi Arabia FDA
- **Co-Chair**: Ms. Kate Kim from Johnson & Johnson Medical Korea succeeded to Ms. Ming Hao Tan

Welcome to New Members:

- Mr. Sung-In Beak from MFDS Korea
- Mr. Young-Soo Seol from ILOODA Korea
- Ms. Young-Soon Jeon from Bard Korea
- Mr. Jian (Jason) Guo from Abbott Vascular China
- Ms. Mandy Kim from Johnson & Johnson Medical Korea
- Mr. Ozawa Keiichiro from FUJIFILM Corporation Japan
- Mr. Pavan Kumar Malwade from Biocon Research Ltd India

Good Bye to:

- Musliha Abdullah from CIBA VISION Malaysia

Total: 32 WG1 Members

WG1 – Members Update

No.	Work Item	Sub-group Leader	Sub-group Members
1	Guidance on regulatory practices for Combination Products	Arthur Brandwood	8 Members
2	Guidance for Minor Change Reporting	Sung-In Baek Young-soo Seol	6 Members
3	White Paper for custom devices manufactured by 3D printer	Sung-In Baek Young-soo Seol	3 Members
4	Good Review Practice Guidelines	Sung-In Baek Young-soo Seol	1 Member
5	Grouping for pre-market submission	Need for a New leader – Project postponed	6 Members

Original WG1 Work Plan

No.	Guideline Title	Target Completion Date
1	Guidance on regulatory practices for Combination Products	Nov 2016
2	Guidance for Minor Change Reporting	Nov 2016
3	White Paper for custom devices manufactured by the 3D printer	Nov 2016
4	Good Review Practice Guidelines	Nov 2016
5	Grouping for pre-market submission	Postponed to 2017-2018

WG1 – Work Plan Updates in 2016

No.	Guideline Title	Status	Target Completion Date
1	Guidance on regulatory practices for Combination Products	Finalized: the 'Proposed Final Document' has been submitted to AHWP Secretary on Nov. 11 for endorsement at Annual Meeting.	Nov 2016
2	Guidance for Minor Change Reporting	Finalized: the 'Proposed Final Document' has been submitted to AHWP Secretary on Nov. 11 for endorsement at Annual Meeting.	Nov 2016
3	e-labeling as an alternate method for compliance to labeling requirement	Proposed as a new topic and agreed among WG1 members to pursue.	2017

[Note] Below items were originally planned, but are on hold.

- White Paper for custom devices manufactured by the 3D printer
- Good Review Practice Guidelines
- Grouping for pre-market submission

AHWP WG2 Updates

AHWP WG3 Updates

WG3 – Pre-market:
Software as a Medical Device (SaMD)

Chair: Dr. Rama Sethuraman (HSA, Singapore)
Co-Chair: Mr. Tony Yip (Elekta Limited, Hong Kong SAR)
Advisor: Dr. ir. Peter W.J. Linders (Philips)

AHWP 20th TC Meeting
Nov 2016, Cebu

Proposed Work Plan 2015 - 2017

Priority	Work Item	Deliverables	Action Plan and Timeline
1	**Guidance document on Qualification of Medical Device Software** *The White paper on this topic that was prepared by the earlier WG1 will be the foundation for this. The appropriate aspects from the recent IMDRF document on Software as Medical Device (SaMD)will be kneaded with the existing white paper to develop this AHWP document*	Guidance document	Q3 2015
2	**Risk Classification of Medical Device Software / SaMD** — *To draw reference from the IMDRF SaMD workgroup and also to develop a AHWP document with adequate examples to illustrate and clarify on risk classification of software MDs*	Guidance document	Q1 2016 (First Draft)

Proposed Work Plan 2015 - 2017

Priority	Work Item	Deliverables	Action Plan and Timeline
3	**White paper / Position paper on Pre-market initial Submission format for SaMD** • To draw up a white paper or position paper for AHWP TC covering the **pre-market submission format** for SaMD — highlighting the need for considering approaches different from those in practice for traditional MDs	White paper / Position paper	Q4 2016 (First draft)

WG Progress Update

No.	Work Item	Status	Achievements
1	**Guidance document on Qualification of Medical Device Software**	Completed	Endorsed in the AHWP Annual Meeting in 2015
2	**Guidance document on Risk Categorisation of Software as a Medical Device**	Published on the AHWP website for public consultation Comments consolidated and document updated	Final version for endorsement in AHWP main meeting (Nov 2016)
3	**White paper on SaMD Pre-market Submission Requirement**	Drafting in progress: First working draft circulated in Nov 2016 but pending completion	
4	**White paper on SaMD change management – Requirements and Processes (NEW)**	First draft in Aug 2017	

Guidance document on Risk Categorisation of Software as a Medical Device

- ***For endorsement Nov 2016***

- **Scope of document:**
  To provide guidance and information to Regulatory Authorities and the Medical Device Industry on the Risk Categorisation of Software as a Medical Device (SaMD).

- **Objective of document:**

  The main aim of this document for medical device software categorisation is to provide information to AHWP member economies' RAs and industry in establishing,a consistent approach to determine the risk categorisation of SaMD based on its intended purpose. The purpose of the document is to introduce a foundational approach, harmonized vocabulary and general and specific considerations for manufacturers, regulators and users alike to address the unique challenges associated with the use of SaMD.

Guidance document on Risk Categorisation of SaMD

- **Summary:**

This guideline is drafted based on currently available IMDRF documents on Software as Medical Devices, AHWP-WG3-SaMD-001:2015 guidance document, AHWP white paper on medical device Software Regulation – Software Qualification and Classification and published guidelines from global agencies including European Union, Health Canada and US FDA with focus on the recent developments in regulation of SaMD.

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

- AHWP-WG3-SaMD-001:2015: Guidance Document on qualification of medical device software
- White Paper on Medical Device Software Regulation – Software Qualification and Classification (AHWP/WG1/F001:2014)

Guidance document on Risk Categorisation of SaMD

- **Acknowledgements to the sub-group**

Shingkoon Cheng (Boston Scientific);
Kelvin Koh (Terumo);
Tony Yip (Elekta) – Co-chair, WG3
Rama Sethuraman (HSA) – Chair, WG3

White paper on SaMD Pre-market Submission Requirement

- First draft under review

- **Scope of document:**
  This document provides a snap shot of the pre-market submission requirements for some regulatory bodies and jurisdictions such as Australia TGA, China CFDA/CMDE, the European Union, Health Canada, Korea MFDS, MHLW Japan and the US FDA. The information collated is with reference to their published guidelines for medical software regulation and pre-market submission requirements.

White paper on SaMD Pre-market Submission Requirement

- **Objective of document:**

The main aim of this white paper is to summarize the current regulatory environment around the world, by including the harmonized view on pre-market submission requirement across jurisdictions, for next development of AHWP guidelines which can serve as member economies' key reference in establishing in a consistent way, an economic and effective approach to the control of medical software in the interest of public health and in the continued innovation of medical software development.

White paper on SaMD Pre-market Submission Requirement

- **Acknowledgements to the sub-group**

Lindsay Tao (J&J);
Young Min, Han (MFDS);
Mohammed K. AL-Amer (Saudi FDA)
Won Bin, Kim (VATECH);
Ms. Young-Jin Lee (Philips);
Jacqueline Monteiro (Philips);
John Baby (Quality Systems and Solution Pte Ltd); &
Tony Yip (Elekta) – Co-chair, WG3

AHWP WG4 Updates

WG4 – Post-market

Chair: Ms Jennifer MAK (Dept of Health, HKSAR)

Co-Chair: Ms Kitty MAO (GE Healthcare, Singapore)

Advisors: Dr Jorge GARCIA (TGA, Australia)

Ms Joanna KOH (Singapore)

AHWP 21st Annual Meeting
24 Nov 2016, Cebu Philippines

Updates (1)

- No. of WG members: 24 (excluding chair and co-chair)
  - 6 from Regulatory Authorities (Hong Kong, Indonesia, Korea, Saudi and Tanzania)
  - 18 from Industry (China, Chinese Taipei, Hong Kong, Indonesia, Korea, Malaysia and Singapore)

Updates (2)

- **Activities**
  - Review of WG4 work plan 2015-2107 & identification of work tasks in 2016
  - WG members grouped into 3 teams each working on a 2016 work task
  - Intra-team collaboration preparing draft document or taking forward the work task
  - WG telecons held on 10 Mar and 13 Oct 2016
  - Progress summary on WG4 matters for WG members (24 Dec 2015, 4 Feb , 26 Apr, 17 May & 15 Sep 2016)

Work Plan 2015 – 2017

Priority	Work Item	Deliverables	Timeline
1	Review and update the existing WG4 guidance documents on Adverse Events (AE) Reporting	Revised Guidance Document	2016 (completed)
2	Review the Safety Alert Dissemination System (SADS)	Review Report	2015 (completed)
3	Arrange Post-market Surveillance (PMS) Training	Training Sessions	2015 (completed)
4	Develop guidelines on Adverse Events (AE) reporting details for specific devices	Guidelines	2016
5	Review and update the existing WG4 guidance documents on SADS	Revised Guidance Documents	2016/2017
6	Develop guidance document for Adverse Event Trending based on GHTF documents	Guidance Document	2016/2017
7	Develop guidelines on proper handling of medical devices after complaint and AEs	Guidelines	2016/2017
8	Conduct survey on the status of post market systems (including both reportable AEs and FSCAs) and challenges of AWHP member economies	Survey Report	2016/2017
9	Identify post market systems (AE or safety alert) or guidance from various regulatory authorities and web sources	Hyperlinks for sharing at the AHWP website	2016

WG Progress Update (1)

since last AHWP TC Leaders Meeting in May 2016 (Seoul)

No.	Work Item	Status	Achievements	Timeline
1	Review and update the existing WG4 guidance documents on Adverse Events (AE) Reporting	**Completed**	• Proposed document conditionally endorsed in the 20th AHWP Annual Meeting and endorsed after the AHWP TC Leaders Meeting in 2016 • Finalized version available on the AHWP website	• 2016
2	Develop guidelines on Adverse Events (AE) reporting details for a specific type of devices	**In progress**	• Percutaneous Coronary Intervention (PCI) devices selected as the specific type • Proposed guidelines expected to be finalized and endorsed in Q4 2016	• Q4 2016

WG Progress Update (2)

since last AHWP TC Leaders Meeting in May 2016 (Seoul)

No.	Work Item	Status	Achievements	Timeline
3	Review and update the existing WG4 guidance documents on Safety Alert Dissemination System (SADS)	**In Progress**	• Proposed document expected to be finalized and endorsed in Q4 2016	• Q4 2016
4	Devise a post-market resource centre	**Completed with on-going updates**	• The initial version of the resource centre is expected to be available in the AHWP website in Q4 2016	• 2016 and on-going

Guidelines for Adverse Event Reporting of PCI devices for Medical Device Manufacturer or its Authorized Representative (1)

- **Scope :**
  - Adverse event (AE) reporting guidelines for Percutaneous Coronary Intervention (PCI) device manufacturer or its authorized representative

- **Objective :**
  - To provide examples on reportable and non-reportable events related to PCI devices
  - To be read in conjunction with the AHWP adverse event reporting guidance of ref. AHWP/WG4/F001:2015

Guidelines for Adverse Event Reporting of PCI devices for Medical Device Manufacturer or its Authorized Representative (2)

Guidelines for adverse event reporting of Percutaneous Coronary Intervention (PCI) devices[1] for the Medical Device Manufacturer or its Authorized Representative

To be read in conjunction with the AHWP adverse event reporting guidance of ref. AHWP/WG4/F001:2015

Reportable events[2]	Non-reportable events
• Death or heart failure that is probably or possibly device-related • Cardiac tamponade (pericardial effusion) or cardiogenic shock • Creation of distal air embolus • Difficulty deflating the balloon or other delivery system or withdrawal complications • Difficulty advancing the stent or crossing the lesion, not associated to procedural or patient factor • Acute/ sub-acute stroke/ cerebrovascular accident • Balloon rupture (if used within rated burst pressure). • Adverse reaction associated with the stent material and/ or delivery system materials, drug or polymer carrier if the reaction is not identified in the IFU • Thromotic/ calcific occlusion or stenosis (in-stent and target vessel) or myocardial infarction (suspected to be stent-related) • Incomplete stent apposition/ expansion (malapposition) or excessive recoil • Coronary or stent embolism • In vivo stent damage or deformation or device fragmentation or device fragment emboli migration • Product defect e.g. device deformation (kink, bent, flare strut, break, twisted etc.), packaging compromised, foreign material, labelling issue & etc. • Unanticipated serious injury	• Side branch occlusion[3] • Distal emboli (tissue, thrombotic/ thrombus, plaque)[3] • Acute arterial perforation/ rupture/ dissection, not associated to malfunction of the device[3] • Arrhythmias, including atrial and ventricular[3] • Angina pectoris[3] • Non-fatal bleeding complications, which may require transfusion/ haemorrhage[3] • Coronary artery spasm[3] • Premature stent dislodgement with or without migration[3] • Difficulty advancing the stent or crossing the lesion, linked to procedural or patient factor[3] • Infection – local and/ or systemic[3] • Peripheral vascular or nerve injury[3] • Death or heart failure if there is evidence that it is not device-related • Haematoma at the vascular access site • Hypotension or hypertension stated in the IFU • Fever or infection or pain at insertion site stated in the IFU • Pseudoaneurysm stated in the IFU and not due to malfunction of the device.

[1] PCI (Percutaneous coronary intervention) devices – they are used in treating obstructive coronary artery disease with nonsurgical technique through percutaneous methods (commonly through femoral or radial arteries) e.g. coronary stents, balloons, guide wires

[2] Reportable adverse events must be reported to the relevant regulatory authority (ies) within the required timeframe. Please refer to the AHWP guidance document of ref. AHWP/WG4/F001:2015 for details

[3] Non-reportable events shall be reported when an adverse trend is identified

Guidance for Safety Alert Dissemination System (SADS) (1)

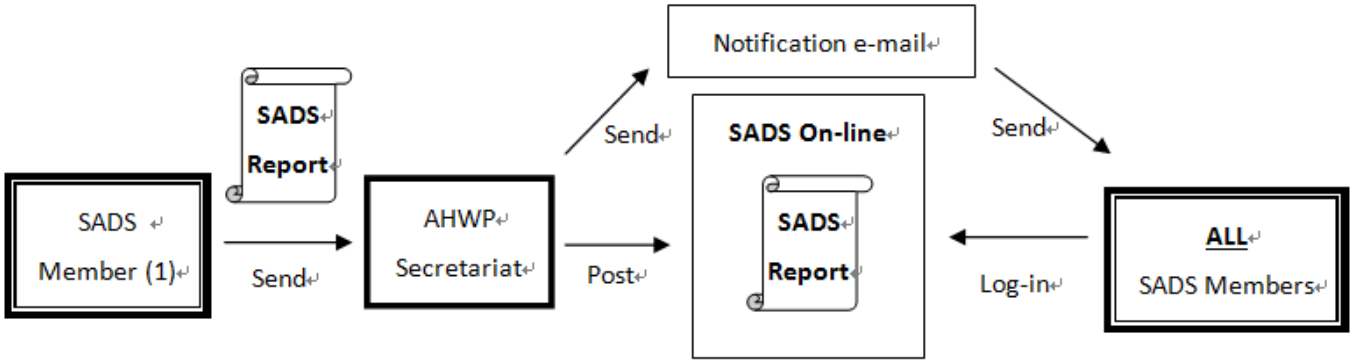
- **Scope :**
  - Guidance on the revised Safety Alert Dissemination System (SADS)

- **Objective :**
  - To provide guidance to Regulatory Authorities (RAs) on the following:
    - Structure of the SADS;
    - Roles and responsibilities of SADS members, manufacturers or their representatives (ARs) in the SADS;
    - Reporting criteria of the SADS report; and
    - Guidelines to fill in a SADS reporting Form

Guidance for Safety Alert Dissemination System (SADS) (2)

- **Summary:**
  - An updated and combined version of the following AHWP guidance documents on SADS:
    (a) Framework for AHWP Safety Alert Dissemination System (SADS) (AHWP/WG2/SADS/001)
    (b) Safety Alert Dissemination System: Safety Alert Dissemination Criteria, Procedures and Form (AHWP/WG2/SADS/002)

  - Contents covering definitions, scope, dissemination mechanism, roles of RAs, manufacturers and their ARs, reporting criteria and reporting form in relation to SADS are updated.



Post-market Resources Centre

- **Scope :**
  - Hyperlinks on post-market regulations and reports
- **Objective :**
  - To provide a “One-Stop” location for easy access of post-market regulations and reports globally
- **Summary:**
  - Contents covering hyperlinks to AE reporting and safety information of different countries, including
    - AHWP Members Economies – China, Chinese Taipei, Hong Kong SAR, Kingdom of Saudi Arabia, Malaysia, Republic of Korea and Singapore
    - IMDRF Countries – Australia, Canada, EU (France, Germany, Switzerland and UK), Japan and the US

AHWP WG5 Updates

AHWP WG6 Updates

AHWP WG7 Updates

WG7 – Quality System Operations & Implementation

Chair: Aidahwaty M.Olaybal

Co-Chair: Ee Bin Liew

Secretary: Chloe Hyo Sung

Advisor: Hideki Asai

AHWP Annual Conference /TC Meeting
Nov 2016, Cebu, The Philippines

Work Plan Update 2015 - 2017

Item	Work Item	Deliverables	Action Plan and Timeline
1	Run survey on practical adoption and develop training materials for all guidance documents	Practical adoption of guidance documents develop by WG7 (AHWP/WG3N4FPDR2) *Guidance on Quality Management System-Medical Devices Requirement for Distributors*	Complete phase 1. Phase 2 for 2016. Conclude survey – remaining countries not contactable Work Item concluded
2	Promote the voice of AHWP in the development of the ISO standards	Stream 2 to comment on the ISO 13485 DIS2 (Deadline is early April 2015) Stream 2 Member have the right to comment on ISO 13485 on behalf of AHWP	ISO standard released March 2016 Handbook draft complete with AHWP input Work Item concluded
3	Develop a feedback mechanism to WG7 work by member economies	Established communication network of regulators responsible for QMS in the member economies with WG7	Stream 3 to find out the regulators responsible for quality management systems in the member economies Lack of response from primary reps to identify the responsible person

WG New Work Items

Work Plan for WG7 2016 - 2017												
Work Items / Time	2016											2017
	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan
Update Guidance on Medical Device Quality Management System - Requirements for Distributors												
Input from ISO13485:2016, editorial corrections, structure remains, only content changed	Complete											
Draft to complete by Mar 2016, target AHWP endorsement by May 2016										Complete		
Continue implementation training for member economies Create best practice process for implementation training >2 trainings conducted for 2016												Complete
Develop a feedback mechanism to WG7 work by member economies Established communication network of regulators responsible for QMS in the member economies with WG7												Complete
Survey for practical adoption for guidance document - Phase 2									Complete			

Survey - Guidance Document Implementation

- A survey for practical adoption for guidance documents has been completed in 2015 and 2016.
- 16 out of 24 member economy countries responded

Survey - Guidance Document Implementation

Development of QMS requirement for distributors

Q. With regards to QMS requirements for distributors;

Are you developing?	***Yet to develop?***	***Developed but amending?***	***Developed and not amending in the near future?***
• Abu Dhabi • Chile • Indonesia • Laos • Saudi Arabia • Taipei • Thailand	• Hong Kong • Jordan • Kuwait • Pakistan	• Korea • Philippines	• Malaysia • Singapore • Tanzania

Survey - Guidance Document Implementation

Adoption for guidance documents

Total 16 countries responded

Q. Have you read the guidance document for QMS requirements for distributors?

Yes	***No***	***Not response***
9	4	3

Q. Would you consider following the guidance document?

Yes	***No***	***Not response***
11	3	2

Survey - Guidance Document Implementation

Adoption for guidance documents - continued

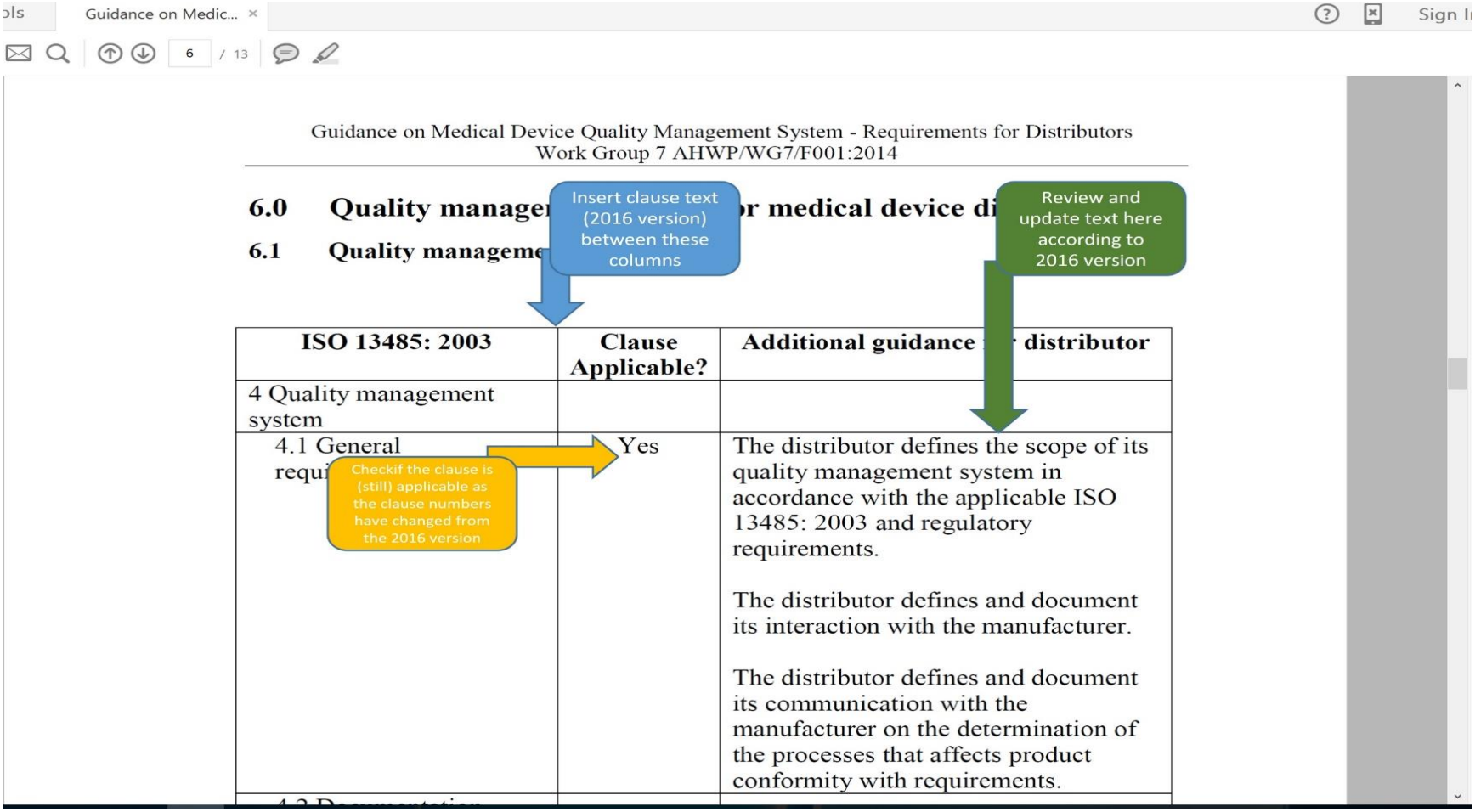
Q. Do you need training on how to use the guidance for your regulations?

- We would like to get training on how to use the guidance and learn more about the technical requirements about distribution and storage and its implementation
- We would be using the guidance document of AHWP as a reference to our GDP implementation
- The training is required to understand the element which covers the distributor activities

Q. Are there reasons why you prefer not to follow the guidance?

- Consideration should be given to the substantial resources required by the distributors in implementing and maintaining a QMS
- We are making revision to align it to the country amended laws
- Currently the process to adopt/adapt this requirement is in progress in Member State of ASEAN

How was the guidance document updated



Quality System Enforcement

Member Economy	Quality System Requirements
Abu Dhabi	
Brunei Darussalam	
Cambodia	
Chile	
Chinese Taipei	M F
Hong Kong SAR, China	
India	
Indonesia	I
Jordan	
Kingdom of Saudi Arabia	M, I
Laos PDR	
Malaysia	M, I
Myanmar	

Member Economy	Quality System Requirements
Pakistan	
People's Republic of China	M, I
Philippines	
Republic of Korea	M F
Singapore	I
South Africa	
State of Kuwait	
Tanzania	
Thailand	M
Vietnam	
Yemen	
Kazakhstan	
Mongolia	

F	Foreign manufacturer inspection
I	Importer/distributor
M	Manufacturer

WG Documents towards endorsement 2016-2018

WG 1

	Tasks	Jan-16	Feb-16	Mar-16	Apr-16	May-16	Jun-16	Jul-16	Aug-16	Sep-16	Oct-16	Nov-16	Dec-16	2017	2018
WG1	Guidance on regulatory practices for Combination Products								Draft			Target for endorsement			
	Guidance for Minor Change Reporting								Draft			Target for endorsement			
	White Paper for custom devices manufactured by the 3D printer													Target for endorsement	
	Guidance for custom devices manufactured by the 3D printer													Target for endorsement	
	Good Review Practice Guidelines													Target for endorsement	
	Grouping for pre-market submission													Target for endorsement	
	E-labeling as an alternate method for compliance to labeling requirement													Target for endorsement	

WG Documents towards endorsement 2016-2018

WG 2

	Tasks	Jan-16	Feb-16	Mar-16	Apr-16	May-16	Jun-16	Jul-16	Aug-16	Sep-16	Oct-16	Nov-16	Dec-16	2017	2018
WG2	Common Template for a Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices											Target for endorsement			
	Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices											Target for endorsement			
	Guidance Document Development: Classification of IVDs											Target for endorsement			
	Guidance Document Development: In Vitro Companion Diagnostic Devices			Draft										Target for endorsement (July 2017)	
	IVD labelling													To be kick off Oct 2017	
	Advertising and promotion													To be kick off Oct 2017	

WG Documents towards endorsement 2016-2018

WG 3

	Tasks	Jan-16	Feb-16	Mar-16	Apr-16	May-16	Jun-16	Jul-16	Aug-16	Sep-16	Oct-16	Nov-16	Dec-16	2017	2018
WG3	Guidance document on Risk Categorization of Software as a Medical Device											Target for endorsement			
	Guidance document on Qualification of Medical Device Software - Endorsed in Annual Meeting Nov 2015														
	White paper on SaMD Pre-market Submission Requirement												First draft	Target for endorsement	
	White paper on SaMD change management - Requirements and Processes													First draft (Aug 2017)	

WG Documents towards endorsement 2016-2018

WG 4

	Tasks	Jan-16	Feb-16	Mar-16	Apr-16	May-16	Jun-16	Jul-16	Aug-16	Sep-16	Oct-16	Nov-16	Dec-16	2017	2018
WG4	Review and update the existing WG4 guidance documents on Adverse Events (AE) Reporting					Target for endorsement									
	Develop guidelines on Adverse Events (AE) reporting details for specific devices											Target for endorsement			
	Review and update the existing WG4 guidance documents on SADS											Target for endorsement			
	Develop guidance document for Adverse Event Trending based on GHTF documents													Target for endorsement	
	Develop guidelines on proper handling of medical devices after complaint and AEs													Target for endorsement	

WG Documents towards endorsement 2016-2018

WG 5-8

	Tasks	Jan-16	Feb-16	Mar-16	Apr-16	May-16	Jun-16	Jul-16	Aug-16	Sep-16	Oct-16	Nov-16	Dec-16	2017	2018
WG5	General Principles of Clinical Investigation Audit & Inspection											Draft circulated for comments		Target for endorsement	
	Develop Guidance document on Clinical Investigation											Review GHTF Docts & Compare with ISO 14155 &13485:2016		Target for endorsement	
	Develop Guidance document on Post Market Clinical Follow up studies														
WG6	Submit the IMDRF documents (N3, N4, N11, N22) for comments as draft proposed documents for AHWP													Target for endorsement	
WG7	Update Guidance on Medical Device Quality Management System - Requirements for Distributors					Target for endorsement									
WG8	Create List of Recognized Standards used in AHWP member economies											List target for revision / update			

Thank You