WG7 – Quality System Operations & Implementation

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AHWP Annual Conference /TC Meeting

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AHWP

Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

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

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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 fo guidance document - Phase 2									Complete			

Survey - Guidance Document Implementation

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- 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

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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

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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

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Adoption for guidance documents - continued

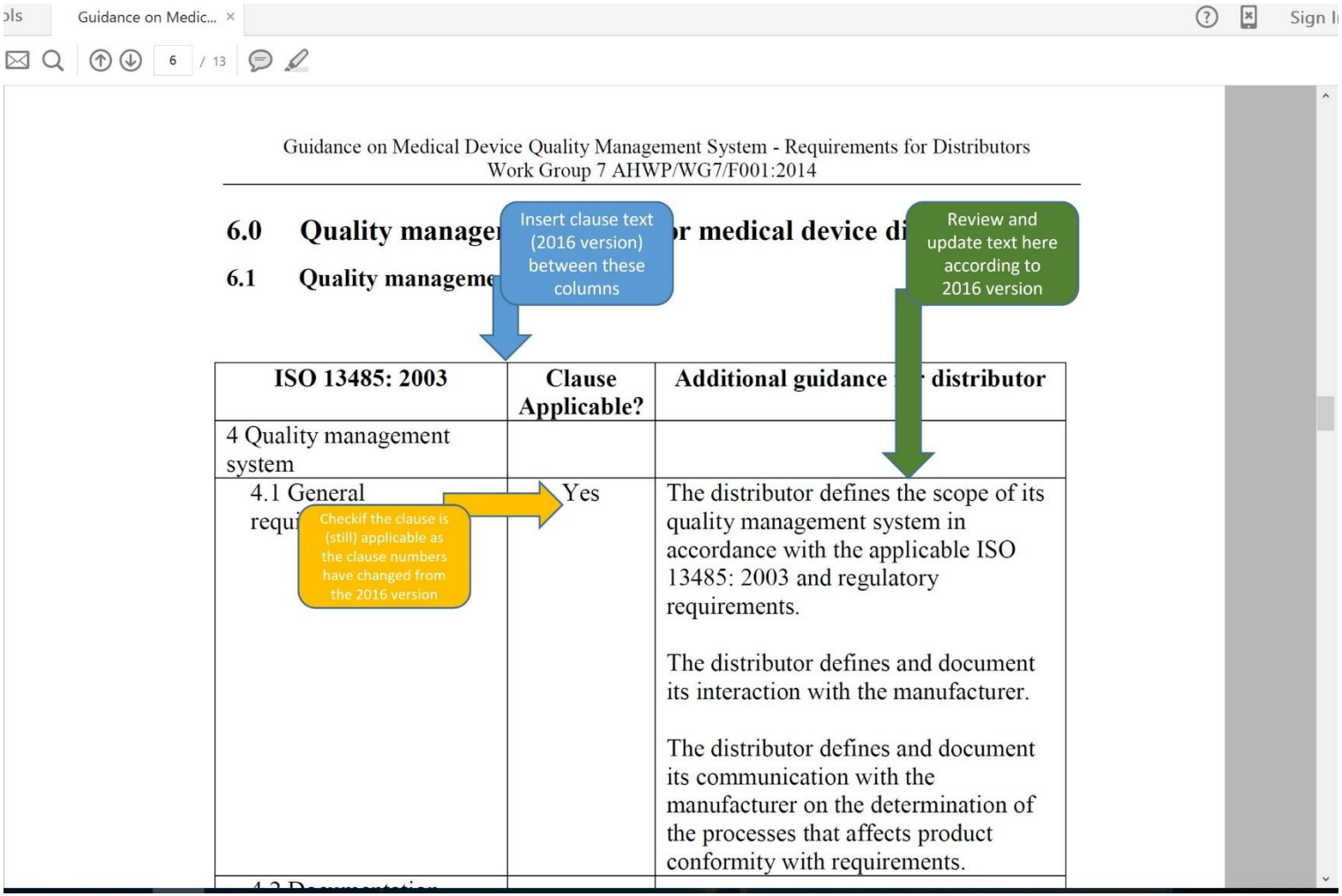
Q. Do you need training on how to use the guidance for your regulations?

- 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

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Thank You