WG7 – Quality System Operations & Implementation

Chair: Aidahwaty M.Olaybal

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Advisor: Hideki Asai

AHWP 19th TC Meeting
5 Nov 2015, Bangkok

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.
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	Complete ISO meeting participation in New Orleans, Denver, Wokingham and Seattle (Plenary mid Nov 2015) - presented on behalf of ISO in APAC MD forum in May 2015 - resolved almost 1400+ comments over the year - progressed to FDIS, ready for final publication Q1 2016
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 - Ongoing

Survey on practical adoption of Guidance Document

Will you consider to adopt?		
Yes	No	No response
9	4	11

AHWP QMS
document adopti

ISO13485:2016 highlights

- More definitions, including importer, distributor
- Better structured, more specific in many areas
- Annexes - comparisons with 2003 version, and ISO9001:2015

Guidance Document Implementation Training - Malaysia

ASIAN HARMONIZATION WORKING PARTY

Oct 20th , 2015
Kuala Lumpur

Guidance Document Implementation Training - Malaysia

Guidance Document Adoption by Member Economies

- Future trainings in 2016
  - set clear expectations on content, deliverables, resources
  - increase trainer pool

WG New Work Items

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	Work Item	Deliverables	Timeline
1	Update Guidance on Medical Device Quality Management System - Requirements for Distributors Input from ISO13485:2016, editorial corrections, structure remains, only content changed Completed by WG Stream Draft to complete by Mar 2016, target AHWP endorsement by May 2016	Updated Guidance document	Q2, 2016
2	Continue implementation training for member economies Create best practice process for implementation training	>2 trainings conducted for 2016	Q4, 2016

Note: Membership confirmation at the start of the calendar year – this is WG7 SOP

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THANK YOU