WG7 – Quality System Operations & Implementation

Chair: Aidahwaty M.Olaybal

Co-Chair: Ee Bin Liew

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Advisor: Hideki Asai

AHWP Annual Conference /TC Meeting

Dec 2017, New Delhi, India

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 (13 member economies indicated they will consider adoption) 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	Formal liaison member in TC210 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	Lack of response from primary reps to identify the responsible person Work item ongoing

Major Achievements for WG7 in our 3-year Term

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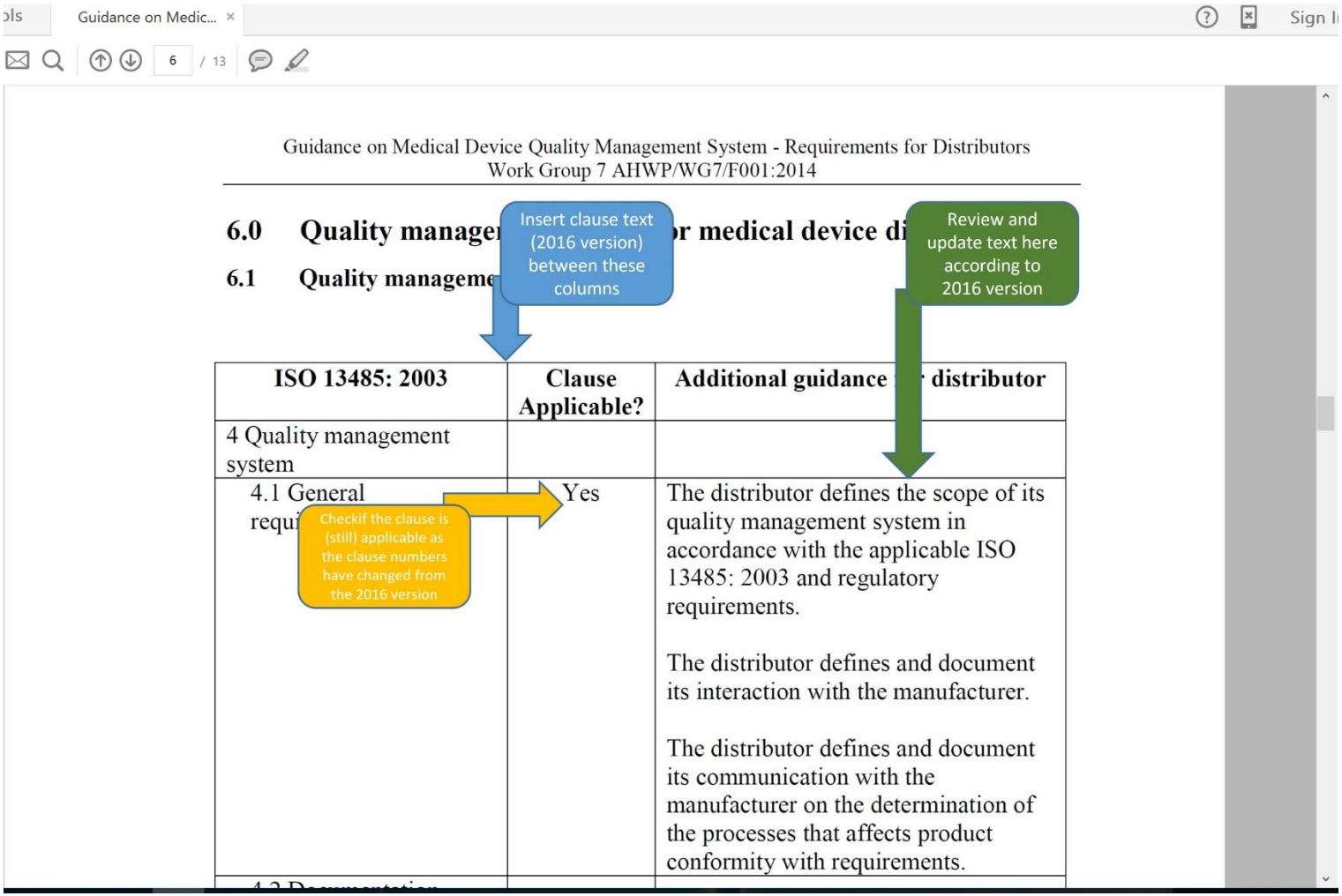
2015

- **Represented ISO** for industry presentation on upcoming ISO13485:2016 release – Shanghai
- **First training on AHWP guidance document -** Malaysia

2016

- Contributed to **ISO13485:2016 release** as part of drafting committee (March 2016)
- **Formal AHWP industry liaison** with ISO TC210
- **>50% complete on survey** for member economy adoption of AHWP guidance document (16/30 responded)
- Revised AHWP guidance document – QMS requirements for importers/distributors. **First AHWP guidance document to be revised.**

How was the guidance document updated



Major achievements for WG7 in our 3-year term

ASIAN HARMONIZATION WORKING PARTY

2017

- Released ISO13485 handbook, (25 Sept), reference AHWP guidance document in bibliography. **Definitive guide for ISO13485 worldwide**
- Revised IAF MD9 (21 June), reference AHWP guidance document in bibliography, and included provision of **up to 50% reduction in auditor man-days** if the entity is an importer/distributor during ISO13485 certification.
- Involved in ISO14971 drafting committee, ISO24971 drafting committee, DGuide 63 drafting committee, and PMS processes ISO TR20416 drafting committee – **to release all standards and TR by 2019.**
- **Attended every ISO TC210 plenary** as AHWP representative for 3 consecutive years.

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Thank you for everyone's support whom without you there would be no such success