WG3 (QMS) update

18th AHWP Annual Meeting

Kuala Lumpur, Malaysia

Dec 2013

By

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WG 3 Membership Status

- Currently 23 members, representing Saudi Arabia, Singapore, Abu Dhabi, Chinese Taipei, Malaysia, India, China, Thailand, Philippines.
- Including 3 members from the US, Japan and Australia who have given us much contributions
- **Review of membership activity and revise membership listing in Jan 2014 as part of WG procedure.**

Consolidated Achievements in 2012

- Since June 2008, AHWP WG3 chair, co chair and members had participated with GHTF SG3 for developing QMS guidance documents that have been adopted:
  - Quality management system – Medical Devices – Guidance on the control of product and services obtained from suppliers. (N17)
  - Quality Management system – Medical Devices – Guidance on corrective action and preventive action. (N18)
  - Quality Management System – Medical devices - Criteria for characterizing the significance of quality management system deficiencies (N19, to be adopted this meeting)

Consolidated Achievements in 2012

- AHWP QMS Survey completed in Oct 2012:
  - Analysis done, and actions for a guidance document addressing the member ecomonies' needs were initiated
- Represent AHWP with ISO TC 210
  - Actively participated in the ISO 13485 revision process.

Achievements for 2013

- Collaboration and participation with ISO TC 210 for developing the new version of ISO13485
  - ISO TC 210 WG1 provides design specification of ISO13485: 20XX. In AHWP this feedback is through the user requirements survey.
  - ISO 13485: 20XX Working Draft (WD)1 received 1064 comments from TC members. AHWP circulated WD to WG3 members and member ecomonies before including AHWP comments in this WD.
  - ISO 13485: 20XX was revising accordingly to create the CD version, which had 520+ comments after clean-up.
  - Ali, Ee Bin, Albert and Jack represented AHWP in the following meetings:

March 2013, Chiba, Japan

- Participated in ISO/TC 210/WG1 meeting for ISO13485-2003 Application of Quality System to Medical devices. Proposed draft document Review and resolution of comments from the Public Consultation Process.11-15 March 2013, Chiba, Japan

- Ali, Ee Bin, Jack and Albert joined different teams to address different sections of the standard

March 2013, Chiba, Japan

- General topics were discussed during the meeting such as:
  - risk management covering process and/or product
  - supplier's application of ISO 13485
  - medical software vs. software for process control and software for QMS
  - consistency in terminology

October 2013, Lyon, France

Participated in ISO/TC210/WG1 meeting for ISO13485-2003 Application of Quality System to Medical Devices. Proposed draft document review. 29th Sep – 2rd Oct 2013 Lyon, France.

October 2013, Lyon, France

- TC210 WG1 worked as an entire group of 33 people to address 520+ comments as a team.
- 50+ comments remained after the meeting, to be addressed by a small group late Oct, and reviewed by the WG via email in Nov 2013.
- No further CD, will submit to up-rev to DIS version

Achievements for 2013

- WG3 Chair represent AHWP TC WG3 with IMDRF MDSAP Working Group and participated in the development of the these doc WG3 also review and comment in these doc:
  - IMDRF Medical Device Single Audit Program (MDSAP) – Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition N3
  - IMDRF Medical Device Single Audit Program (MDSAP) – "Competence and Training Requirements for Auditing Organizations"N4
  - IMDRF Medical Device Single Audit Program (MDSAP) – Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing OrganizationsN5
  - IMDRF Medical Device Single Audit Program (MDSAP) – Regulatory Authority Assessor Competence and Training RequirementsN6

Achievements for 2013

- New Items:
  - Medical Device Single Audit Program (MDSAP) – Auditing Organizations Assessments, Recognition, and Remediation (NWI)
  - Medical Device Single Audit Program (MDSAP) – Regulatory Authority Assessment Method Guidance(NWI)

The IMDRF Documents are in final draft and have been submitted for endorsement from MB.

Achievements for 2013

- From the QMS Survey results, WG3 started to draft a guidance document on the application of ISO13485 for importers / distributors.
- Currently under review by WG3 members.

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F:\Commentstemplate WG3.docx

- The format of the guidance document will be expanded to include guidance for small manufacturers in 2014

ISO 13485 Guidance Document for Importer / Distributor

IMDRF and ISO Meeting Summaries

Day	Month	Year	City	Country	Meeting
28- 31	January	2013	Brasilia	Brazil	IMDRF
11-15	March	2013	Chiba	Japan	ISO
9- 12	July	2013	Tokyo	Japan	IMDRF
10 -13	September	2013	Maryland	USA	IMDRF
29-3	September / October	2013	Lyon	France	ISO

WG3 Work Plan 2013 - 2014

Work Items / Time	2013								2014										
	Jan	Feb	Mar	Apr	May – Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov
Review Guidance documents (all documents currently hosted by IMDRF)	Review N99 1-10, N15, N17, N18, N19. Documents sent for WG member for comments.										Discuss guidance document adoption by AHWP member economies								
ISO13485 / TC210 work	Review and comment on any coming update related to ISO 13485 2003 and TC 210 documents		Continue ISO 13485 and TC 210 documents work. Japan March 11-15 2013			Continue ISO 13485 and TC 210 documents work. France Oct 30-Nov 2 2013		Complete addressing all 500+ comments pre-CD.			CD released, and pending meeting in Stockholm Nov 2014							Completed work for ISO13485 Discuss work on ISO/TR 16949	
QMS survey for AHWP **(completed 2012)** Guidance document for importer/ distributor / small MFG	Propose definition of importer to be included in ISO13485			Draft the guidance document for importer/ distributor		Review by WG3 members Present progress in AHWP meeting in Dec 2013			Complete guidance document and prepare for voting for member economies' adoption Draft section for guidance for small manufacturers										
(IMDRF) MDSAP	Participate and comment on WG3 (PD1) N3R3 doc. Brazil 28 Jan 31 Jan 2013		Reviewed Auditing Organization criteria and Auditor Competency and Training Requirements WG (PD2)/N3R5 WG (PD1)/N4R2 by mid June 2013			Continue MDSAP Document Work													
Meetings	**IMDRF – MDSAP Meeting in Brazil Jan,2013**		**ISO/TC210 Meeting in Chiba, Japan Mar 2013**	**IMDRF –MDSAP Tokyo ,Japan July 2013**		**IMDRF – MDSAP Silver Spring, Maryland USA Sep 2013**	**ISO/TC210 Meeting in Lyon, France Oct 2013**	**AHWP Annual meeting KL, Malaysia Dec 2013**										**ISO/TC210 Meeting in Stockholm Nov 2014**

Work Plan Progress 2012-2014

Priority	Work Item	Deliverables	Action Plan and Timeline
I  	AHWP QMS Survey; QMS Adoption and Implementation in AHWP member economies	Completed all member economies survey forms, full analysis of results Develop a strategy for assisting countries to prioritize QMS activities based on QMS survey results and local activities (manufacturing, distribution)	**Survey completed** Needs for guidance document for ISO13485 is recognized. Albert Li tasked to draft with help from WG3 members
I	Guidance document for the application of ISO13485 for importers / distributors / small manufacturers	Complete Phase 1 guidance document for importers / distributors Complete Phase 2 guidance document for small manufacturers in the same document Review by AHWP member economies for adoption Propose to be adopted by the next revision of ISO/TR 16949	Review by members, complete review by Jan 2014. Draft by March 2014, review by members Apr – Jun 2014, complete by Jul 2014 Send out for review by member economies, address comments Possibly at Nov 2014 TC210 meeting in Stockholm.

Work Plan Progress 2012-2014

Priority	Work Item	Deliverables	Action Plan and Timeline
2 	Joint AHWP - WG3 GHTF SG3 activity	N19 "Nonconformity Grading System for Regulatory Purposes and Information Exchange"	**Completed, N19 released**
3 	Joint AHWP WG3 GHTF SG3, ISO/TC210 /WG1 meetings	ISO13485 update (user requirements survey, TC210 collaboration etc.) AHWP join ISO/TC210 Continue working and providing input on the revision of ISO 13485 - 2003	WG3 Chair & S. Advisor Participated. March 27-29 ,2012 .Chiswick UK **(Completed)** AHWP Accepted as a Liaison Member with ISO. **Completed. WG3 members Ali, Ee Bin, Jack Albert Li are now members** **500+ comments for CD completed,** now awaiting TC210 meeting in Stockholm
4	QMS Training Program	Develop training and information sharing program for QMS in conjunction with ISO Start QMS training program with 13485 guidance document for importer / distributor	To work with WG6 (Training) (Engage with WG6) Any time after Feb 2014

Work Plan Progress 2012-2014

Priority	Work Item	Deliverables	Action Plan and Timeline
5	Review released documents N17 Quality management system – Medical devices - Guidance on the control of products and services obtained from suppliers. N18 Quality management system – Medical Devices – Guidance on corrective action and preventive action and related QMS processes N15 R8/2005 Implementation of Risk Management Principles and Activities Within a Quality Management System N99-10 (Edition 2) Quality Management Systems - Process Validation Guidance	Revised to be more useful and usable guidance documents for adoption in AHWP member economies Must resolve the issue on member economies' adoption!!	TO complete by 2014 General AHWP issue TBD

Questions & Answers