ASIAN HARMONIZATION WORKING PARTY

WG7: QMS – Operations and Implementation

(formerly WG3 – Quality Management Systems)

WG3 (QMS) update
18th TC &19th AHWP Annual Meeting
Seoul , Republic of Korea
NOV 2014

By
Ali Al Dalaan (WG Chair)
Ee Bin Liew (WG Co-chair)

Achievements

- Guidance documents development 0ct 2008-Nov 2014.

- AHWP QMS Survey completed in Oct 2012:
  - Analysis done, and actions for a guidance document addressing the member economies' needs were initiated.

- ISO TC210 Activities

AHWP WG3

- Survey completed in 2012

Member Economies	Importer	Distributor/ Seller/ Authorized Representative	Manufacturer	OEM	Component Suppliers	Service Providers
Saudi Arabia	Yes	Yes	Yes	Yes	Yes	Yes
Abu Dhabi*	No	No	No	No	No	No
Yemen*	No	No	No	No	No	No
Jordan	No	No	Yes	Yes	No	No
Kuwait*	No	No	No	No	No	No
South Africa	no response	no response	no response	no response	no response	no response
Chile	No	No	No	No	No	No
Pakistan*	No	No	No	No	No	No
India	no response	no response	no response	no response	no response	no response
South Korea	Yes	Yes	Yes	Yes	No	No
China	Yes	Yes	Yes	Yes	Yes	Yes
Chinese Taipei	No	No	Yes	Yes	Yes	No
Hong Kong SAR	No	No	Yes	Yes	No	No
Singapore	Yes	Yes	Yes	Yes	No	No
Malaysia	No	No	No	No	Yes	Yes
Thailand	No	No	Yes	Yes	No	No
Philippines	No	No	Yes	Yes	No	No
Indonesia	Yes	Yes	Yes	Yes	No	Yes
Vietnam	No	No	Yes	Yes	Yes	Yes
Laos	Yes	Yes	Yes	No	No	No
Myanmar*	No	No	No	No	No	No
Brunei*	No	No	No	No	No	No
Cambodia*	No	No	No	No	No	No

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Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED FINAL DOCUMENT

Title: **Guidance on Medical Device Quality Management System**
- **Requirements for Distributors**

Author Working Group 7: Quality Management System - Audit & Assessment

Date July 2014

Mr. Ali M AL-DALAAN
Chair, Working Group 7

Guidance on Medical Device Quality Management-Requirements for Distributors

- AHWP TC WG3 provides this guidance document on the implementation of quality management systems to ensure their conformity with ISO 13485: 2003 expectations, and to ensure the medical device complies with the specifications and quality assurance requirements specified by the manufacturer
- Another purpose of this guidance document is to assist regulatory authorities and/or conformity assessment bodies in the planning and the performance for regulatory auditing of distributor under their jurisdiction.

GHTF SG3

- Since June 2008, AHWP WG3 chair, co chair and members had participated with GHTF SG3 for developing QMS guidance documents that have been adopted

- GHTF/SG3/N19:2012 - Quality management system - Medical devices - **Nonconformity Grading System** for Regulatory Purposes and Information Exchange

GHTF SG3

- GHTF/SG3/N18:2010 GHTF SG3 - Quality management system - Medical Devices - Guidance on corrective action and preventive action **(CAPA)** and related QMS processes

- GHTF/SG3/N17:2008 GHTF SG3 - Quality Management System - Medical Devices - Guidance on the Control of Products and Services Obtained from Suppliers **(Supplier Controls)**

IMDRF MDSAP WG

- IMDRF/MDSAP WG/N11FINAL:2014 MDSAP **Assessment and Decision Process** for the Recognition of an Auditing Organization
- IMDRF/MDSAP WG/N3FINAL:2013 **Requirements for Medical Device Auditing Organizations** for Regulatory Authority Recognition
- IMDRF/MDSAP WG/N4FINAL:2013 **Competence and Training** Requirements for Auditing Organizations
- IMDRF/MDSAP WG/N5FINAL:2013 **Regulatory Authority Assessment Method** for the Recognition and Monitoring of Medical Device Auditing Organizations
- IMDRF/MDSAP WG/N6FINAL:2013 **Regulatory Authority Assessor Competence** and Training Requirements

2012 Meetings

Day	Month	City	Country	Meeting	Who attended?
30-3	January / February	Mountain View, California	USA	GHTF / ISO	Ali
27-29	March	London	UK	ISO	Ali,Jack
9-12	July	Ottawa	Canada	GHTF	Ali
9-11	November	Santa Clara	USA	ISO	Albert

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2013 Meetings

Day	Month	City	Country	Meeting	Who attended?
28- 31	January	Brasilia	Brazil	IMDRF	Ali
4-7	Feb	Melbourne	Australia	IMDRF	Ali
11-15	March	Chiba	Japan	ISO	Ali, Ee Bin, Albert, Jack
9- 12	July	Tokyo	Japan	IMDRF	Ali
10 -13	September	Maryland	USA	IMDRF	Ali
29-3	September / October	Lyon	France	ISO	Ali, Ee Bin, Albert

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2014 Meetings

Day	Month	City	Country	Meeting	Who attended?
25 -27	March	San Francisco	USA	IMDRF	Ali
7-10	July	London	UK	IMDRF	Ali
8-12	September	Stockholm	Sweden	ISO	Ee Bin, Albert, Jack
15-18	September	Washington DC	USA	IMDRF	Albert

Work in Progress

- Continue to participate in ISO/TC 210/WG1 meeting for ISO13485-2003 Application of Quality System to Medical devices
- Provide training program for AHWP member economies in order to guide them on how to apply the guidance document

For Endorsement - Guidance on Quality Management System-Medical Device Requirements for Distributors

Scope of the document

- All AHWP member economies, for organizations that distribute or import medical devices

Objective of the document

- To provide medical device distributor as well as importer of AHWP member economies with the guidance on the implementation of quality management systems to ensure their conformity with ISO 13485: 2003 expectations.

Summary

- The distributor must ensure the products meet the requirements specified by regulatory authority and the manufacturers when they distribute, deliver or service medical devices.
- The safety and performance of finished medical devices may be affected by various conditions such as warehouse conditions, transportation, installation, servicing, duration of storage, and user training. Post-market surveillance activities such as collection of customer feedback, implementation of field safety corrective actions for the associated medical devices may be conducted by the manufacturer through cooperation with its distributors.
- To ensure the medical device continue to comply with the specifications and quality assurance requirements specified by the manufacturer, AHWP TC WG3 developed this guidance for organizations that distributes or import medical devices.
- Another purpose of this guidance document is to assist regulatory authorities and/or conformity assessment bodies in the planning and the performance for regulatory auditing of the distributors under their jurisdiction.
- This document provides guidance on the applicability and implementation of ISO 13485: 2003 clauses for medical device distributors.

Future Action Plan

- Implement guidance documents in AHWP member economies
- Continue to participate actively in TC210 WG1
  - Complete revision of ISO13485 (mid 2015)
  - Begin drafting revision of ISO/TR14969
  - Potentially give input to revision of ISO9001
- Review IMDRF- MDSAP Documents to developed pilot program among AHWP member economy (liaise withWG6)

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Thank You