WG6 – Quality System Audit & Assessment

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AHWP 19th TC Meeting
5 Nov 2015, Bangkok

AHWP
Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Work Plan 2015 - 2017

Priority	Work Item	Deliverables	Action Plan and Timeline
1	Finalizing Importer & Distributor Guidance doc.	Guidance document	Q4, 2015
2	Conducting training session during annual meeting on adopted guidance documents	Work shop	Annual meeting training
3	Reviewing IMDRF final document N3, N4, N5 & N6 for adoption	Guidance document	Q3, 2017

WG Progress Update

since last AHWP Seoul TC Meeting in 2014

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Work Item		Deliverables	Timeline
1	Reviewing IMDRF proposed documents N8R2 and N24R2	Guidance document	Q2, 2015
2	Finalizing the Distributor Guidance doc.	Guidance document	Q3, 2015
3	Conducting training session during annual meeting on adopted guidance documents	Workshop	Q4, 2015
3	Aligning WG6 documents with WG7 documents		Q1, 2016
4	Reviewing IMDRF final document N11 &N22	Guidance document	Q1, 2016
5	Reviewing IMDRF final document N3 &N4	Guidance document	Q3,2016
6	Reviewing IMDRF final document N5 &N6	Guidance document	Q1, 2017
7	Submit the IMDRF documents for comments as draft proposed documents for AHWP ME	Draft documents	Q2, 2017
8	Final documents to be submitted for comments	Final documents	Q3, 2017
9	Endorsement on the adopted documents during annual meeting	Final adopted document	Q4, 2017

IMDRF Final Documents

- N3:

Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition.

- N4:

Competence and Training Requirements for Auditing Organizations.

- N5:

Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations.

- N6:

Regulatory Authority Assessor Competence and Training Requirements

- N8:

Guidance for Regulatory Authority Assessors on the Method of Assessment for MD SAP Auditing Organizations

- N11:

MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization

- N22:

MDSAP: Overview of Auditing Organization Assessment and Recognition Decision Related Processes.

N4: Competence and Training Requirements for Auditing Organizations.

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This document applies to recognized Auditing Organizations conducting audits of a medical device manufacturer for regulatory purposes.

N5: Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations.

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The Assessment Program defines how Regulatory Authorities will recognize, monitor, and re-recognize Auditing Organization

N6: Regulatory Authority Assessor Competence and Training Requirements

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Adherence to this document and its requirements will help in:

1- Mitigate the risk of inconsistent or ineffective assessments of Auditing Organizations by

2- Ensuring that Regulatory Authority personnel have the necessary competence and training before conducting an assessment or participating in a decision to recognize an Auditing Organization.

N11: MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization

This document define:

1- The process and lifecycle for recognizing, maintaining, or ceasing recognition of an Auditing Organization.

2- The process of managing, grading, and closure of assessment nonconformities issued to an Auditing Organization; and,

3- The outcomes of an initial, surveillance, or re-recognition assessment process of an Auditing Organization.

Guidance on Regulatory Auditing of Quality Management System of Medical Device Distributors: Auditing Strategies

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- ## Scope of paper:

provide medical device distributor of AHWP member economies with the guidance on the implementation of quality management systems to ensure their conformity with Quality management systems - Requirements.

- ## Objective of paper:

1. The effectiveness of the distributor's QMS.
2. Harmonization and mutual recognition of audit results.
3. Determining how problems associated with the QMS are recognized and addressed
4. The audit transparency

Auditing Strategies

- Summary:
  1. This guideline will limit its coverage to ISO 13485:2003. Where additional regulatory requirements apply and are part of the scope of the audit,
  2. This guideline applies to all kinds of audit (initial, surveillance audits, etc..)
  3. Will determine the subsystem elements selected for the audit.
  4. This guidance applies to an organization which distributes or imports medical devices.

Regulatory Audit Report Guidance Document

- Scope of paper:

  This document is intended to be used by regulators and auditing organizations as a guide for writing a report of a regulatory medical device quality management system audit

- Objective of paper:

  1. To document the audit scope, type of audit, audit objectives, the audit criteria, what was covered during the audit, and the audit findings
  2. To evaluate the auditee's compliance status, the effectiveness of the implementation of quality management system, and draw audit conclusions
  3. To allow the exchange of audit reports between regulators and/or auditing organizations

Audit Report

- Summary:
  1. This guideline promotes consistency in audit reports – important in harmonization.
  2. The audit report should demonstrate that the audit was sufficiently thorough and complete.
  3. This guideline will provide a structure for audit reports.
  4. Having reports that are consistent in content will facilitate the review and exchange of audit reports.
  5. This document may also be used in support of bilateral and multilateral agreements.

Distributor Auditing Checklist

- Scope of paper:

  Provide the auditor a complete check list based on the audit criteria.

- Objective of paper:

  Support the auditor to complete the audit within the audit scope and audit criteria

- Summary:

  A documents of 4 pages contains table with 23 items covering distributor QMS.

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Thank you