WG6 – Quality System Audit & Assessment

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Member List

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Ms. Sumati Randeo	India	Industry
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Miss Hailey Chu Hui-ju	Chinese Taipei	Industry
Mr. Peter Kyongho	Korea	Industry
Mr. Kenneth Cheing Teng Wan	Singapore	Industry

Group Action Plan

Work Item	Deliverables	Status
A guidance to understanding best practices in audit life cycle management	GD	Call for comments
A guidance to understanding presently available audit duration determination systems.	GD	Call for comments
Conduct training session	workshop	Done
A guidance for auditing supplier to medical devices manufacturers	GD	Call for comments

Guidance to understanding best practices in audit life cycle management

This document is intended to guide the regulator on several IMDRF documents with different topics on the audit life cycle from different angles.

- AOs req. for RA recognition. (N3)
- Training, competence, and qualification of various personnel who represent AO. (N4)
- RA methods for recognition & monitoring by defining assessment program based on N3&N4 requirements. (N5)
- General framework on the competence and training requirements of assessors representing RA. (N6)
- Provides guidance on how a regulatory authority should conclude the assessment often auditing organization and to develop a strategy for continual monitoring. (N11)

Purpose

This guidance document serves to present and summarize the current best practices on how to ensure that auditing organization shall be assessed in respect of their competence and qualifications.

Guidance to understanding presently available audit duration determination systems

Presently 2 systems are widely used.

- The International Accreditation Forum has published a series of documents to guide Certification Bodies in determination of audit time MD9 & MD5
  - does not stipulate minimum/maximum times but provides a framework that shall be utilized within a CAB's documented procedures to determine appropriate audit duration, taking into account the specifics of the client to be audited
  - Audit day = 8h, # of personnel depends on the scope of the audit, the percentage of the on-site audit and the off-site audit, with considering not to reduce the on-site audit less than 80% of the total audit duration, Additional time required for planning and report writing will not be a justification for reducing the on-site audit duration.
- Alternatively, the regulators who presently participate in the MDSAP scheme have developed a determination scheme
  - Calculation of the audit duration is primarily based on the number of tasks associated with audit type

it is important that regulators are able to have a technical basis to determine the duration of an audit it is planning

Purpose

This guidance document serves to summarize the current best practices on audit duration determination with the aim of eventually developing an audit duration guidance for regulators for the purpose of auditing medical device manufacturers and distributors.

Guidance for auditing suppliers to Medical devices Manufacturers

The following major steps serve as a guide in the audit of the Purchasing controls Subsystem:

- Verify that procedures for conducting supplier evaluations have been established
- Verify that the manufacturer evaluates and maintains effective controls over suppliers
- Verify that the manufacturer assures the adequacy of specifications for products and services that suppliers are to provide, and defines risk management responsibilities and any necessary risk control measures
- Verify that records of supplier evaluations are maintained

Purpose

The purpose of auditing the purchasing control subsystem is to verify that the manufacturer's processes ensure that products, components, materials and services provided by suppliers, (including contractors and consultants) are in conformity

References

- ISO 13485: 2003 Medical devices — Quality management systems — Requirements for regulatory purposes
- IAF MD5 & MD9
- IMDRF/MDSAP WG/N3 FINAL:2016 (Edition 2)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
- IMDRF/MDSAP WG/N8 FINAL: 2015 Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations
- IMDRF/MDSAP WG/N11FINAL:2014 MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization


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