GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

FINAL DOCUMENT

Title: **A Guide to Understanding Best Practices in Audit Life Cycle Management**

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Acknowledgements

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1. Preface

The document herein is published by the Global Harmonization Working Party (GHWP), a voluntary group of representatives from medical device regulatory authorities and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development process.

2. Introduction

Auditing the quality management system of economic operators is a universal requirement of medical device legislatures. To this, the objective of auditing medical device manufacturers serve to confirm that devices designed and manufactured consistently meet specified requirements including regulatory and state of the art specifications. Likewise, auditing distributors serve to ensure that processes including those related to control of distribution records, post market requirements and specifications related to installation and servicing are continually fulfilled In the course of establishing an auditing model in fulfilment of regulatory requirements, it is essential that various aspects of the auditing model are managed and controlled

3. 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.

4. Scope

The scope of this guidance document encompasses quality management system auditing processes which a Regulatory authority may implement in its efforts to appoint and qualify auditing organizations. Alternatively, a Regulatory authority which intends to act as an auditing organization shall also find the guidelines described herein of immense value.

5. References

IMDRF/MDSAP WG/N3 FINAL: 2016 (Edition 2) Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition

IMDRF/MDSAP WG/N4 FINAL: 2021 Competence and Training Requirements for Auditing Organizations

IMDRF/MDSAP WG/N5 FINAL: 2013 Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations

IMDRF/MDSAP WG/N6 FINAL: 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 DSAP Assessment and Decision Process for the Recognition of an Auditing Organization

6. Discussion

6.1 Presently available guidelines

The requirements of the international standard, ISO 17025 (now in its 2017 edition) is widely recognized as the final authority in respect of accreditation of quality management system conformity assessment bodies. In this regard, the requirements specified in this ISO document apply as assessment criteria when an accreditation organization assesses a certification body. In parallel, auditing organizations for medical devices are themselves certification bodies what engaged in auditing clients who are involved in various phases off the life cycle of a medical device. Importantly, the stakeholders involved in designing and manufacturing of medical devices shall be audited continually to ensure that medical devices fulfill applicable regulatory requirements pertaining to quality management system. While the requirements of 17021 prevail where assessment of an auditing organization is concerned, medical devices regulators who intend to adopt the requirements of ISO 17021 should also review the IMDRF documents discussed in this guidance. The situations which necessitate the incorporation of IMDRF guidance documents include at least the following:

- Certain ISO 17021 requirements may be irrelevant in the case where a regulatory authority itself serves as the auditing organization.
- Additional guidance specific to the medical device industry to supplement ISO 17201 Requirements.

In light of this, this GHWP document is intended to guide an interested regulator on this IMDRF guidance documents which are discussed in remaining sections of Section 6. AA general summary of each document is given in Section 7.0.

6.2 IMDRF/MDSAP WG/N3FINAL:2013

This document should be read together with ISO 17025 (now in its 2017 edition) as a Regulator develops the overarching requirements on the quality management system requirements which an auditing organization must fulfill. While ISO 17025 serves to provide the core requirements, WG/N3:2013 supplements additional requirements which may apply in the context of a medical devices. Also, it is widely recognized that certain ISO 17021 may not be relevant to an auditing organization which is in essence a regulatory authority itself. To this, the document WG/N3:2013 explicitly explains which requirements are of no relevance and how the situation shall be addressed.

6.3 IMDRF/MDSAP WG/N4FINAL:2021 (Edition 2)

The document WG/NF 2021 specifically addresses the qualification of various personnel who represent the auditing organization. This document will assist regulators in developing requirements on how the auditing organizations they are assessing will qualify and authorize its personnel including lead auditors, auditors, final reviewers, technical experts, etc. The requirements specified in this procedure which a regulator may utilize includes requirements pertaining to education, experience and competence. In addition the document also specifies the need for an auditing organization to re-evaluate the competence of its personnel using a combination of monitoring methods. The 2021 version of this document includes requirements such as reaffirmation of the code of conduct on an annual basis as given in IMDRF MDSAP WG N3 clause 7.1.6.

To address the diversity of medical devices on any given market, this guidance document has classified the required knowledge of medical devices into specific classes such as non-active medical devices, active non implantable medical devices, active implantable medical devices, in vitro diagnostic medical devices etc. These broad groups are further divided by the writers into secondary groupings in order that the qualification of auditing personnel maybe further specified and detailed where necessary. For example, non-active medical devices are divided into secondary groupings which include non-active implants, medical devices for wound care, non-active dental devices, and general non active medical devices.

6.4 IMDRF/MDSAP WG/N5FINAL:2013

The document WG/N5 2013 supports a medical device regulator by providing a framework on how an auditing organization shall be assessed. Technical requirements such as various types of audits and assessments including details and significance of Stage 1 assessments, stage two on site assessments and witnessed audits are comprehensively discussed alongside those for surveillance on site assessments and re recognition on site assessments. Further, the document provides an assessment method which allows the regulatory authority to identify and subsequently focus on process elements to be assessed. These also describe the relative risks if any of the audited processes are shown to be not in compliance with the audit criteria.

6.5 IMDRF/MDSAP WG/N6 FINAL: 2013

The document, WG/N6 FINAL: 2013 provides a general framework on the competence and training requirements of assessors representing the regulatory authority. A regulate authority will understand the IMDRF requirements for ensuring that assessors are competent. These requirements include entry level requirements, prerequisite education and experience and competence requirements.

6.6 IMDRF/MDSAP WG/N8 FINAL: 2015

The document, WG N8 2015 is established to provide guidance to the documents WG N5 and WG N 6.

6.7 IMDRF/MDSAP WG/N11 FINAL: 2014

The document, WG N11 2014 specifies a Decision process for a regulatory authority to determine if an auditing organization can be recognized after the initial assessment(s) have concluded. Included herein is the specified process for reporting of nonconformities arising from the assessment of an auditing

organization, including a prescribed system for grading of nonconformities. The regulatory authority is also guided on the standard contents of an assessment report.

7. Summary

The following is a summary of the roles of the IMDRF documents described in Section 6.0

Document	Present Revision	Summary of role
IMDRF/MDSAP WG/N3FINAL:2013	2013	Provides additional requirements which an auditing organization must comply with. Also provides guidance on supplement the interpretation of situations where a specific ISO 17025 requirement is not suitable to be followed by regulatory authorities who also serve as an auditing organization or unit.
IMDRF/MDSAP WG/N4FINAL:2021 (Edition 2)	2021	Defines and establishes competence and training requirements for personnel representing the auditing organizations that it will recognize
IMDRF/MDSAP WG/N5FINAL:2013	2013	Guides the regulatory authority on how to assess auditing organizations
IMDRF/MDSAP WG/N6FINAL:2013	2013	Guides the regulatory authority on how to qualify its assessors who shall assess auditing organizations
IMDRF/MDSAP WG/N8 FINAL: 2015	2015	Provides additional guidance on documents IMDRF/MDSAP WG/N5 FINAL: 2013 and IMDRF/MDSAP WG/N6 FINAL: 2013

IMDRF/MDSAP WG/N11FINAL:2014	2014	Provides guidance on how a regulatory authority should conclude the assessment of an auditing organization and to develop a strategy for continual monitoring

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