GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED DOCUMENT

Title: **Guidance for Auditing Supplier to Medical Device Manufacturers**

Authoring Groups: Work Group 7 - Quality System Auditing

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Abdullah Al Rasheed

Chair of Former Working Group 6

Table of Content

1. Preface

The document herein was produced by the Asian 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

Suppliers of raw materials and components are examples of stakeholders whose output ultimately affects the medical device's safety and effectiveness. The decision to audit suppliers as part of regulatory audit performed on a medical device manufacturer is a critical one. While it is impossible to audit all suppliers particularly if one considers that subcontracting is so widely practised in the medical device industry today, to decision to perform (or not perform) an audit must be based on a risk based approach.

3. Purpose

This document sets forth guiding principles adapted from the EU Notified Body (NBOG) Best practice guide i.e. NBOG 2010-1

4. Scope

The scope of this guidance document encompasses quality management system auditing processes to be established and implemented by Regulatory authorities and/or the conformity assessment bodies appointed by them under prevailing legislature

5. References

NBOG's Best Practice Guide NBOG BPG 2010-1 Guidance for Notified Bodies auditing suppliers to medical device manufacturers

6. Audit of the purchasing system of the manufacturer

6.1 General

The manufacturer should establish and maintain documented procedures and records to ensure that products or services purchased from their suppliers meet the relevant regulatory requirements.

Purchasing controls will be first assessed by the Regulator or conformity assessment body at the premises of the manufacturer. Hereby, the auditing entity should use section 7.4 of EN ISO 13485 and the requirements set forth in the MDSAP document Audit Approach P0002.005 Revision Date 2020-09-01.

Objective: 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. This is particularly important when the finished product or service cannot be verified by inspection (e.g. sterilisation services).

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

1. Verify that procedures for conducting supplier evaluations have been established. (ISO 13485:2016: 7.4.1)

- Documented process/product controls for manufacturer and supplier
- Supplier Management Procedures

2. Verify that the manufacturer evaluates and maintains effective controls over suppliers, so that specified requirements are met. (ISO 13485:2016: 7.4.1)

- Supplier selection criteria & decision rationale
- Competency of the selector of the supplier
- Supplier agreements (see Appendix 2 for details)
- Change Management Methodology and Records

3. 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. (ISO 13485:2016: 7.4.2)

- Specifications, requirements, procedures & work instructions
- Documented list of the risks identified for the products and services supplied, and linkage to design and planning
- Quality Requirements documented

- Capability assessment of the supplier
- Contracts, Purchase Orders

4. Verify that records of supplier evaluations are maintained. (ISO 13485:2016 7.4.1)

- Audits Reports (1st, 2nd, & 3rd Party)
- Correspondence (Supplier File; e.g. Change control, audits, CAPAs)
- Minutes of Meetings with Supplier
- CAPA relating to products and services supplied
- Verification of incoming products

5. Determine that the verification of purchased products and services is adequate. (ISO 13485:2016: 7.4.3)

- Acceptance procedures for incoming products
- Specifications & Procedures
- Documented process/product controls for manufacturer and supplier

Evaluate the Purchasing Controls subsystem for adequacy based on findings."

6.2 When should the actual supplier be audited?

The auditors should determine and document the need to audit at a supplier's premises depending on:

– the outcome of the audit of the manufacturer's purchasing process (as outlined in Appendix 1) and other processes, described above.

The auditing entity should have predefined decision criteria, which they use to decide, based on audit outcome if an audit of a particular supplier is required.

Information derived from the audit may include:

- information of the product realisation processes, including data from incoming acceptance activities and production controls
- whether the manufacturer performs an inspection on the product or service supplied
- whether faults in the product supplied can be detected at some later stage in production
- whether the history/data relating to suppliers is sufficient

- whether there is third party certification of suppliers and whether this certification alone is adequate

– the criticality of the item or process being purchased, i.e. the effect purchased product/service might have on the subsequent product realisation or the final product

Critical items or processes may include:

- Finished products
- Primary packaging
- Sterilisation
- Contract laboratories (e.g. biocompatibility)
- Services (Design, Distribution, and Regulatory Compliance etc.)
- Labeling
- Other similar cases where the conformity of the finished medical device is significantly influenced by the activity of the supplier and the manufacturer cannot demonstrate sufficient control over the supplier via purchasing controls and incoming acceptance activities

Note: It is the responsibility of the manufacturer to determine which are critical items or processes and how their purchase is controlled. This depends on the manufacturer's risk management activity. However, the auditing organization may decide to visit suppliers deemed by the manufacturer to be non-critical.

– In response to post market information

- Field Safety Corrective actions impacting on the supplier's processes or products
- Complaints relating to the supplier's processes or products
- Post-market information, e.g. clinical investigations, public information etc., relating to the supplier's processes or products

In principle, premises of critical suppliers should be audited. In cases where the manufacturer is not able to give satisfactory evidence to the Conformity Assessment Body that purchase of critical products or services meet the specified requirements (e.g. relying solely on the supplier's certification to ISO 9001 or ISO 13485), the Conformity Assessment Body needs to audit the control of processes on the premises of the manufacturer's suppliers (e.g. sterilisation suppliers). The Notified Body has to audit each of these suppliers unless there is enough evidence provided by the manufacturer demonstrating that sufficient controls have been established and implemented.

6.3 What should be audited at supplier premises?

The objective of an audit at a supplier's premises is to:

- verify manufacturer's supplier control is effective to ensure the purchased product or service conforms to the specified requirements

- assess the supplier's ability to provide a product or service that consistently meets specified manufacturer requirements including quality requirements

An audit at a supplier should be carried out as part of the audit of the manufacturer's purchasing activity. It should not take the place of a Second Party1 audit carried out on behalf of the manufacturer.

An audit at a supplier assesses the implementation of the requirements placed upon the supplier by the manufacturer as documented in the agreement between the two parties. The adequacy of this agreement, including its scope, should be assessed as part of the audit of the manufacturer. Although ISO 13485 or an annex of the relevant directive may be used to assist in the assessment of the suitability and implementation of the agreement, the audit of a supplier does not necessarily assess the supplier against the whole of ISO 13485 or an annex of the relevant directive.

Any nonconformity identified in the supplier audit will normally be documented as nonconformity against the manufacturer.

Audits at supplier's premises need to be adequately documented. This can be done either in the audit report of the manufacturer's quality system or in separate report(s). If a separate report is written, the Conformity Assessment Body should make clear the reason for the audit of the particular supplier and should address the audit report to the manufacturer and not to the supplier.

It is the manufacturer's responsibility to discuss the reported findings of the audit with the supplier and to follow up on any nonconformity raised. However, if agreed by all parties, the results of the audit at the supplier may also be made available to the supplier for information.

The rationale for auditing a particular supplier should be documented either in the audit report or in a separate document generated as part of the preparation for the audit.

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