PROPOSED DRAFT

DOCUMENT

Global Harmonization Task Force

Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers

Part 5: Audits of manufacturer control of suppliers

Authoring Group: Study Group 4

Date: 13. November 2009 – Proposed Draft

Table of Contents

Preface

The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory agencies 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.

There are no restrictions on the reproduction, distribution or use of this document; however, incorporation of this document, in part or in whole, into any other document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the Global Harmonization Task Force.

1.0 Introduction

This document follows on from SG4/N28R4:2008: Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 1: General Requirements and SG4/N30R20:2006: Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy.

It is based on the principle set out in Section 3 of SG3/N17:2008 Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers:

> *"Within existing regulatory frameworks the term "manufacturer" may be defined differently. However, each regulatory authority ultimately holds one "manufacturer" of medical devices or entity primarily responsible for meeting regulatory quality management system requirements. This "manufacturer" or entity, that has the ultimate responsibility for its quality management system, cannot relinquish (contractually or otherwise) its obligation and responsibility over any or all functions within the quality management system. This means the responsibility for complying with the quality management system requirements cannot be delegated to any supplier of products and services."*

2.0 Scope

This document gives guidance for the auditing of a manufacturer's purchasing controls, including the audit of the suppliers when suppliers should be audited and what a supplier audit should cover, adding to the guidance given in N28 and N30.

3.0 Rationale

This guideline will provide additional information about audit strategy to regulators, auditing organizations and to auditors for auditing a manufacturer's purchasing controls as well as on the performance of audits at the manufacturer's supplier(s).

The main aim of the guidance is to promote consistency in conducting audits – a necessity for harmonization and mutual recognition of audit results.

4.0 References

SG3/N17:2008 Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers

SG4/N28R4:2008: Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 1: General Requirements

SG4/N30R20:2006: Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy

SG4/N33R16:2007: Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports

SG1/N055:2009 : Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer

5.0 Definitions

5.1 Supplier (ISO 9000:2005, Clause 3.3.6) Organization or person that provides a product

EXAMPLE: Producer, distributor, retailer or vendor of a product, or provider of a service or information.

NOTE 1: A supplier can be internal or external to the organization.

NOTE 2: In a contractual situation a supplier is sometimes called "contractor or consultant".

NOTE 3: For the purpose of this document, the supplier refers to an organization or person outside the QMS of the manufacturer

NOTE 4: This document addresses suppliers outside of the QMS of the manufacturer. Suppliers within the QMS of the manufacturer are addressed in GHTF SG4/N83 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 4: Multiple Site Auditing

NOTE 5: In the context of auditing medical device manufacturers, this definition applies regardless of the legal or financial relationship between the manufacturer and the supplier.

5.2 Manufacturer (SG1(PD)/N055R6**)**

Any natural or legal person who designs and/or manufactures a medical device with

the intention of making the finished medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by a third party(ies).

> *Note:* the term "Virtual Manufacturer" is sometimes used for a manufacturer which subcontracts nearly all of the design, production and other activities associated with making the finished medical device on the market.

5.3 Critical supplier

A supplier delivering materials, components, or services, that may influence the safety and performance of the product. (N33)

> *Note:* In the context of audit of medical device manufacturers, a critical supplier is a supplier of a product or service, the failure of which to meet specified requirements could cause unreasonable risk to the patient, clinician or others, or could cause a significant degradation in performance.

This can include suppliers of services which are needed for compliance with QMS or regulatory requirements, eg internal audit contractors or EU Authorised Representatives

6.0 Audit Principles

6.1 General principles

Purchasing controls should always be first assessed at the premises of the manufacturer and the guidance from N30 7.6 is reproduced below, together with some examples of objective evidence derived from GHTF/SG3/N17:2008 which may be used by the auditor. Depending on factors such as the outcome of this assessment, the degree of incoming inspection, and the criticality of the outsourced product or process, it may be necessary for the conformity assessment body to visit the supplier's premises – see Para 5.2.

"*N30 7.6 Purchasing Controls Subsystem*

The Purchasing Controls subsystem should be considered a main subsystem for those manufacturers who outsource essential activities such as design and development and/or production to one or more suppliers.

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., sterilization services).

Major Steps: The following major steps serve as a guide in the audit of the Purchasing Controls Subsystem. The bullet points, which give examples of objective evidence, were drawn from the flow chart reflected as Figure 1 in SG3 N17 on page 9 .

1. *Verify that procedures for conducting supplier evaluations have been established.(ISO 13485:2003: 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 13485:2003: 7.4.1)*
    - *Supplier selection criteria & decision rationale*
    - *Competency of the selector of the supplier*
    - *Supplier agreements*
    - *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 13485:2003: 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 13485:2003: 7.4.1)*
    - *Audits Reports (1st, 2nd, & 3rd Party)*
    - *Correspondance (Supplier File) (e.g.; Change control, audits, CAPAs etc)*
    - *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 13485:2003: 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 Decision on whether to audit at the supplier premises

This decision should be based on GHTF/SG4/N28R4:2008 10.4.4:

> *"The manufacturer should establish and maintain documented procedures to ensure that purchased product or services from their suppliers meet the relevant regulatory requirements. In cases when the manufacturer is not able to give satisfactory evidence to the audit team that purchased product or services meet the specified requirements, the auditing organization may need to audit the control of processes on the premises of the manufacturer's suppliers (e.g. sterilization suppliers)."*

The auditor(s) should determine the need to audit at the supplier premises. The reasons for deciding to audit at the supplier premises should be documented. The decision should take into account:

- *Regulatory Requirements*
- The criticality of the item or process being purchased, i.e. the effect the purchased product/service might have on the subsequent product realization or the final product (see SG3(PD)N17/R7 3.3.1)

    Critical items or processes may include:

    - Finished product
    - Primary packaging
    - Sterilization
    - 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
    - Contract Laboratories (e.g.; Biocompatibility)
    - Services (e.g.; Design, Distribution, Regulatory Compliance)

- Labeling

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

- The outcome of the audit of the manufacturer's purchasing and other processes. This can include:
    - Information derived from the audit of the product realization processes, including data from incoming acceptance activities and production controls
    - Whether the manufacturer performs an inspection on the product or service supplied, or whether faults in the product or service supplied will be detected at some later stage of production
    - Insufficient history
    - Lack of 3rd Party Certification
- In response to post market information.
    - Complaint
    - Post market information, eg manufacturer studies, public information etc

6.3 Audit at supplier premises

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

- to verify manufacturer's supplier control is effective to ensure the purchased products conform to the specified requirements
- assess the supplier's ability to provide a product or service that consistently meets specified manufacturer requirements including quality requirements

Note: The exact objective may vary according to the regulatory regime.

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

An audit at a supplier assesses the implementation of the requirements placed upon supplier by the manufacturer as documented in the agreement between the two parties. The adequacy of the agreement should be assessed as part of the audit of the Manufacturer. See 5.1 1.

Although ISO13485 or other regulatory requirements may be used to assist in the examination 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 other regulatory requirements.

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

Note : Some regulatory authorities may require nonconformities to be addressed directly to the supplier.

6.4 Reporting

The audit at a supplier may be covered in the audit report given to the manufacturer, or may be in a separate report.

If a separate report is written of the audit at a supplier, it should make clear the reason for the audit.

Note: Although the audit report may be addressed to the manufacturer and not the supplier, in some jurisdictions and situations the audit report will go only to the supplier.

It is the manufacturer's responsibility to discuss the findings with the supplier and to take any necessary action.

The auditing organization's rationale for auditing a supplier should be documented. This may be included in the audit report, it may also be in a separate document generated as part of the preparation for the audit. The rationale needs to be completed after the audit.

Note: Some regulatory authorities may require rationale for not auditing a critical supplier.