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FINAL DOCUMENT

Global Harmonization Task Force

Title: Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: General Requirements - Supplement No. 4 - Compilation of Audit Documentation (Clause 5.7)

Authoring Group: Study Group 4

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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.

Preface

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1.0 Introduction

This document has been written to provide assistance in the application of the 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: General requirements' and should be read in conjunction with that document.

Auditing organisations should establish a system to document and archive records of all regulatory audits to demonstrate the compliance status history for any manufacturer that has been audited.

The type, format and extent of the documentation required by the auditing organisation will depend upon a number of factors including the nature of their roles and responsibilities in the regulatory process.

The benefits of compiling audit documentation are as follows:

For the auditing organisation:

- Audit documentation assists the auditing organisation in making and supporting a decision about the compliance status of the manufacturer and appropriate action as required.
- The next auditor to audit the manufacturer will have information on the manufacturer's regulatory history and quality system activities reviewed during the previous audit.

For the manufacturer:

- Audit documentation results have the potential to benefit manufacturers' management such that improvements of the quality system or products can be initiated.

2.0 References

Guidelines for Regulatory Auditing of Quality Systems of Medical Devices Manufacturers, Part 1: General Requirements (GHTF SG 4(99)28).
Clause references refer to this guideline.

3.0 Definitions

Compliance status is the outcome of the quality system assessment to determine conformance with regulatory requirements (Clause 4.11).

4.0 Scope

This document provides guidelines for compiling audit documentation within auditing organisation for internal use.

This document does not address the exchange of audit documentation between auditing organisations.

The following are examples of the relevant documents although some may not be essential for all audits.

5.0 Pre audit

(a) Regulations and/or standards applied.

(b) Report on any pre-audit visits made to the manufacturer.

(c) Results and any conclusions from the pre-assessment of the manufacturer's quality system if conducted before the site visit and as permitted by the regulatory system. (Clause 11.1.2)

(d) Report on last audit together with:

- i. Non-conformities from last audit.
- ii. Quality system element audit history from last audit.
- iii. Action items recommended from last audit.
- iv. Corrective action programme and supporting documentation from last audit. (Clause 12)

(e). Record of audit team selection including resolution of any matters concerning conflict of interest and any observers if proposed. (Clause 11.1.4)

(f) Site visit audit plan. (Clause 11.1.3)

(g) Post market surveillance data. (Clause 8.3a)

(h) Manufacturer's application for an initial audit providing information about the organisation, location address, and range of devices covered by the audit, working language(s) etc.

(i) Information about changes to the manufacturer's quality system. (Clause 8.3 b. i & ii)

(j) Information about changes to the manufacturer's range of medical devices within the scope of the quality system to be audited. (Clause 8.3 b. iii)

6.0 Observed Audit Process

(a) Checklists used by auditors during the audit. (Clause 11.1.5)
(b) Hand-written or other notes made by the auditors during the audit. (Clause 11.1.5)
(c) Record of documents reviewed, if information is not recorded in items 6a or 6b.
(d) Record of quality system elements audited.
(e) Record of processes, device designs and corrective action inputs audited
(f) Copies of manufacturer's documentation collected during the audit. (Clause 11.2.2.2)
(g) Observations and non-conformities identified during the audit (Clause 11.2.3) and the names of the key staff interviewed.
(h) Record of medical devices affected by major non-conformities (Clause 11.2.4).
(i) Report prepared by the audit team at the end of the audit (Clause 11.3).
(j) Opening and closing meeting attendance record.
(k) Corrective actions closed out during the audit or corrective actions promised at the closing meeting and projected completion dates if provided.
(l) Action items recommended for next audit.
(m) Advisory information for manufacturer for maintaining and improving the quality system.

7.0 Post Audit

(a) Report prepared by the audit team for the auditing organisation and auditee.
(b) Action items recommended for the next audit if not addressed during the audit (item 6 l above).
(c) Review of audit by the auditing organisation.
(d) Correspondence with manufacturer on corrective action plans etc.
(e) Corrective action programme arising from this audit and any supporting documentation (e.g. objective evidence). This documentation would normally be used in the auditing organisation review of the audit and taken into account in the audit decision. (Clause 12).
(f) Compliance status decision record.
(g) Conformity assessment document (certificates and/or letter as appropriate).
(h) Plans for the next audit.