



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED DOCUMENT

Title: Regulatory Audit Report Guidance Document

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Mr Abdullah AL RASHEED
Chair, Working Group 6

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Preface

The document herein was produced by the Asian Harmonization Working Party (AHWP), 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.

Introduction

This document gives guidance to regulators, auditing organizations and auditors on the content of audit reports. However, it may also help the auditee understand and respond to the audit findings.

Potential benefits for the regulators and auditing organizations include:

- Greater consistency in audit reports both among auditors within an auditing organization and between auditing organizations
- Greater collaboration between regulators/auditing organizations in regard to regulatory audits
- Increased confidence in audits performed by an auditing organization and acceptance of those audits by other regulators
- Saving resources
- Guidance for countries developing medical device regulatory systems

Potential benefits for the Importer / Distributer of medical devices include:

- Improved communication that results in improved quality management systems and product quality and safety
- Greater consistency in audit reports
- Reducing the number of times a single Importer / Distributer undergoes audits
- Saving resources
- Increased confidence in, and acceptability of, audit reports

1.0 Scope

This document is intended to be used by regulators and auditing organizations as a guide for writing a report of a regulatory medical device quality management system audit. Such audits will be based on the process approach to quality management system requirements.

It may be necessary to address additional regulatory requirements to meet the needs of the regulators receiving and using the audit report. The level of detail in the audit report will vary according to its likely use. This guideline describes a report which can be exchanged with other regulatory or auditing Organizations with which the auditing organization has a formal relationship concerning confidentiality.

2.0 Purpose

The purposes of this document are to harmonize the content of audit reports and to provide guidance on best practices for reporting audit results.

3.0 Rationale

This guideline promotes consistency in audit reports – important in harmonization and mutual acceptance of audit results.

The audit report should demonstrate that quality management system and regulatory requirements were audited and that the audit was sufficiently thorough and complete.

This guideline will provide a structure for audit reports that may be used in multiple jurisdictions, promoting consistency and uniformity and will assist the auditor in preparing a report for use by multiple regulators and/or auditing organizations.

Having reports that are consistent in content will facilitate the review and exchange of audit reports. Acceptance of audit reports by multiple regulators should eventually reduce the number of audits for manufacturers.

This document may also be used in support of bilateral and multilateral agreements.
Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device
Manufacturers

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4.0 References

GHTF/SG4/N28R2: Guidelines for Regulatory Auditing of Quality Systems of Medical Device
Manufacturers – Part 1: General Requirements (1999)

GHTF/SG4/N30R18: Guidelines for Regulatory Auditing of Quality management systems of
Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy (final document 16 February
2006)

GHTF/SG2/N36R7: Manufacturer's Trend Reporting of Adverse Events US FDA 21 CFR Part 820 –
Quality System Regulation (October 7, 1996, Federal Register 61 FR 52602)

ISO 9000:2005: Quality Management Systems – Fundamentals and Vocabulary ISO 13485:2003:
Medical devices – Quality Management Systems – Requirements for Regulatory Purposes

ISO 19011:2002: Guideline for Quality and/or Environmental Management Systems Auditing

AHWP/WG4/NXPDRX: Guidance on Regulatory Auditing of Quality Management System of Medical
Device Distributors: Auditing Strategies

5.0 Definitions

Adverse event:

An “Adverse Event” is either a malfunction or a deterioration in the characteristics or performance of a sold medical device [including accessory(s) and labeling] or use error, which either has caused or could have caused or contributed to death, or serious injury to health of patients or other persons. (GHTF SG 2/N36R7)

Audit:

A systematic independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled. (ISO 19011:2002)

Note 1: Regulatory audit: The audit of a quality management system to demonstrate conformity with quality management system requirements for regulatory purposes.

Note 2: For the purpose of these guidelines, “audit” means a regulatory audit

Audit findings

Results of the evaluation of the collected audit evidence against audit criteria

Note: Audit findings can indicate either conformity or nonconformity with audit criteria or opportunities for improvement (ISO 19011:2002)

Compliance / Conformity

Fulfillment of regulatory requirements

Note: In this document the terms “compliance” and “conformity” are used interchangeably whereas in some jurisdictions they may have distinct and different meanings.

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Critical supplier

A critical supplier is a supplier delivering materials, components, or services, that may influence the safety and performance of the product.

Designating Authority (DA)

Body established within government or empowered by government to designate auditing organizations, suspend or withdraw their designation or remove their suspension from designation.

Distributor:

Any natural or legal person that distributes, deliver, install or services medical devices in accordance with the requirements specified by manufacturer.

Note 1: An Authorized Representative is a natural or legal person that receives a written mandate from a manufacturer of another jurisdiction to act on his behalf for specified task including the obligation to represent the manufacturer in its dealing with regulatory requirements.

Note 2: An importer is a natural or legal person that imports products from a manufacturer of another jurisdiction.

Nonconformity

Nonfulfillment of a requirement
(ISO 9000:2005)

Note: For explanation of the term “major nonconformity” see SG4N28

Regulatory audit report

The regulatory audit report is a document or set of documents from the regulatory audit team containing administrative data, a summary of the locations, functions or processes that were audited, audit findings and conclusions.

Note: For the purpose of these guidelines, “audit report” means a regulatory audit report

Regulatory requirements

Any part of a law, ordinance, decree, or other regulation which applies to medical device Manufacturers.

Note 1: Guidelines, draft documents or the like should not be used as regulatory Documents and should not be construed as such unless formally promulgated.
[GHTE/SG4/(99)28]

Note 2: For the purpose of this guidance regulatory requirements are restricted to those pertaining to the quality management system.

6.0 Objectives and User Needs of a Regulatory Audit Report

6.1 Audit report objectives

The audit report comprises the documented evidence of a regulatory audit. It should contain sufficient information:

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- To document the audit scope, type of audit, audit objectives, the audit criteria, what was covered during the audit, and the audit findings

- To evaluate the auditee's compliance status, the effectiveness of the implementation of quality management system, and draw audit conclusions
- To allow the exchange of audit reports between regulators and/or auditing organizations

6.2 User needs for the auditing organization/regulator

The auditing organization/regulators may use audit reports for the following:

- To provide a record of the auditing activities
- To evaluate the auditee's compliance with regulatory requirements
- To evaluate the conformity of the quality management system against the audit Criteria
- To provide evidence for a regulatory decision
- To prepare for the next audit
- To provide an audit history
- To trend compliance history for the auditee
- To trend compliance for the industry
- To follow up on adverse event reports
- To evaluate the performance of the auditor(s)
- To improve consistency between auditors

6.3 User needs for the designating authority that oversees the auditing organizations

The designating authority that oversees the auditing bodies uses audit reports:

- To assess the competence of the auditing organization and their auditors
- To monitor the performance of the auditing organizations and their auditors
- To improve consistency between auditing organizations and their auditors

6.4 User needs for the auditee

The auditee use audit reports:

- To provide a record of the auditing activities and audit scope
- To provide evidence of compliance to regulatory requirements
- To learn about the status of the quality management system (including nonconformities)
- To get feedback for further improvement of the quality management system
- To prepare for the next audit
- To provide an audit history
- To trend compliance history
- To provide evidence of compliance to regulatory authorities/auditing organizations as part of product registration/license activities
- To carry out necessary corrective and preventive actions

7.0 Main points of a Regulatory Audit Report

The auditing organization/regulator may adopt reporting procedures that suit its needs. The items contained in this chapter should be included in the audit report as a minimum requirement.

The report shall be typed and may be in a format that can be stored and transferred electronically. Trade secrets and proprietary information should be identified in the report to ensure confidentiality. This guideline provides a recommended order of report elements as described in sections 8.1 through 8.6 below.

Note: The language of the report should be agreed upon between the auditee and the auditing organization prior to the start of the audit. In many cases, the ultimate use of the report will dictate the language of the report.

7.1 Data concerning auditee

- 7.1.1 Auditee's name, address, phone #, fax #, e-mail
- 7.1.2 Company's identification or registration number for each regulatory authority covered by this audit (if applicable)
- 7.1.3 Description of the auditee (e.g., approximate number of employees covered by the audit scope, organization chart, hours of operations, shifts, and any seasonal variations, device name(s) and estimated number or percent of device(s) exported, listed by country). If a facility other than the main site of the auditee exists and/or is being audited, then the relationship of that site to the main site should be given.
- 7.1.4 The corporate identity and company names of the manufacturer
- 7.1.5 Status of any relevant certification
- 7.1.6 Products scope/product families and classifications covered by the audit (using an applicable nomenclature system, e.g. Global Medical Device Nomenclature (GMDN), where feasible)
- 7.1.7 Name, location and activity of critical suppliers, if applicable
- 7.1.8 Management representative responsible for the quality management system
- 7.1.9 Information from previous audit including date, name of auditing organization, name of auditor(s), audit criteria, subsystems covered and result, if applicable
- 7.1.10 Additional information regarding compliance history of the auditee, if relevant
- 7.1.11 Auditee's representative or key contact person(s) (if different from 8.1.8) for
 - a. Arranging the audit
 - b. Receiving the final audit report
 - c. Receiving regulatory correspondence
- 7.1.12 Exclusions and non-application of requirements in the quality management system

7.2 Data concerning audit

- 7.2.1 Type of audit (e.g. initial, surveillance, special audit)
- 7.2.2 Audit scope, objectives, and criteria against which the audit was conducted (regulation(s) and standard(s))
- 7.2.3 On-site audit dates and time
- 7.2.4 Total audit time (auditor days)
- 7.2.5 Identification of the auditing organization and audit team members (including technical experts) and their roles and responsibilities
- 7.2.6 Language(s) of the audit
- 7.2.7 Identification of interpreter(s), if applicable

- 7.2.8 Observer(s) and their organization, if applicable
- 7.2.9 List of documentation reviewed prior to the audit, including document identification and revision status

7.3 Audit trail

- 7.3.1 Description of activities covered during the audit. Write a summary of the key elements for each of the subsystems audited:
- Management
 - Corrective and Preventive Actions (report data sources available for review, and which ones were reviewed)
 - Purchasing Controls
 - Documentation and Records
 - Customer Related Processes

Note: These are the subsystems in GHTF/SG4/N30, Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy.

The subsystem summary (ies) should include:

- Areas of the site visited (e.g., incoming inspection, manufacturing areas, quality control laboratories, etc) and, where relevant, persons interviewed
- Activities and processes evaluated, including the reason for their selection
- Documents reviewed, including document number, revision etc
- Specific references to records reviewed, e.g., complaints files, batch records etc
- Specific references to products reviewed, e.g., work in progress, component etc.
- Statement concerning compliance with the standard or regulation(s) being audited, e.g
- Conforming comments for improvement, if applicable
- nonconformity (including major nonconformities)

Note: If a comment for improvement is recorded in the audit report which suggests non-compliance but does not lead to nonconformity, it should be clear why nonconformity was not raised. If a checklist without any further information is used to demonstrate coverage in a particular area then this should be described in the written narrative report.

- 7.3.2 Description of recalls, field safety corrective actions, product removals, or product replacements since the last audit, if applicable
- 7.3.3 Description of any follow-up on specific complaints or adverse event reports performed by the auditee
- 7.3.4 Identification of any requested information that was refused and any obstacles encountered that could compromise the reliability of the audit findings and conclusions
- 7.3.5 Identification of nonconformities, including:
- i) details of each nonconformity
 - ii) the audit criterion or the specific regulatory requirement to which it applies
 - iii) the relative significance with respect to regulatory requirements
 - iv) the date for submission of any corrective action plans
- 7.3.6 Details of any corrective action(s) taken during the audit

Note: When nonconformity is found, a record of this should be completed even if the auditee corrects the nonconformity during the audit.

- 7.3.7 Verification of effective implementation of corrective action(s) from previous audit
- 7.3.8 Description of any items or comments for improvement not given in list of nonconformities, if applicable
- 7.3.9 The proposed time frame for responding to the nonconformities, if applicable
- 7.3.10 Follow-up items for the next audit
- 7.3.11 Details of information provided during the closing meeting, including auditee's responses
- 7.3.12 Unresolved diverging opinions between audit team and auditee
- 7.3.13 any areas not audited although within the audit scope

7.4 Conclusion

- 7.4.1 Summary and conclusions regarding the conformity of the auditee's quality management system with each set of audit criteria
- 7.4.2 Summary and conclusions regarding the effectiveness of the quality management system in meeting quality objectives
- 7.4.3 Auditor's recommendation to the auditing organization (as applicable):
 - a) Follow up action(s) including proposed time schedule(s)
 - b) For the initial or continued certification
- 7.4.4 Confirmation that audit objectives have been met or an explanation as to why Not

7.5 Signature and dating of report

- 7.5.1 Date of the audit report
- 7.5.2 Audit team members' names, titles and organizations (signature and/or stamp of auditors on report)

7.6 Attachments (used to support the content of the report)

- Audit plan(s) (if applicable)
- Attendance sheet for opening and closing meetings (if applicable)
- Relevant auditing organization documents
- Evidence available to support the nonconformities
- Checklist used by the auditor
- Nonconformity reports if issued separately