



Global Harmonization Task Force

Proposed Document

Title: **Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports**

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1 **Preface**

2
3 This document was produced by the Global Harmonization Task Force, a voluntary group
4 of representatives from medical device regulatory agencies and the regulated industry.
5 The document is intended to provide nonbinding guidance for use in the regulation of
6 medical devices, and has been subject to consultation throughout its development.

7
8 There are no restrictions on the reproduction, distribution or use of this document;
9 however, incorporation of this document, in part or in whole, into any other document, or
10 its translation into languages other than English, does not convey or represent an
11 endorsement of any kind by the Global Harmonization Task Force.

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13
14 **1. Introduction**

15
16 This document gives guidance to regulators, auditing organizations and auditors on the
17 content of audit reports. However, it may also help the auditee understand and respond to
18 the audit findings.

19
20 Potential benefits for the regulators and auditing organizations include:

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

29
30 Potential benefits for the manufacturer of medical devices include:

- 31 • Improved communication that results in improved quality management systems and
32 product quality
33 • Greater consistency in audit reports
34 • Reducing the number of times a single manufacturer undergoes audits
35 • Saving resources
36 • Increased confidence in, and acceptability of, audit reports.

37
38 This document has been prepared by GHTF Study Group 4 “Regulatory Auditing”.
39 Comments or questions about the use of this guidance document should be directed to the
40 Chair of SG 4 whose contact details may be found on the GHTF web page
41 (www.gh tf.org).
42

1 **2.0 Scope**

2
3 This document is intended to be used by regulators and auditing organizations as a guide
4 for writing a report of a regulatory medical device quality management system audit.
5 Such audits will be based on the process approach to quality management system
6 requirements (e.g. ISO 13485:2003 and 21 CFR Part 820). This is described in
7 “Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device
8 Manufacturers, Part 2: Regulatory Auditing Strategy”.

9
10 It may be necessary to address additional regulatory requirements to meet the needs of
11 the regulators receiving and using the audit report.

12
13 The level of detail in the audit report will vary according to its likely use. This guideline
14 describes a report which can be exchanged with other regulatory or auditing
15 organizations with which the auditing organization has a formal relationship concerning
16 confidentiality.

17
18
19 **3.0 Purpose**

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

22
23
24 **4.0 Rationale**

25
26 This guideline promotes consistency in audit reports – important in harmonization and
27 mutual acceptance of audit results.

28
29 The audit report should demonstrate that quality management system and regulatory
30 requirements have been covered and that the audit was sufficiently thorough and
31 complete.

32
33 This guideline will provide a structure for audit reports used in multiple jurisdictions,
34 promoting consistency and uniformity and will assist the auditor in preparing a report for
35 use by multiple regulators and/or auditing organizations. Having reports that are
36 consistent in content will facilitate the review and exchange of audit reports. Acceptance
37 of audit reports by multiple regulators should eventually reduce the number of audits for
38 manufacturers.

39 This document can also be used in support of bilateral agreements.
40
41

5.0 References for applicable documents

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

6.0 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 labelling] 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 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

Fulfilment 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.

1 **Critical supplier**

2 A critical supplier is a supplier delivering materials, components, services, which may
3 influence the safety and performance of the product.

4
5 **Designating Authority (DA)**

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

9
10 **Nonconformity**

11 Nonfulfilment of a requirement
12 (ISO 9000:2005)

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

14
15 **Regulatory audit:**

16 The audit of a quality management system to demonstrate conformity with quality
17 management system requirements for regulatory purposes.

18 **Note:** For the purpose of these guidelines, “audit” means a regulatory audit.
19 (GHTF SG 4 N 30)

20
21 **Regulatory audit report**

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

25 **Note:** For the purpose of these guidelines, “audit report” means a regulatory audit report
26

27 **Regulatory requirements**

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

30 **Note 1:** Guidelines, draft documents or the like should not be used as regulatory
31 documents and should not be construed as such unless formally promulgated.
32 (GHTF SG 4 N 28)

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

35
36
37 **7.0 Objectives and User Needs of an Audit report**

38
39 **7.1 Audit report objectives**

40
41 The audit report comprises the documented evidence of a regulatory audit. It should
42 contain sufficient information:
43

- 1 • To document the type of audit, the audit criteria, what was covered during the audit,
2 and the audit findings
3 • To evaluate the auditee`s compliance status and effectiveness of the implementation
4 of the quality management system and draw audit conclusions
5 • To allow the exchange of audit reports between regulators and/or auditing
6 organizations
7

8 **7.2 User needs for the auditing organization/regulator**

9

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

- 11 • To provide a record of the auditing activities
12 • To evaluate the auditee`s compliance with regulatory requirements
13 • To provide evidence for a regulatory decision
14 • To prepare for the next audit
15 • To provide an audit history
16 • To trend compliance history for the auditee
17 • To trend compliance for the industry
18 • To follow up on adverse event reports
19 • To exchange information between auditing organizations/regulators
20 • To evaluate the performance of the auditor(s)
21 • To improve consistency between auditors
22

23 **7.3 User needs for the designating authority that oversees the auditing organizations**

24

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

- 26 • To assess the competence of the auditing organization and their auditors
27 • To monitor the performance of the auditing organizations and their auditors
28 • To improve consistency between auditing organizations and their auditors
29

30 **7.4 User needs for the manufacturer and/or auditee**

31

32 The manufacturer and/or auditee use audit reports:

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

8.0 Main points for 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.

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.

8.1 Data concerning auditee

8.1.1 Auditee's name, address, phone #, fax #, e-mail

8.1.2 Company's ID # for each regulatory authority covered by this audit (if applicable)

8.1.3 Description of the auditee (e.g., approximate number of employees covered by the audit scope, organization chart, hours of operations and any seasonal variations, percent of export). 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.

8.1.4 The corporate identity and company names of the manufacturer

8.1.5 Status of any relevant certification

8.1.6 Products scope/product families and classifications covered by the audit (using an applicable nomenclature system, e.g. Global Medical Device Nomenclature (GMDN), where feasible)

8.1.7 Name, location and activity of critical suppliers, if applicable

8.1.8 Management representative for the quality management system

8.1.9 Date of previous audit, name of last auditor and result, if applicable

8.1.10 Additional information regarding compliance history of the auditee, if relevant

8.1.11 Auditee's representative or key contact person(s) for

a. Arranging the audit

b. Receiving the final audit report

c. Receiving regulatory correspondence

8.2 Data concerning audit

8.2.1 Type of audit (e.g. initial, surveillance, special audit)

8.2.2 Audit criteria against which the audit was conducted (regulation(s) and standard(s))

8.2.3 On-site audit dates and time

8.2.4 Total audit time (auditor days)

1 8.2.5 Identification of the auditing organization and audit team members (including
2 technical experts) and their roles and responsibilities

3 8.2.6 Interpreter, if applicable

4 8.2.7 Observer(s) and their organization, if applicable

5 8.2.8 List of documentation reviewed prior to the audit, including
6 document identification and revision status

7 8 **8.3 Audit trail**

9
10 8.3.1 Description of activities covered during the audit. Write a summary description
11 of the key elements covered under the following subsystems:

- 12 • Management
- 13 • Design and Development (describe the project(s) reviewed)
- 14 • Product Documentation
- 15 • Production and Process Controls (describe product and process/es reviewed)
- 16 • Corrective and Preventive Actions (report data sources available for review,
17 and which ones were reviewed)
- 18 • Purchasing Controls
- 19 • Documentation and Records
- 20 • Customer Related Processes

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

24
25 The subsystem summary(ies) may include:

- 26 • Areas of the site visited (e.g., incoming inspection, manufacturing areas,
27 quality control laboratories, etc) and, where relevant, persons interviewed
- 28 • Activities and processes evaluated, including the reason for their selection
- 29 • Documents reviewed, including document number, revision etc
- 30 • Specific references to records reviewed, e.g., complaints files, batch
31 records etc
- 32 • Specific references to products reviewed, e.g., work in progress,
33 components etc
- 34 • Statement concerning compliance with the standard or regulation(s) being
35 audited, e.g.,
 - 36 ○ conforming
 - 37 ○ comments for improvement, if applicable
 - 38 ○ nonconformity (including major nonconformities)

39 **Note:** If a comment for improvement is recorded in the audit report which does
40 not lead to a nonconformity, it should be clear why a nonconformity was not
41 raised.

42
43 If a checklist without any further information is used to demonstrate coverage in
44 a particular area then this should be supported in the written narrative report.

- 1 8.3.2 Description of recalls, product removals, or product replacements since the last
2 audit, if applicable
- 3 8.3.3 Description of major changes to products or significant changes to processes,
4 organizational structure, ownership, key personnel and quality management
5 system since the last audit
- 6 8.3.4 Description of any follow-up on specific complaints or adverse event reports, if
7 applicable
- 8 8.3.5 Identification of any requested information that was refused
- 9 8.3.6 Details of each nonconformity (referenced to relevant regulation or standard)
10 and relative severity with respect to regulatory requirements
- 11 8.3.7 Details of corrective action(s) taken during the audit
- 12 **Note :** When a nonconformity is found, a record of this should be completed
13 even if the auditee corrects the nonconformity during the audit.
- 14 8.3.8 Verification of effective implementation of corrective action(s) from previous
15 audit
- 16 8.3.9 Description of any items or comments for improvement not given in list of
17 nonconformities, if applicable
- 18 8.3.10 The proposed time frame for responding to the nonconformities, if applicable
- 19 8.3.11 Follow-up items for the next audit
- 20 8.3.12 Details of information provided during the closeout meeting, including
21 auditees responses
- 22 8.3.13 Unresolved diverging opinions between audit team and auditee

23 **8.4 Conclusion**

- 24
- 25
- 26 8.4.1 Summary and conclusions regarding the conformity of the
27 auditee's quality management system with the audit criteria
- 28 8.4.2 Auditor's recommendation to the auditing organization (as applicable):
29 a) Follow up action(s) including proposed time schedule(s)
30 b) For the initial or continued certification

31 **8.5 Signature and dating of report**

- 32
- 33
- 34 8.5.1 Date of the audit report
- 35 8.5.2 Lead auditor, auditor(s) names, titles and organizations (signature and/or stamp
36 of auditors on report)

37 **8.6 Attachments (that could be used to support the content of the report)**

- 38
- 39 • Audit plan(s) (if applicable)
- 40 • Attendance sheet for opening and closing meetings (if applicable)
- 41 • Relevant auditing organization documents
- 42 • Evidence available to support the nonconformities
- 43 • Checklist used by the auditor
- 44 • Nonconformity reports if issued separately

SG4



**Study
Group 4**

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History file:

**Development of SG 4 / N 33 „Guidelines for Regulatory Auditing of Quality
Systems of Medical Device Manufacturers –
Part 3: Regulatory Audit Reports”**

Date d-m-y	SG 4 N 33...	Tasks
1.3.2003	N 6 R2	Audit reports: User needs Basis for N 33
24.9.2003	N 6 R3	At meeting in Bern, Switzerland, updating the main requirements for N 33
22.12.2003	R 1	Structure of N 33
Dec 2003 – March 2005	N 330 – N 339	Development of requirements for N 33 for Audit Report Matrix
4.2.2004	R 4	After written comments draft for Atlanta meeting
3.5.2004	R 5	After written comments draft for Tokyo meeting
21.9.2004	R 6	At Canberra meeting revision of first half of document
7.4.2005	R 7	Revision of N 33 incl. new chapter 7
1.9.2005	R 8	Total revision of chapter 7 for Gaithersburg meeting
15.9.2005	R 9	Working Draft after Gaithersburg meeting incl. changes
15.9.2005	R 9a	Clean version of WD
16.11.2005	R 10	Working Draft after Luebeck meeting incl. changes
24.11.2005	R 10a	Clean version of WD incl. template
16.2.2006	R 11	In Taipei: Implementing 4 comments (partly extensive!)
22.3.2006	R 12	Working Draft after Taipei
3.4.2006	R 12	Proposed Document, but not sent to SC (ident. With 22.3.)
28.6.2006	R 13	Final corrections, Proposed Doc, will be sent to SC for comments

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