FINAL DOCUMENT

Global Harmonization Task Force

Title: Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers General Requirements Supplement No. 6 Observed Audits of Conformity Assessment Bodies

Authoring Group: Study Group 4

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Rita Maclachlan, GHTF Chair

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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.

1.0 Introduction

This document sets out guidance for conducting observed audits of Conformity Assessment Bodies (CABs). The approach is based on that applied by GHTF Study Group 4 when carrying out observed audits in support of the development of guidance for the general requirements for regulatory audits.

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.

Note: One of the applications for this document could be for confidence building programmes incorporated into Mutual Recognition Agreements (MRAs).

A number of countries and trade blocs are entering into Mutual Recognition Agreements that include the medical device industry sector. These agreements involve the recognition of conformity assessments made against the regulatory requirements of the importing MRA Party by formally designated bodies in the exporting Party.

There are transitional arrangements in some MRAs to permit the two Parties to establish confidence in the competence of the CABs carrying out the assessments. In respect of quality system requirements, these confidence building periods may require CABs to conduct audits that are observed by agencies from the country or trade bloc whose regulations are being applied as the basis for conformity assessment.

2.0 References

Reference documents

a) Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: General requirements. SG4(99)28.

b) Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: part 4 Mutual Recognition Agreement confidence building audit reports. Working draft 4.1 – in preparation. SG4(98)55RevDefinitions

3.0 Definitions

See 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: General requirements' SG4(99)28 .

In addition, the following terms are used in this document.

a) Observing authority (OA)

The organisation responsible for observing the audit conducted by the CAB and assessing its ability to evaluate conformity with the regulatory requirements of the OA.

b) Conformity Assessment Body (CAB)

The auditing organisation, working outside the jurisdiction of the OA, responsible for conducting the audit of the medical device manufacturer against the regulatory requirements of the OA.

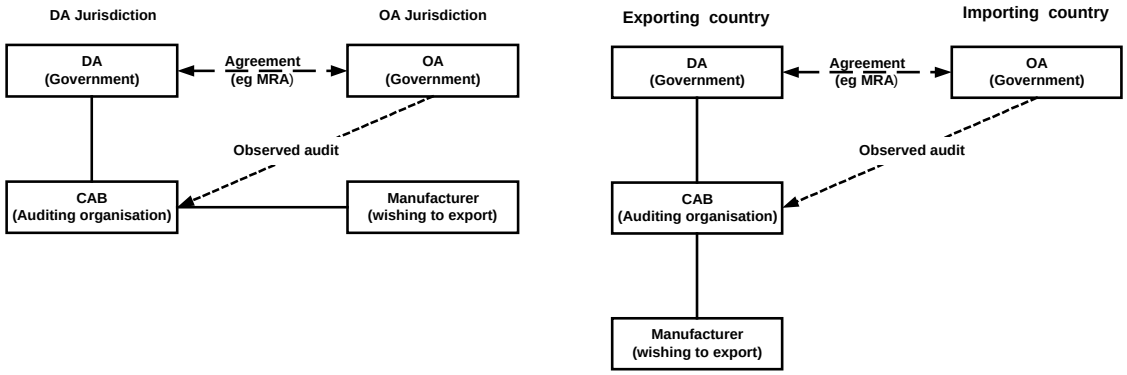
c) Designating Authority (DA)

The authority, responsible for identifying, designating, monitoring, suspending and withdrawing designation of the CAB conducting the observed audit.

The OA and DA are independent of each other.

Note. In the case of observed audits conducted as part of an MRA, the OA represents the importing party and the DA represents the exporting party. The MRA defines the full authority of the OA and DA.
In cases when the importing party does not recognise activities of the exporting CAB, an agreement between the DA and OA may be necessary.

Examples of this guidance applied to regional and jurisdictional relationships.



4.0 Objectives

The objectives of the observed audit process described in this document are intended to provide:

a) For the Observing authority (OA)

i. Evidence of the competence of the CAB to conduct audits of a medical device manufacturer against the regulatory requirements of the OA;

ii. Evidence that the DA has carried out an effective assessment of the CAB's competence

iii. Evidence on which to take an appropriate compliance decision;

b) For the Conformity Assessment Body (CAB)

i. Opportunity to demonstrate their competence to conduct audits against the regulatory requirements of the OA.

ii. Information that may be applied in subsequent audits concerning the application and interpretation of the regulatory requirements of the OA.

c) For the Designating Authority (DA)

i. Evidence on the effectiveness of their assessment of the CAB's competence.

ii. Information to assist when monitoring the performance of the CAB and when conducting assessments.

d) For the medical device manufacturer

A compliance decision by the OA obtained without the need for a separate OA audit (e.g. approval to market).

5.0 Assumptions

For the purposes of the observed audit described in this document the following assumptions are made.

(a) The CAB will be conducting the audit to a defined and documented procedure.

(b) In advance of the observed audit, the CAB has ensured that the audit team has the relevant knowledge of the OA's regulatory requirements.

(c) The CAB audit team is experienced in conducting audits of medical device manufacturers.

(d) The criteria to be applied by the OA when assessing the CAB will be documented in advance and copied to both the DA and CAB.

(e) The scope and format of the observers' report should be agreed in advance with the DA and communicated to the CAB.

(f) Confidentiality is to be assured in advance of the observed audit through agreements between the OA and DA and the DA and CAB.

(g) The CAB and the manufacturer have agreed to participate in the observed audit process.

6.0 Observed Audit Process

a) General principles

During the course of the on site audit, it is intended that the CAB audit team and OA observer collaborate to ensure that the objectives are met. For this purpose a number of briefing meetings between the CAB audit team and the OA observer are incorporated. These are intended to provide sufficient opportunity for collaboration and exchange of information, in order to reach a satisfactory conclusion to the audit. The meetings may marginally increase the duration of the observed audit and should be planned in advance.

The OA, DA, CAB and manufacturer should discuss and agree in advance, the number of observers to be included in the audit. To minimise disruption, the number of observers should be kept to a minimum. One per auditor is considered the optimum ratio.

b) Process

i. The OA communicates to the CAB the type of audit to be conducted (e.g. for initial or routine surveillance) and any additional relevant information.

ii. As necessary, effective interpretation support for the OA observer is to be provided.

iii. The manufacturer should make the audit team aware of any health and safety matters (General requirements; clause 9.3(d)) and the audit team leader should alert the observer(s) to these issues.

iv. The CAB prepares the audit plan, which will include the audit dates, times and locations of briefing and other meetings with the OA observer. The CAB informs the manufacturer, the DA and the OA.

v. Prior to the observed audit, an initial briefing meeting should be held between the OA observer and the CAB audit team to review the audit plans and discuss any special requirements.

vi. The audit should be conducted following the CAB's defined and documented procedures consistent with the condition for designation.

vii. During the opening meeting with the manufacturer's senior managers, the role, responsibilities and functions of the observer(s) should be confirmed and any questions arising from this should be resolved before the audit continues.

viii. During the audit, the observer(s) take no active part in the audit process but "observe" the activities, interviews, and documents reviewed by the auditor.

ix. At agreed intervals (e.g. at the middle and end of each working day), the CAB audit team and the OA observer review progress, clarify issues and resolve any questions concerning the audit process and information collected.

x. Prior to the closing meeting with the manufacturer, the CAB audit team reviews their conclusions with the OA observer. All issues between the CAB and the OA relative to the manufacturer's compliance with the regulatory requirements of the OA must be resolved so that the OA observer agrees with the nonconformities and quality observations to be presented at the closing meeting

xi. The CAB audit team, with the observer(s) present, holds a closing meeting with the manufacturer (General requirements; clause 11.2.5).

xii. Following the closing meeting the OA observer holds a de-briefing with the CAB audit team, involving, as appropriate other representatives from the CAB (e.g. management) and the DA. The purpose is to review the conduct of the audit in providing evidence of compliance against the OA's regulatory requirements.

xiii. The CAB team leader writes the report immediately for the manufacturer (General requirements, clause 11.3.2.) and prepares a report together with any additional relevant documentation that is sent to the OA

xiv. The OA makes its compliance status decision on the manufacturer's quality system, takes any necessary action and involves the CAB as appropriate in any follow up action required of the manufacturer.

xv. The OA observer promptly prepares a report of the observed audit to:

- address each of the OA's assessment criteria covered by the activities of the CAB;
- record matters of fact concerning the conduct of the audit; and;
- make recommendations (i.e. regarding competence status of CAB, auditor training, procedures and auditing techniques)

xvi. The OA report is sent to the CAB and the DA.