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Global Harmonization Working Party

Towards Medical Device Harmonization

# FINAL DOCUMENT

**Title:** Guidance to Supplier Audit for Medical Device Manufacturers

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# Acknowledgements

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# Preface

This Guidance Document was developed by Global Harmonization Working Party (GHWP), Working Group 7 on Standards. GHWP is 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 subject to consultation throughout its development process.

This Guidance Document shall be read in conjunction with the current laws and regulations used in member economies.

In this Guidance Document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission; and

— "can" indicates a possibility or a capability.

# 0 Introduction

Medical device manufacturers should establish supplier audit procedure to review and evaluate suppliers, in accordance with the requirements of local laws and regulations to ensure that the purchased products (goods/service) meet the quality requirements of the medical devices.

# 1 Scope

This document provides guidance for medical device manufacturers on control of products and services obtained from suppliers. The supplier in this document is an independent organization provides the products (goods/service) to medical device manufacturers.

# 2 Terms and Definitions

For the purposes of this guideline, the terms and definitions given in ISO 13485:2016 and the following apply.

## 2.1 Supplier

Organization providing products (goods/service).

Example: Manufacturer, distributor, retailer or vendor of a products (goods/service).

NOTE 1 Suppliers are external to the organization.

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

NOTE 3 This guideline does not cover "individuals" who provide products (goods/service) to the organization.

## 2.2 Audit

Systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

## 2.3 Supplier Access Audit

Audit to introduce new suppliers into the organization's supply system.

## 2.4 Supplier Routine Audit

Conduct routine audit of existing qualified suppliers, including but not limited to the effectiveness and suitability of the operation of the quality management system, and conduct periodic performance evaluations and audits to promote continuous improvement of suppliers.

## 2.5 Supplier for-Cause Audit

Supplier for-cause audit is triggered by one or more special problems to confirm whether the supplier violates relevant laws and regulations, contracts, and acts that affect the effectiveness of the quality management system.

### 2.6 Extended Audit

When necessary, medical device regulatory authorities may conduct extended inspection on the suppliers who provide products or services for the development, production, marketing, use and other activities of medical devices.

### 2.7 Supplier Extended Audit

When necessary, manufacturer may conduct extended audit on its upstream components manufacturer.

## 3 Audit Principle

The audit principle serves as the basis for evaluating candidate suppliers, including but not limited to national laws and regulations, standards, specifications, contracts, product requirements, and specific requirements proposed by manufacturers.

The guideline is based on the following audit principles: risk-based approach; audit approach that considers risks and opportunities.

Manufacturer should classify the purchased goods and suppliers according to the degree of impact of the purchased products (goods/services) on the product or quality system and based on the output of risk management. Supplier audit should adopt differentiated auditing criteria for different categories of suppliers according to the requirements of risk management. Supplier audits should be conducted according to the risk study and differentiated for different categories of suppliers, such as on-site audit, document audit, remote audit, etc. The audit should focus on the products (goods/service) provided, such as research and development, production environment, manufacturing process and traceability, arrival inspection, process control, final release, change management, equipment, storage and transportation, and the implementation of quality agreements.

## 4 Supplier Selection and Management Procedure

### 4.1 Comprehensive Access Audit of Potential Suppliers

Manufacturer should establish the corresponding supplier access requirements based on the requirements for purchasing products (goods/service), including products (goods/service) category, acceptance criteria, specifications, protocols, drawings, procurement quantities etc., to review and maintain records of supplier business status, production capacity, quality

management system, product quality, delivery period, and other related content. On-site audits of suppliers should be conducted when necessary, or production verification and evaluation of small sample products should be carried out to ensure that the purchased products (goods/service) meet the requirements.

### 4.2 Process Monitoring

Manufacturer should establish monitoring procedure during the use of the purchased product to ensure that purchased product meets specified purchasing requirements continuously. Processes including testing and using of purchased products, inspection of the final product, as well as control of nonconforming products should be reviewed, and records should be maintained.

### 4.3 Assessment Management

Manufacturer should establish the procedure of supplier assessment management. Manufacturer should sign agreements with key suppliers, which specify the technical and quality requirements for the purchased items, and clarify the quality responsibilities assumed by both parties and the suppliers need to cooperate with possible future extended audits and supplier extended audits.

Comprehensive evaluation of suppliers should be carried out on a regular basis, reviewing and analyzing the quality, technical level and delivery ability of purchased products (goods/service) they supply. Periodic supplier audit reports should be formed. When the evaluation finds that there are major defects in the supplier that may affect the quality of the purchased items, the procurement should be suspended, and the risks posed to the products by the purchased products (goods/service) already in use should be analyzed in a timely manner, and corresponding measures should be taken. Manufacturer should establish supplier files, including procurement contracts or agreements, lists of procured products (goods/service), supplier qualification documents, quality standards, acceptance criteria, and periodic supplier audit reports.

When there are significant changes in production conditions, specifications, drawings, production process, quality standards and inspection methods and other key factors that may affect the product quality, manufacturer should require the supplier to notify the above changes in advance and reassess to the supplier. On-site audits of the suppliers can be conducted if necessary.

## 5 Key Points of Audit

### 5.1 Document Audit

5.1.1 Qualification of suppliers, including legal production and operation certificates of enterprises, etc..

5.1.2 Documents related to the supplier's quality management system.

5.1.3 Supplier's main products, production capacity and other documents.

5.1.4 Supplier's main product performance, specification and model, safety evaluation materials or inspection or test report which meet the requirements of manufacturers.

5.1.5 Other documents and materials as agreed between the manufacturer and the supplier.

### 5.2 On-site Audit

5.2.1 Manufacturer should verify the capabilities of the supplier personnel to ensure that the supplier has the capability to perform the production activities by matching personnel.

5.2.2 Manufacturer should be strictly in accordance with the provisions of the requirements of the supplier supply chain audit to ensure that products provided by the supplier to the enterprise are in accordance with the supply batch to provide a valid inspection report or other quality qualification documents. For example, production process control records/reports, etc.

5.2.3 Manufacturer should verify the using status of instruments, equipment and tools used in the production process of suppliers, including but not limited to the identification, calibration and maintenance as required by the quality management system.

5.2.4 Manufacturers should also verify other quality assurance capabilities of suppliers, such as production environment, technical process, production flow, inspection, storage and transportation and other factors that may affect the quality and safety of purchased goods. Special attention should be paid to whether the inspection capacity and inspection methods (including sampling methods) provided by the supplier meet the requirements, and whether it can ensure that the supplied goods continuously meet the requirements of the manufacturer.

5.2.5 Manufacturer should focus on whether there are customer complaints, adverse events, Vigilance System, Field Safety Corrective Actions (FSCA), advisory notices, etc. caused by the problems of goods/service provided by the suppliers. If so, manufacturer should verify whether the measures taken at the supplier have been effectively implemented during onsite audit.

### 5.3 Change Management Audit

Manufacturer should verify the supplier change management. Significant changes (including the production site, raw material supplier, key processing process, key production equipment, and product performance/version) independently triggered by the supplier and requested by the manufacturer to the suppliers should be informed and approved by the manufacturer. The supplier should implement the internal change according to the requirements of the management system and the final result should meet the requirements of the manufacturer.

Manufacturers and suppliers can define the requirements for change management in the relevant agreed agreement and jointly promote the effective management of changes.

### 5.4 Extended Audit

For outsourcers of design, development, production, sterilization and other activities, as well as suppliers whose products and services have a greater impact on the finished product and quality system，the manufacturer should monitor the them based on the output of risk management and the classification. And the manufacturer should inform these suppliers of the risks that may be caused by extended audit, and they can apply for extended audit exemption to the regulatory authorities by providing sufficient evidence and effective controls.

## 6 Audit Activities

### 6.1 Audit Planning

Manufacturer should consider objectives, risks, requirements, processes and resources to ensure and confirm the ability to meet regulatory requirements. A supplier audit planning program should be formed and approved based on the products and services provided by the supplier and the results of the risk assessment.

Supplier audit planning should consider the followings, include but not limited to:

a) Identify the objectives, scope, approach, and criteria for the audit based on the needs of the supplier;

b) Audit types include system audit, in-process quality audit and product quality audit;

c) Product or services provided;

d) Technical and specification documentations;

e) Based on the output of product risk management requirements for raw materials.

6.1.1 Qualification of Audit Team

a) Manufacturers should designate departments or personnel responsible for the supplier audits. Auditors shall be familiar with relevant regulations and have corresponding professional knowledge and working experience;

b) The qualification of audit team should meet the requirements of 7.0 in ISO 19011:2018.

6.1.2 Feasibility Confirmation of Audit Type

6.1.2.1 Feasibility confirmation of on-site audit. Manufacturers should analyze the feasibility of on-site audit and consider the following factors:

a) Supplier and manufacturer fully cooperate;

b) Organize on-site audit with sufficient time and resources provided by suppliers;

c) Supplier provides manufacturer with required information;

d) Determine the audit approach to be implemented based on the results of the feasibility confirmation analysis of the audit approach.

6.1.2.2 Access audit may adopt on-site audit; routine audit may adopt document audit, on-site audit, and remote audit; for-cause audit should adopt on-site audit.

6.1.2.3 Manufacturers may adopt appropriate audit approach based on the type of risk and classification level of the products(goods/service) provided.

6.1.3 Criteria for Audit Conclusion

Manufacturer should establish the criteria for judgment based on the audit mode and the risk type and classification level of the products (goods/service) provided.

## 6.2 Audit Preparation

6.2.1 Information communication

Audit leader should inform the supplier of audit plan at least one week in advance, and communicate with the supplier to confirm the following:

a) Confirm supplier audit representatives;

b) Confirm competence during the implementation of the audit process;

c) Confirm relevant information on audit objectives, scope, criteria, methods and audit team members;

d) Confirm applicable legal, regulatory and other requirements related to the activities, processes, products and services of supplier;

e) Establish agreement with supplier to determine the extent of disclosure and handling of confidential information;

f) Confirm the arrangement of audit time, place and personnel;

g) Confirm logistics support for audit and other precautions.

6.2.2 On-site Preparation for Audit Activities

a) Supplier should ensure that there is a relatively independent audit space/location and appropriate office and network facilities;

b) According to the process involved in the audit, the supplier should be equipped with the protective equipment required for the audit process, such as helmet, mask, earplug, etc.;

c) Supplier should arrange appropriate attendants and translators (if required) on site according to the audit plan.

6.2.3 Supplier should complete the preparation of documents and materials prior to audit, including but not limited to:

a) Introduction of enterprise and product;

b) Qualification of enterprise: legal business certificate, quality system/product certificate (if necessary);

c) Personnel roster (indicate the key position personnel, such as enterprise head, management representative, production head, quality head, technical head, product release reviewer, inspector and operators operating key process and special process);

d) Quality System Documents: Quality Objectives, Quality Manual, List of Controlled Documents, Procedure Documents, Management Review Record, Internal Audit Record, List of Changes, List of Corrective and Preventive Actions, etc.;

e) Product standard (if necessary);

f) Other documents to be provided.

6.2.4 Preparation of Supplier Manufacturing/Inspection Activities (for production suppliers)

Supplier should arrange manufacturing/inspection activities in accordance with the audit plan to ensure that they are available for audit during the audit. If necessary, the appropriate personnel can be arranged to simulate the operation on site.

## 6.3 Conduct Audit Activities

6.3.1 Build Team

Audit team should be established, including lead auditor and auditors, and, if necessary, technical experts. Audit team should include lead auditor and auditors, technical experts can be included if necessary. The number of audit team members and their responsibilities and tasks shall be determined according to the scope, type, criteria and purpose of the audit.

6.3.2 Audit Plan

The audit plan should reflect the scope, purpose and risk management requirements of audit, including but not limited to the following contents:

a) Purpose, scope and criteria of audit;

b) Time, place, personnel and documents for audit as well as the arrangement of meeting;

c) Audit type;

d) Communication, confidentiality and security of the audit process.

The audit team should prepare a checklist based on the purpose, scope and criteria of the supplier audit. Lead auditor assigns specific tasks to auditors according to the purpose, scope

and criteria of audit.

#### 6.3.3 Opening Meeting

The opening meeting should be chaired by lead auditor, attended by the supplier 's managers and relevant personnel.

#### 6.3.4 Audit Contents

Audit team conducts audit on supplier according to audit implementation plan, and fills in audit record in audit checklist.

Special attention should be paid to whether the inspection capability provided by the supplier meets the requirements and the ability to ensure a continuous supply of products that meet the requirements.

When special processes are involved, attention should be paid to the validation of process capability.

Special products (goods/service) (such as outsourcing), relevant laws and regulations should be paid attention to and relevant requirements must be covered during audit.

#### 6.3.5 Audit Type

Auditors collect objective evidence by inquiry, conversation, examination of documentation and on-site observation, and evaluate the evidence based on the audit criteria to form audit findings.

#### 6.3.6 Audit Communication

During the audit process, regular meetings within the audit team are used to summarize the audit findings and progress. If necessary, adjust the review plan. During the audit process, communicate with the supplier in a timely manner on the audit progress and important findings.

#### 6.3.7 Closing Meeting

Closing meeting is held to identify strengths, opportunities for improvement and conclude the audit with the supplier. The closing meeting should be chaired by the audit team leader, and the supplier's managers should attend. Disagreements between the audit team and the supplier on audit findings and conclusions shall be resolved. A sign-in record shall be kept for the final meeting.

#### 6.3.8 Audit Report

The audit team should provide a complete and accurate audit report. Supplier audit report includes, but are not limited to:

a) Complete, accurate and clear audit records;

b) Non-conformity;

c) Supplier Quality Management System Strengths and Suggestions for Improvement;

d) Audit summary and conclusion.

6.3.9 Remote Audit

In principle, remote audit should follow the above audit process and be implemented by referring to "Guidance on Remote Inspection".

### 6.4 Audit Conclusion

According to audit planning and implementation of audit activities, conclusion should be issued, including:

a) Passed;

b) Failed;

c) Re-audit after CAPA; audited by means of necessary documents or records audit and on-site follow-up audit. For suppliers requiring improvement, the supplier should submit CAPA plan on schedule as required by the audit report and take improvement measures as planned. Manufacturers should confirm the effectiveness of supplier improvement measures and conduct secondary audit if necessary.

### 6.5 Audit Follow-up Activities

For the suppliers passed the audit or passed the re-audit after CAPA, manufacturer should issue the formal audit results, and both parties continue the cooperation in the next stage. For the suppliers failed the access audit, it is recommended to terminate the cooperation. For the suppliers already included in the qualification list, if the audit fails, it is recommended that the manufacturer should take corresponding control measures based on the risks of the products.

## 7 Supplier Audit of Procurement with Special Characteristics

Based on the risk management principles and the specificity of certain suppliers for final product quality, it is recommended to pay more special attention to the certain suppliers when conducting audit to ensure the purchased items meet quality requirements during production.

For audit of such suppliers, in addition to the strict implementation of the audit clauses of this guidance, corresponding qualification documents and process documents/records should also be checked or obtained based on the particularity of the products(goods/service) provided by the supplier, and corresponding supplier extended audits should be implemented to identify potential risks.

### 7.1 Supplier of Animal-derived Material

7.1.1 Verify relevant qualification certificates, such as animal quarantine certificate, animal epidemic prevention certificate, and adequate quarantine standards, etc.

7.1.2 Possible/Potential Infectious Viruses and Infectious Pathogens controls.

7.1.3 If necessary, conduct supplier extended audits on feeding conditions, feed, storage and transportation, etc..

### 7.2 Supplier of Allogenic Raw Materials

7.2.1 Supplier qualifications, such as legal certificates or confirmation documents from the ethics committee, and voluntary donation agreement.

7.2.2 Relevant technical supporting documents, such as donor screening technical requirements, donor pathogens, and necessary serologic test reports.

7.2.3 If a third-party cooperating institution exists, an supplier extended audit should be conducted according to section 7.2.1 and 7.2.2 of this guidance when necessary.

### 7.3 Supplier Providing Sterilization Services

7.3.1 Verify their qualification certificates, such as those related to environmental protection and fire protection, as well as their occupational safety and protection status.

7.3.2 Verify the operating status and supply capacity, such as corresponding sterilization cycle records, comprehensive sterilization process validation, and release controls.

7.3.3 Conduct on-site audit if necessary.

### 7.4 Supplier Providing Special customized items

Special customized items can be conducted based on the customized requirements and specification**s.**

7.4.1 Integrity of design and development control documents, design transfer documents, and corresponding records, clarifying the responsibilities of both parties.

7.4.2 Supplier's production process control records, including process parameter setting and process validation, quality control and release control, and conducting on-site audits.

7.4.3 If a third-party cooperating institution exists, an supplier extended audit should be conducted according to clauses 7.4.1 and 7.4.2 of this guidance when necessary.

## 8 Appendices

N/A

## Reference Documents

*[1] T/CAQ 10108-2018 Supplier Audit Guidance*

*[2] Guidelines for Supplier Audit of Medical Device Manufacturers (NMPA Announcement on Issuing Guidelines for Supplier Audit of Medical Device Manufacturers ([2015] No. 1)*

*[3] ISO 19011:2018 Guidelines for auditing management systems*

*[4] ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes*

*[5] SG3 (PD)/N17R7 Quality Management Systems - Medical Devices - Guidance on Supplier Controls for Products and Services*

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