Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

# FINAL DOCUMENT

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| **Title:** | Guidance on Regulatory Auditing of Quality Management System of Medical Device Distributors: Auditing Strategies |
| **Authoring Group:** | Work Group 6, Quality Management System: Audit & Assessment |
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## 1.0 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.

## 2.0 Introduction

A medical device distributor delivers medical devices provided by the manufacturer to end users in accordance with the requirements specified by the manufacturer. A distributor may provide services of medical devices. In some AHWP jurisdictions, distributors are required to comply with Good Distribution Practice (GDP). The distributor performs activities which are part of product lifecycle.

AHWP develops the Guidance on Medical Device Quality Management System – Requirements for Distributors (AHWP/WG7/F001: 2014) to provide medical device distributor of AHWP member economies with the guidance on the implementation of quality management systems to ensure their conformity with ISO 13485: 2003 Medical devices - Quality management systems - Requirements for regulatory purposes.

Regulatory auditing is part of conformity assessment procedures in a medical device regulatory model. This document is intended to provide guidance to regulators and auditing organizations conducting audits of quality management systems of medical device distributors based on the process approach to quality management system requirements. It has been prepared by Asian Harmonization Working Party Technical Committee Working Group 6.

This guidance document shall be reviewed in light of future revisions of ISO 13485:2003 and Guidance on Medical Device Quality Management System – Requirements for Distributors (AHWP/WG7/F001:2014)

This guidance should be read in conjunction with GHTF/SG4/N30:2010 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy and AHWP/WG7/F001: 2014 Guidance on Medical Device Quality Management System – Requirements for Distributors.

# 3.0 Rationale and Scope

## 3.1 Rationale

This guidance provides basic information about audit strategy to regulators and auditing organizations for auditing quality management system of medical device distributors

The guidance aims to promote consistency in conducting audits of medical device distributors and assist AHWP members in harmonization and mutual acceptance of audit results.

## 3.2 Scope

This guideline is intended to be used by regulators and auditing organizations conducting quality management system audits of medical device distributors based on the process approach to quality management system requirements (e.g., ISO 13485:2003).

Although an audit of a medical device distributor may incorporate quality management system requirements not related specifically to ISO 13485:2003 (e.g., ISO 9001) and/or regulatory managements, this guideline will limit its coverage to ISO 13485:2003. Where additional regulatory requirements apply and are part of the scope of the audit, the auditor will need to consider these by identifying and documenting them in the audit objective and criteria.

This guideline applies to initial and surveillance audits and can apply to other audits as they are defined in "Guidance on Medical Device Quality Management System – Requirements for Distributors (AHWP/WG7/F001: 2014)"as a guide for auditing organizations. The purpose of the other audits will determine the subsystem elements selected for the audit. This guidance applies to an organization which distributes or imports medical devices.

## 4.0 References

*ISO 13485: 2003 Medical devices — Quality management systems — Requirements for regulatory purposes*

*GHTF/SG1/N29:2005 Information Document Concerning the Definition of the Term 'Medical Device'.*

*GHTF/SG4/N30:2010: Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers –Part 2: Regulatory Auditing Strategy*

## 5.0 *AHWP/WG7/F001: 2014: Guidance on Medical Device Quality Management System – Requirements for Distributors*Definitions

### 5.1 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.

### 5.2 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.

**Note 3**: An Importer is a type of distributor in many AHWP jurisdictions. A Distributor (normally the Importer) may also be an Authorized Representative. If an Authorized Representative does not distribute or import medical devices - for instance, a lawyer or a consultant - it does not need to implement a QMS per this guidance.

### 5.3 Manufacturer

Any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s). (GHTF SG1/N55: 2009). This may also be referred to as the Product Owner

**Note** Manufacturer may be defined differently by AHWP member economies.

## 6.0 General Remarks on Regulatory Auditing Strategy for Distributor

The audit should be process-oriented and should preferably follow the workflow processes of the medical device distributor.

### 6.1 Objectives

The audit should be planned and conducted in such a way that the following objectives are achieved:

- the effectiveness of the distributor's quality management system is assessed in a systematic and effective manner within a reasonable time
- the results of the audit are consistent regardless of which auditing organization or individual auditors conduct the audit. The ultimate goal is for harmonization and mutual recognition of audit results
- the audit determines how problems associated with the quality management system are recognized and addressed
- the audit is transparent to the auditee

### 6.2 Auditing quality management system

An audit should focus on the overall effectiveness of the quality management system rather than individual requirements. Subsystems have been identified with applicable quality management system requirements.

See Table 1 of GHTF/SG4/N30:2010 for subsystems and associated ISO 13485: 2003 clauses and AHWP/WG7/F001: 2014for further guidance on applicable ISO 13485: 2003 clauses for medical device distributors.

The following sections of GHTF/SG4/N30:2010 apply to audits of distributors:

6.3 Auditing Approaches
6.4 Process Based Auditing
6.5 Sampling
6.6 Audit Planning
6.7 Guidance for Logistics during an Audit
6.8 Links

## 7.0 Auditing Subsystems

There is a specific goal for auditing each subsystem. The planning of auditing subsystem should be process based (section 6.2) and should enable the achievement of the goal. The auditing should verify the conformity with the requirements that are addressed by each subsystem.

For the purposes of regulatory auditing, distributors should apply risk management principles in the quality management processes. Risk management activities should be audited concurrently with the relevant subsystems.

### 7.1 Management subsystem

| GHTF/SG4/N30:2010 7.1 Management subsystems | Applicable? | Additional guidance for auditing distributor |
|---|---|---|
| **Objective:** The purpose of the management subsystem audit is to verify that the top management ensures that an adequate and effective quality management system has been established and maintained. | | |
| 1. Verify that a quality manual, management review and quality audit procedures, quality plan, and quality management system procedures and instructions have been defined and documented. (ISO 13485:2003: 4.1, 4.2) | Yes | Verify that the distributor<br>● defines the scope of its quality management system in accordance with the applicable ISO 13485: 2003 and regulatory requirements,<br>● document its interaction with the manufacturer, and<br>● defines and documents its communication with the manufacturer on the determination of the processes that affects product conformity with requirements. |
| 2. Verify that a quality policy and objectives have been defined and documented and steps taken to achieve them. (ISO 13485:2003: 5.3, 5.4) | Yes | There is no specific guidance for this clause. |
| 3. Verify that the product realization process incorporates risk management planning, and ongoing review of the effectiveness of risk management activities ensuring that policies, procedures and practices are established for analysing, evaluating and controlling risk.(ISO 13485:2003: 7.1) | Yes | Verify that the distributor plans to meet requirements for preservation of product to ensure the product quality if applicable. |

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| 4. Review the manufacturer's organizational structure and related documents to verify that they include provisions for responsibilities, authorities (e.g., management representative), resources, competencies and training. (ISO 13485:2003: 5.1, 5.5.1, 5.5.2, 6.1, 6.2) | Yes | There is no specific guidance for this clause. |
| 5. Verify that management reviews are being conducted and that they include a review of the suitability and effectiveness of the quality management system.(ISO 13485:2003: 5.6) | Yes | There is no specific guidance for this clause. |
| 6. Verify that internal audits of the quality management system are being conducted and that they include verification of corrective and preventive actions.(ISO 13485:2003: 8.2.2) | Yes | There is no specific guidance for this clause. |
| 7. The audit commences and ends with the management subsystem, however between the opening and closing of management subsystem the other subsystems are audited. | Yes | There is no specific guidance for this clause. |
| At the conclusion of the audit a decision should be made as to whether top management has taken the appropriate actions to ensure a suitable and effective quality management system is in place. | | |

## 7.2 Design and development subsystem

| GHTF/SG4/N30:2010 7.2 Design and development subsystem | Applicable? | Additional guidance for auditing distributor |
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| **Objective:** The purpose of auditing the design and development subsystem is to verify that the design and development process is controlled to ensure that medical devices meet user needs, intended uses and specified requirements.<br><br>Note: Subsystem 7.2 is not applicable to the distributor except for ISO 13485: 2003 7.1 and 7.3.7. | | |

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| 1. Verify if products are by regulation subject to design and development procedures including risk management (e.g., hazard identification, risk evaluation and risk control). (ISO 13485:2003: 7.1, 7.3) | No | This clause is not applicable to audit of distributor. |
| 2 Review documents describing the design process and select sufficient records to cover the manufacturer's product range. Focus on individual products rather than families.<br><br>Criteria for selection:<br><br>■ product risk<br>■ complaints or known problems<br>■ age of design (prefer most recent) | Yes | Verify that the distributor does not implement design and development process except for design and development change. |
| 3. Review the design plan for the selected product(s) to understand the design and development activities, including assigned responsibilities and interfaces.(ISO 13485:2003: 7.3.1) | No | This clause is not applicable to audit of distributor. |
| 4. For the product design record(s) selected, verify that design and development procedures have been established and applied. (ISO 13485:2003: 7.3.1) | No | This clause is not applicable to audit of distributor. |
| 5. Verify that design inputs were established and address customer functional, performance and safety requirements, intended use, applicable regulatory requirements, and other requirements essential for design and development. (ISO 13485:2003: 7.2.1, 7.3.2) | No | This clause is not applicable to audit of distributor. |

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| 6. Review medical device specifications to confirm that design and development outputs meet design input requirements. Verify that the design outputs essential for the proper functioning of the medical device have been identified. (ISO 13485:2003: 7.3.3) | No | This clause is not applicable to audit of distributor. |
| 7. Verify that risk management activities are defined and implemented and that risk acceptability criteria are established and met throughout the design and development process. Verify that any residual risk is evaluated and, where appropriate, communicated to the customer (e.g., labelling, service documents, advisory notices, etc.). (ISO 13485:2003: 7.1, 7.3.2)<br><br>Note: It may be necessary to audit other subsystems to verify that risk acceptability criteria are met and residual risk is communicated if necessary. | No | This clause is not applicable to audit of distributor. |
| 8. Verify that design validation data show that the approved design meets the requirements for the specified application or intended use(s). (ISO 13485:2003: 7.3.6) | No | This clause is not applicable to audit of distributor. |
| 9. Verify that clinical evaluations and/or evaluation of the medical device safety and performance were performed if required by national or regional regulations. (ISO 13485:2003: 7.3.6) | No | This clause is not applicable to audit of distributor. |
| 10. If the medical device includes software, verify that the software was part of the medical device's design and | No | This clause is not applicable to audit of distributor. |

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| development validation. (ISO 13485:2003: 7.3.1, 7.3.6) | | |
| 11. Verify that design changes were controlled and verified or where appropriate validated and that design changes have been addressed.(ISO 13485:2003: 7.1, 7.3.5, 7.3.7) | Yes | Verify that the distributor establishes and maintains processes for notifying manufacturer of planned changes. |
| 12. Verify that design reviews were conducted. (ISO 13485:2003: 7.3.1, 7.3.4) | No | This clause is not applicable to audit of distributor. |
| 13. Verify that design changes have been reviewed for the effect on products previously made and delivered, and that records of review results are maintained.(ISO 13485:2003: 7.3.7 ) | Yes | Verify if the distributor notifies manufacturer of planned changes that may affect the product. |
| 14. Determine if the design was correctly transferred to production. (ISO 13485:2003: 7.3.1) | No | This clause is not applicable to audit of distributor. |
| Evaluate the Design and Development subsystem for adequacy based on findings. | | |

### 7.3 Product documentation subsystem

| **GHTF/SG4/N30:2010 7.3 Product documentation subsystem** | **Applicable?** | **Additional guidance for auditing distributor** |
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| **Objective:** The purpose of auditing the Product Documentation Subsystem is to verify that the manufacturer's documentation ensures that products meet customer and regulatory requirements. | | |
| 1. Verify if there are documents needed by the organization to ensure planning, operation and control of its processes. (ISO 13485:2003: 4.2.1d) | Yes | Verify if the distributor establishes and maintains the file required by ISO 13485: 2003 4.2.1d and defines the complete distribution process and, if applicable, installation and servicing. |
| 2 Select Product Documentation for sufficient product(s) to cover the manufacturer's product range.(ISO 13485:2003: 7.1, | Yes | There is no specific guidance for this clause. |

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| 7.2, 7.3.3)<br><br>Criteria for selection:<br><br>● product risk<br>● complaints or known problems<br>● age of design (prefer most recent) | | |
| For the product(s) selected verify that documentation includes (if required by national or regional regulations):<br><br>● evidence of conformity to requirements, including standards used<br>● medical device description including instruction for use, materials and specification<br>● summary of design verification and validation documents including clinical evidence<br>● labeling<br>● risk management documents<br>● manufacturing information including major suppliers<br><br>Note: This does not prevent the auditor from assessing additional documentation. | Yes | Verify that documentation includes:<br><br>● medical device description including instruction for use,<br>● labelling,<br>● risk management documents applicable for distribution processes, and<br>● distribution process (if applicable, installation and servicing) |
| Evaluate the Product Documentation Subsystem for adequacy based on findings. | | |

## 7.4 Production and process controls subsystem

| GHTF/SG4/N30:2010 7.4 Production and process controls subsystem | Applicable? | Additional guidance for auditing distributor |
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| **Objective:** The purpose of auditing the production and process control subsystem (including testing, infrastructure, facilities and equipment) is to verify that the | | |

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| manufacturer's production and process controls are able to ensure that products will meet specifications. | | |
| 1. Verify that the product realization processes are planned – including any necessary controls and controlled conditions. (ISO 13485:2003: 7.1, 7.5.1) | Yes | Verify that the distributor establishes documented distribution and servicing processes in accordance with manufacturer's requirements. |
| 2. Verify that the planning of product realization is consistent with the requirements of the other processes of the quality management system. (ISO 13485:2003: 7.1) | Yes | There is no specific requirement for this clause. |
| 3. Review production processes considering the following criteria. Select one or more production processes to audit.<br><br>Criteria for selection:<br><br>● CAPA indicators of process problems<br>● use of production process for higher risk products<br>● new production processes or new technologies<br>● use of the process in manufacturing multiple products<br>● processes not covered during previous audits<br><br>Note: For auditing a sterilization process see Appendix 4 | Yes | Criteria for selection:<br><br>● CAPA indicators of process problems<br>● use of distribution and servicing processes for higher risk products<br>● new products<br>● use of the processes in multiple products<br>● processes not covered during previous audits |
| 4. Verify that the processes have been validated if the result of the process cannot be verified. Verify that the validation demonstrates the ability of the processes to achieve planned result. (ISO 13485:2003: 7.5.2) | Yes | This clause applies if the distributor:<br><br>● utilizes computer software in distribution, servicing or quality management system,<br>● delivers medical devices that may be affect |

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| | | adversely during transportation. |
| 5. Verify that the equipment used in production and process control has been adjusted, calibrated and maintained. (ISO 13485:2003: 7.5 , 7.6) | Yes | Verify that the distributor controls the equipment used in distribution and servicing processes. |
| 6. Verify that the processes are controlled and monitored and operating within specified limits. In addition, verify that risk control measures identified by the manufacturer in production processes are controlled, monitored and evaluated. (ISO 13485:2003: 7.1, 7.5) | Yes | There is no specific guidance for this clause. |
| 7. Verify that risk control measures are applied to delivery, installation and servicing, where applicable. (ISO 13485:2003: 7.5.1.1, 7.5.1.2.2 and 7.5.1.2.3) | Yes | There is no specific guidance for this clause. |
| 8. Determine the links to other processes. (ISO 13485:2003: 4.1, 4.2) | Yes | There is no specific guidance for this clause. |
| 9. Verify that personnel are appropriately qualified and/or trained to implement/maintain the processes.(ISO 13485:2003: 6.2.2) | Yes | There is no specific guidance for this clause. |
| 10. Verify that the infrastructure and the work environment are adequate. (ISO 13485:2003: 6.3, 6.4) | Yes | Verify that the infrastructure and the work environment are in accordance with the requirements specified by the manufacturer. |
| 11. Verify that identification and traceability for processes and products are in place and are adequate. (ISO 13485:2003: 7.5.3) | Yes | Verify that the identification and traceability control processes are in accordance with the requirements specified by the manufacturer. |
| 12. If the process is software controlled, verify that the software is validated for its intended use. (ISO 13485:2003: 7.5.2.1) | Yes | See 4 of this section. |
| 13. Verify that the control of | Yes | There is no specific guidance for |

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| the monitoring and measuring devices is adequate. (ISO 13485:2003: 7.6) | | this clause. |
| 14. Verify that the system for monitoring and measuring of products is adequate. Ensure that any identified risk control measures are implemented. (ISO 13485:2003: 7.6, 8.2.4) | Yes | There is no specific guidance for this clause. |
| 15. Verify that acceptance activities assure conformance with specifications and are documented. (ISO 13485:2003: 8.2.4, 8.2.4.1, 8.2.4.2) | No | This clause is not applicable to the audit of distributor. |
| 16. Verify that the control of nonconforming products is adequate. (ISO 13485:2003: 8.3) | Yes | Verify that the distributor controls the nonconforming product in accordance with the requirements specified by the manufacturer. |
| Evaluate the Production Processes subsystem for adequacy based on findings. | | |

### 7.5 Corrective and preventive actions – CAPA subsystem

| GHTF/SG4/N30:2010 7.5 Corrective and preventive actions – CAPA subsystem | Applicable? | Additional guidance for auditing distributor |
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| **Objective:** The purpose of auditing the CAPA subsystem (including reporting/tracking) is to verify that manufacturer's processes ensure that information is collected and analysed to identify actual and potential product and quality problems, and that these are investigated, and appropriate and effective corrective and preventive actions are taken. | | |
| 1. Verify that CAPA system procedure(s) which address the requirements of the quality management system have been established. (ISO 13485:2003: 4.1, 4.2, 8.5) | Yes | There is no specific guidance for this clause. |
| 2. Verify that accurate information is analysed for input into the CAPA system and that corrective and preventive actions were effective. (ISO 13485:2003: 8.4, 8.5) | Yes | There is no specific guidance for this clause. |
| 3. When a CAPA results in | Yes | There is no specific guidance for |

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| a design change, verify that the hazard(s) and any new risks are evaluated under the risk management process. (ISO 13485:2003: 7.1) | | this clause. |
| 4. Determine if all appropriate sources of CAPA data have been identified and are being monitored to determine action when indicated. Confirm that data from these sources are analysed, using valid statistical methods where appropriate, to identify existing product and quality problems that may require corrective action. (ISO 13485:2003: 8.1, 8.2.3, 8.4) | Yes | There is no specific guidance for audit of distributor. |
| 5. Determine if all appropriate sources of CAPA data have been identified and are being monitored to determine action when indicated. Confirm that data from these sources are analysed, using valid statistical methods where appropriate, to identify existing product and quality problems that may require corrective action. (ISO 13485:2003: 8.1, 8.2.3, 8.4) | Yes | There is no specific guidance for audit of distributor. |
| 6. Verify that controls are in place to prevent distribution of nonconforming products. (ISO 13485:2003: 8.3) | Yes | Verify that he distributor controls the nonconforming product in accordance with the requirements specified by the manufacturer. |
| 7. Confirm that corrective and preventive actions were implemented, effective, documented and did not adversely affect finished devices. (ISO 13485:2003: 8.2.3 8.5.2, 8.5.3) | Yes | There is no specific guidance for this clause. |
| 8. Determine if relevant information regarding nonconforming product and quality problem(s) and | Yes | Verify that relevant information is communicated between the distributor and manufacturer. |

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| corrective and preventive actions has been supplied to management for management review. (ISO 13485:2003: 5.6.3) | | |
| 9. Verify that medical device reporting is done according to the applicable regulatory requirements. (ISO 13485:2003: 8.5.1) | Yes | Verify that the distributor :<br>● establishes documented procedures for the issue and implementation of advisory notices in accordance with the requirements specified by the manufacturer or applicable regulatory requirements.<br>● maintains the records of customer complaint investigations and share the information with the manufacturer/ authorized representative<br>● establishes documented procedures to the notification of adverse events or recall on behalf of the manufacturer that meet the reporting criteria specified by the national regulatory authorityor its designated organization, if applicable. |
| 10. Confirm that the manufacturer has made effective arrangements for gaining experience from the post production phase, handling complaints (see also 7.8.3), and investigating the cause of non-conformance related to advisory notices/recalls with provision for feed back into the corrective and preventive action subsystem. (ISO 13485:2003: 7.2.3, 8.2.1) | Yes | Verify that the distributor documents feedback applicable to the product and its supply from the post-production phase in accordance with the requirements specified by the manufacturer and applicable regulatory requirements. |
| 11. Confirm that the manufacturer has made | Yes | Verify that the distributor's advisory notices/recalls |

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| effective arrangements for the issue and implementation of advisory notices/recalls. (ISO 13485:2003: 8.5.1) | | processes are adequate to applicable regulatory requirements and the manufacturer's requirements. |
| Evaluate the Corrective and Preventive Actions subsystem for adequacy based on findings. | | |

## 7.6 Purchasing controls subsystem

| GHTF/SG4/N30:2010 7.6 Purchasing controls subsystem | Applicable? | Additional guidance for auditing distributor |
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| The Purchasing Controls subsystem should be considered a main subsystem for those manufacturers who outsource essential activities such as design and development and/or production to one or more suppliers<br><br>**Objective:** The purpose of auditing the purchasing control subsystem is to verify that the manufacturer's processes ensure that products, components, materials and services provided by suppliers, (including contractors and consultants) are in conformity. This is particularly important when the finished product or service cannot be verified by inspection (e.g., sterilization services). | | |
| 1. Verify that procedures for conducting supplier evaluations have been established. (ISO 13485:2003: 7.4.1) | Yes | There is no specific guidance for this clause. |
| 2. Verify that the manufacturer evaluates and maintains effective controls over suppliers, so that specified requirements are met. (ISO 13485:2003: 7.4.1) | Yes | There is no specific guidance for this clause. |
| 3. Verify that the manufacturer assures the adequacy of specifications for products and services that suppliers are to provide, and defines risk management responsibilities and any necessary risk control measures. (ISO 13485:2003: 7.4.2) | Yes | There is no specific guidance for this clause. |
| 4. Verify that records of supplier evaluations are maintained. (ISO 13485:2003: 7.4.1) | Yes | There is no specific guidance for this clause. |
| 5. Determine that the verification of purchased | Yes | There is no specific guidance for this clause. |

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| products and services is adequate. (ISO 13485:2003: 7.4.3) | | |
| Evaluate the Purchasing Controls subsystem for adequacy based on findings. | | |

### 7.7 Documentation and records subsystem

| GHTF/SG4/N30:2010 7.7 Documentation and records subsystem | Applicable? | Additional guidance for auditing distributor |
|---|---|---|
| **Objective:** The purpose of auditing the documentation and records subsystem is to verify that the manufacturer's documentation processes ensure that relevant documents are adequately controlled and that relevant records are available. | | |
| 1. Verify that procedures have been established for the identification, storage, protection, retrieval, retention time and disposition of documents and records. (Including change control). (ISO 13485:2003: 4.2.3, 4.2.4) | Yes | Verify that the retention period of documents and records is defined in accordance with the requirements specified by the manufacturer or applicable regulatory requirements. |
| 2. Confirm that documents and changes are approved prior to use. (ISO 13485:2003: 4.2.3) | Yes | There is no specific guidance for this clause. |
| 3. Confirm that current documents are available where they are used and that obsolete documents are no longer in use. (ISO 13485:2003: 4.2.3) | Yes | There is no specific guidance for this clause. |
| 4. Verify that required documents and records are being retained for the required length of time. (ISO 13485:2003: 4.2.1, 4.2.4) | Yes | See 1 of this section. |
| Evaluate the Documentation and Records subsystem for adequacy based on findings. | | |

### 7.8 Customer related processes subsystem

| GHTF/SG4/N30:2010 7.8 Customer related processes subsystem | Applicable? | Additional guidance for auditing distributor |
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| **Objective:** The purpose of auditing customer related processes subsystem is to verify that customer related processes ensure that requirements including regulatory | | |

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| requirements are addressed by the quality management system. | | |
| 1. Review product requirements to verify that they address the intended use as well as customer and regulatory requirements. (ISO 13485:2003: 7.2.1, 7.2.2) | Yes | There is no specific guidance for this clause. |
| 2. Confirm that incoming orders and related information are reviewed to assure that any conflicting information is resolved and the manufacturer can fulfil the customer's requirements. (ISO 13485:2003: 7.2.2) | Yes | There is no specific guidance for this clause. |
| 3. Confirm that the manufacturer has made effective arrangements for handling communications with customers including documenting customer feedback to identify quality problems and provide input into the corrective and preventive action subsystem. (ISO 13485:2003: 7.2.3, 8.2.1) | Yes | Verify that the distributor<br>● determines and implements effective arrangements for communicating with customers in accordance with the requirements specified by the manufacturer, if applicable.<br>● defines and documents the arrangement in relating to customer complaints and field actions including recall with the manufacturer if required by applicable regulatory requirements. |
| 4. Confirm that customer feedback is analysed in the product realization process and used to re-evaluate the risk assessment and, where necessary, adjust the risk management activities. (ISO 13485:2003: 7.1, 7.2.3) | Yes | See 3 of this section. |
| Evaluate the Customer related processes subsystem for adequacy based on findings. | | |