Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

FINAL DOCUMENT

Title: Guidance on Medical Device Quality Management System
- Requirements for Distributors

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Table of Contents

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

To ensure the safety, effective performance and quality of medical devices, a quality management system (QMS) has been required by regulatory authorities in many jurisdictions. Regulatory auditing is part of conformity assessment procedures in a medical device regulatory model.

ISO 13485: 2003 Medical devices - Quality management systems - Requirements for regulatory purposes, is widely accepted by regulators as the basis of the appropriate QMS requirements for medical device organizations that need to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services. ISO 13485: 2003 specifies requirements for a quality management system that can be used by an organization for the design and development, production, distribution, installation and servicing of medical devices, and the design, development, and provision of related services. This guidance document shall be reviewed in light of future revisions of ISO13485.

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.

This document is intended 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 expectations. It has been prepared

by Asian Harmonization Working Party Technical Committee Working Group 3. It is expected that the reader of this document is proficient with the requirements of ISO 13485: 2003.

3.0 Rationale and Scope

3.1 Rationale

The activities of design and development, production, distribution, installation and servicing of medical devices shall be implemented by the manufacturer under a documented quality management system in accordance with ISO 13485 and related regulatory requirements. The distributor must distribute, deliver or service medical devices to ensure the products meet the requirements specified by the manufacturers.

Safety and performance of finished medical devices may be affected by various conditions such as warehouse conditions, transportation, installation, servicing, duration of storage, and user training. Collection of customer feedback and implementation of correction and corrective actions, post-market surveillance activities, implementation of field safety corrective actions for the associated medical devices may be conducted by the manufacturer through cooperation with its distributor. A documented quality management system for a distributor ensures the conformity of medical devices through its life cycle.

To ensure the medical device complies with the specifications and quality assurance requirements specified by the manufacturer, Asian Harmonization Working Party developed this guidance an organization which distributes medical devices.

Another purpose of this guidance document is to assist regulatory authorities and/or conformity assessment bodies in the planning and the performance for regulatory auditing of distributor under their jurisdiction i.e. the scope of activities subjected to auditing, the requirements and the basis for assessing conformity

3.2 Scope

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'.

5.0 Definitions

5.1 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.

5.2 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 Quality management system for medical device distributor

6.1 Quality management system

ISO 13485: 2003	Clause Applicable?	Additional guidance for distributor
4 Quality management system		
4.1 General requirements	Yes	The distributor defines the scope of its quality management system in accordance with the applicable ISO 13485: 2003 and regulatory requirements. The distributor defines and document its interaction with the manufacturer. The distributor defines and document its communication with the manufacturer on the determination of the processes that affects product conformity with requirements.
4.2 Documentation requirements		
4.2.1 General	Yes	For each type or model of medical device, the distributor should establish and maintain a file either containing or identifying documents defining product specifications and quality management system requirements which apply to the distributor These documents shall define the complete distribution process and, if applicable, installation and servicing.
4.2.2 Quality manual	Yes	The scope of quality management system of a distributor is defined in accordance with this guidance and applicable regulatory requirements.
4.2.3 Control of documents	Yes	The retention period of documents is defined in accordance with the requirements specified by the manufacturer or applicable regulatory requirements.
4.2.4 Control of records	Yes	The retention period of the records is defined in accordance with the requirements specified by the manufacturer or applicable regulatory requirements.

6.2 Management responsibility

ISO 13485: 2003	Clause Applicable?	Additional guidance for distributor
5 Management responsibility		
5.1 Management commitment	Yes	There is no specific guidance for this clause.
5.2 Customer focus	Yes	There is no specific guidance for this clause.
5.3 Quality policy	Yes	There is no specific guidance for this clause.
5.4 Planning	Yes	There is no specific guidance for this clause.
5.4.1 Quality objectives	Yes	There is no specific guidance for this clause.
5.4.2 Quality management system planning	Yes	There is no specific guidance for this clause.
5.5. Responsibility, authority and communication		
5.5.1 Responsibility and authority	Yes	There is no specific guidance for this clause.
5.5.2 Management representative	Yes	There is no specific guidance for this clause.
5.5.3 Internal communication	Yes	There is no specific guidance for this clause.
5.6 Management review		
5.6.1 General	Yes	Management shall demonstrate, with objective evidence, management commitment through the establishment of the quality management system, and adherence to the quality policy, procedures and objectives defined for the distributor.
5.6.2 Review input	Yes	There is no specific guidance for this clause.
5.6.3 Review output	Yes	There is no specific guidance for this clause.

6.3 Resource management

ISO 13485: 2003	Clause Applicable?	Additional guidance for distributor
6 Resource management		
6.1 Provision of resources	Yes	There is no specific guidance for this clause.
6.2 Human resources	Yes	
6.2.1 General	Yes	Personnel at all levels of the distributor performing work affecting the fulfillment of appropriate regulatory requirements and quality management system compliance shall be competent on the basis of appropriate education, training, skills and experience.
6.2.2 Competence, awareness and training	Yes	There is no specific guidance for this clause.
6.3 Infrastructure	Yes	The distributor determines, provides, and maintains the infrastructure needed to achieve conformity to product requirements as specified by the manufacturer.
6.4 Work environment	Yes	The distributor determines and manages the work environment needed to achieve conformity to product requirements as specified by the manufacturer.

6.4 Product realization

ISO 13485: 2003	Clause Applicable?	Additional guidance for distributor
7 Product realization		
7.1 Planning of product realization	Yes	The distributor shall plan to meet requirements for preservation of product quality through storage and distribution, and installation and servicing if these are applicable.
7.2 Customer-related processes		
7.2.1 Determination of requirements related to the product	Yes	This clause is applicable to the distributor with respect to the manufacturer's requirements. Such as requirements for delivery

7.2.2 Review of requirements related to the product	Yes	This clause is applicable to the distributor with respect to the manufacturer's requirements.
7.2.3 Customer communication	Yes	The distributor shall determine and implement effective arrangements for communicating with customers in accordance with the requirements specified by the manufacturer, if applicable. The distributor shall define and document the arrangement in relating to customer complaints and field actions including recall with the manufacturer if required by regulatory requirements.
7.3 Design and development		
7.3.1 Design and development planning	No	This clause is not applicable to the distributor
7.3.2 Design and development inputs	No	This clause is not applicable to the distributor.
7.3.3 Design and development outputs	No	This clause is not applicable to the distributor.
7.3.4 Design and development review	No	This clause is not applicable to the distributor.
7.3.5 Design and development verification	No	This clause is not applicable to the distributor.
7.3.6 Design and development validation	No	This clause is not applicable to the distributor.
7.3.7 Control of design and development changes	Yes	Distributor is expected to notify manufacturer of planned changes that may affect the product.
7.4 Purchasing		
7.4.1 Purchasing process	Yes	This clause is applicable if the distributor purchases product or service that affects the quality of the final product. For example, the distributor might lease premises, have storage conditions that need monitoring such as cold rooms, use a third party for transport - all of which could require purchasing.
7.4.2 Purchasing information	Yes	This clause is applicable if 7.4.1 applies. The distributor shall maintain purchasing information in accordance

		with the traceability requirement specified by the manufacturer.
7.4.3 Verification of purchased product	Yes	There is no specific guidance for the distributor, importer.
7.5 Production and service provision		
7.5.1 Control of production and service provision		
7.5.1.1 General requirements	Yes	Requirements set forth in g) of the first paragraph and second paragraph are not applicable to the distributor. Note: activities such as labelling, primary packaging are not within the scope of this guidance document
7.5.1.2 Control of production and contamination control		
7.5.1.2.1 Cleanliness of product and contamination control	Yes	a), b), and d) of this clause is not applicable to the distributor.
7.5.1.2.2 Installation activities	Yes	This clause is applicable if the distributor carries out installation in accordance with the requirements specified by the manufacturer.
7.5.1.2.3 Servicing activities	Yes	This clause is applicable if the conducts servicing activities in accordance with the requirements specified by the manufacturer. Regulatory requirements may define the servicing activities applicable to the distributor.
7.5.1.3 Particular requirements for sterile medical devices	No	This clause is not applicable to the distributor.
7.5.2 Validation of processes for production and service provision		
7.5.2.1 General requirements	Yes	Clauses regarding validation of computer software and related records is applicable. Some distributors may use software to control inventory &

		distribution records (FIFO, control of nonconforming product, distribution records needed for traceability).
7.5.2.2 Particular requirements for sterile medical devices	No	This clause is not applicable to the distributor.
7.5.3 Identification and traceability		
7.5.3.1 Identification	Yes	The distributor shall identify the product with the suitable means as specified by the manufacturer or applicable regulatory requirements
7.5.3.2 Traceability		
7.5.3.2.1 General	Yes	The distributor shall implement documented procedures for traceability as specified by the manufacturer or applicable regulatory requirements
7.5.3.2.2 Particular requirements for active implantable medical devices and implantable medical devices	Yes	The first paragraph of this clause is not applicable to the distributor.
7.5.3.3 Status identification	Yes	There is no specific guidance for the distributor.
7.5.4 Customer property	Yes	There is no specific guidance for the distributor.
7.5.5 Preservation of product	Yes	The distributor establishes documented procedures or work instructions in accordance with the requirements specified by manufacturer for preserving the conformity of product during delivery to the intended destination including special storage and transportation conditions, if applicable.
7.6 Control of monitoring and measuring devices	Yes	There is no specific guidance for the distributor.

6.5 Measurement, analysis and improvement

ISO 13485: 2003	Clause Applicable?	Additional guidance for distributor, importer
8 Measurement, analysis and improvement		
8.1 General	Yes	There is no specific guidance for the distributor.
8.2 Monitoring and measurement		
8.2.1 Feedback	Yes	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.
8.2.2 Internal audit	Yes	The distributor may outsource internal audit process if it is a small business.
8.2.3 Monitoring and measurement of processes	Yes	There is no specific guidance for the distributor.
8.2.4 Monitoring and measurement of product		
8.2.4.1 General requirements	No	This clause is not applicable to the distributor.
8.2.4.2 Particular requirements for active implantable and implantable devices	No	This clause is not applicable to the distributor.
8.3 Control of nonconforming product	Yes	This clause is not applicable to the distributor except the first and the fourth paragraphs (4th para begins *Records of the nature of the nonconformities …)* Paragraph 6 on nonconformity detected after delivery is also applicable. Note: The distributor manages a non-conformance if it occurs within their own quality system. Disposition of product is determined either by the manufacturer or jointly with the distributor
8.4 Analysis of data	Yes	There is no specific guidance for the distributor.
8.5 Improvement		
8.5.1 General	Yes	The distributor establishes documented procedures for the issue and

		implementation of advisory notices in accordance with the requirements specified by the manufacturer or applicable regulatory requirements. The distributor maintains the records of customer complaint investigations and share the information with the manufacturer/ authorized representative The distributor establishes documented procedures to the notification of adverse events or recall on behalf of the manufacturer that meet national regulatory authority specified reporting criteria to the national regulatory authority or its designated organization, if applicable.
8.5.2 Corrective action	Yes	The distributor shall implement corrective actions as specified by the manufacturer or applicable regulatory requirements
8.5.3 Preventive action	Yes	The distributor shall implement preventive actions as specified by the manufacturer or applicable regulatory requirements