HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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MEDICAL DEVICE GUIDANCE

GN – 31 : Quality Management System (QMS)

Requirements for licensing of Importers and Wholesalers of Class A Medical Devices

HSA
Health Sciences Authority

INTRODUCTION

1.1. Purpose

This document sets out the Quality Management System (QMS) requirements for licensing of importers and wholesalers dealing solely in Class A medical devices.

In the event of any contradiction between the contents of this document and any written law, the latter shall take precedence.

1.2. Background

The existing requirements for the licensing of importers and wholesalers of Class A medical devices were critically re-examined with the objective to stratify the regulatory requirements of dealers handling medical devices of different risk classifications.

In line with the lower risk classification for Class A medical devices, HSA has introduced a set of QMS requirements for importers and wholesalers of only Class A medical devices. These QMS requirements encompass streamlined criteria of the GDPMDS standard.

The objective of the QMS requirements is to guide the importers and wholesalers in ensuring the quality and integrity of Class A medical devices throughout the supply chain. Conformance to these QMS requirements however, does not imply compliance to any written laws. It is the responsibility of the organization to ensure that they are in compliance with all applicable laws in force.

1.3. Assessment of Importers and Wholesalers of Class A Medical Devices

The assessment of this group of dealers will be carried out by HSA and no 3rd party GDPMDS certification and audit are required for the licence approval, renewal or amendment for these importers and wholesalers. These dealers will be allowed to deal only in Class A medical devices and applicable licence conditions will be reflected in their importer and wholesaler licences accordingly. Notwithstanding, these dealers may still opt to continue with formal 3rd party GDPMDS certification which affords the certified company greater flexibility to deal with a wider scope of the various risk classes of medical devices.

To facilitate post-market surveillance and monitoring, importers and manufacturers will be required to declare and periodically update HSA on the list of Class A medical devices (exempted from product registration) imported/manufactured on a 6-monthly basis. The need for submission of update to HSA on the Class A medical devices which are exempted from product registration has previously been made as a requirement for renewal of these dealer licences.

For importers and wholesalers of Class B, C & D medical devices, the licensing requirements remain status quo, i.e. mandatory formal GDPMDS certification and surveillance audits by 3rd party Certification Bodies.

In general, the assessment of the importers and wholesalers may not require an on-site audit of the company. Notwithstanding, selectively on a risk-based approach, HSA may conduct inspections of licensees to verify their compliance with the QMS requirements and the regulations when deemed necessary.

1.4. Scope

This set of QMS requirements is applicable to all companies that import and/or supply by wholesale **only** Class A medical devices in Singapore. For companies that import and/or supply by wholesale Class A medical devices

and other classes of medical devices, please refer to HSA's Regulatory Guidance on Medical Device Technical Specification *TS-01: Good Distribution Practice for Medical Devices – Requirements*.

1.5. Application

The QMS requirements are specific to companies providing solely Class A medical devices, regardless of the type or size of the organization.

If any requirement is deemed not to be applicable based on the characteristics of the medical device(s), the company does not need to implement such a requirement. However, a justification has to be provided for the exclusion from fulfillment of that particular requirement.

When the term "where applicable" is used to qualify a requirement, it is deemed to be "applicable" unless the company can document a justification otherwise.

1.6. Definitions

Definitions are intended as guidance for the purpose of this document. These definitions are not taken verbatim from the written law and should not be used in any legal context. These definitions are meant to provide guidance in layman terms.

ADVERSE EFFECT: any debilitating, harmful or detrimental effect that the medical device has been found to have or to be likely to have on the body or health of humans when such a medical device is used by or administered to humans.

ADVERSE EVENT: any event or other occurrence, that reveals any defect in any medical device or that concerns any adverse effect arising from the use thereof.

COMPLAINT: any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market.

DISTRIBUTION: for the purposes of this guidance note, means the release, delivery and post-delivery activities conducted by the company.

EXPORT: with its grammatical variations and cognate expressions, means to take or cause to be taken out of Singapore by land, sea or air.

FIELD SAFETY CORRECTIVE ACTION (FSCA): any action taken to reduce a risk of death or serious deterioration in the state of health of a person associated with the use of a medical device. This may include:

- the return of the medical device to its product owner;
- the replacement or destruction of the medical device;
- any action regarding the use of the medical device that is taken in accordance with the advice of its product owner;
- the clinical management of any patient who has used the medical device;
- the modification of the medical device;
- the retrofitting of the medical device in accordance with any modification to it or any change to its design by its product owner
- the making of any permanent or temporary change to the labelling or instructions for use of the medical device; or
- any upgrade to any software used with the medical device, including any such upgrade carried out by remote access;

In accessing the need of the FSCA, the product owner is advised to use the methodology described in the *ISO 14971:2007 Medical devices – Application of risk management to medical devices.*

IMPORT: with its grammatical variations and cognate expressions, means to bring or cause to be brought into Singapore by land, sea or air.

MEDICAL DEVICE: any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article that is intended by its product owner to be used, whether alone or in combination, for humans for one or more of the specific purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of any disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification, or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices; or
- providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

PREMISES: any location that is used for activities dealing with medical devices, including storage, manufacture, etc.

PACKAGING: in relation to a medical device, means the container and other packaging material in which the medical device is supplied.

PACKING: the process of repackaging a medical device from its original packaging into another packaging, without breach of the primary packaging, before the medical device is sold or supplied.

PRIMARY PACKAGING: in relation to a medical device, means packaging that maintains the sterility or integrity of the medical device

PRODUCT OWNER: means a person who sells a medical device under his own name, or under any trade-mark, design, trade name or other name or mark owned or controlled by him, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

WHOLESALE: in relation to a medical device, means any one or more of the following:

- supplying the medical device to a person who obtains the medical device for the purposes of supplying it again to some other person;
- supplying the medical device to a person as a commercial sample in the normal course of a lawful trade;
- supplying the medical device to a Government department or statutory body which requires the medical device for the purposes of the public service or use in connection with the exercise of any statutory power;
- supplying the medical device to a person or an institution concerned with scientific education or research which requires the medical device for the purpose of education or research;
- supplying the medical device to a person who requires the health product for the purpose of enabling him to comply with any requirements made by, or in pursuance of, any written law with respect to the medical treatment of persons employed by that person in any business or trade carried out by that person;

- supplying the medical device to a person who requires to use the medical device, other than by way of administration to one or more persons, for the purpose of his business or trade;
- supplying the medical device by export to a party outside Singapore.

2. QUALITY MANAGEMENT SYSTEM

2.1. Personnel

2.1.1. Key personnel in charge of warehousing operations should possess appropriate competency, knowledge and experience, and where applicable, the relevant professional and technical qualifications for the tasks assigned to them.

2.1.2. Organisation chart showing the arrangements of the reporting lines for the key personnel, their designations and description of job responsibilities should be available.

2.1.3. Initial and continuing training on the QMS requirements and job functions should be provided to all personnel. Training records of all personnel should be maintained.

2.2. Premises and Equipment

2.2.1. The company should ensure that the premises and equipment used are suitable and adequate to ensure proper conservation and distribution of medical devices.

2.2.2. Premises should have sufficient security to prevent unauthorised access and misappropriation of medical devices.

2.2.3. The storage areas should be dry, clean and free from litter and dust. Written cleaning instructions should be available to ensure the storage areas are cleaned regularly. Regular checks should be performed and records of cleaning maintained.

2.2.4. The company should ensure that the storage areas are free from pest infestation. Regular checks should be performed and records of pest control maintained.

2.2.5. Smoking, eating and drinking should be prohibited in areas used for storage and handling of medical devices.

2.3. Storage, Stock handling and Deliveries

2.3.1. The company should provide suitable and adequate storage to ensure proper conservation of the medical devices.

2.3.2. Upon receipt, each incoming delivery of medical devices should be checked to ensure that specified requirements are met. The type and nature of checks should be stated in a written work instruction. Records of this verification for receipt of stock should also be maintained.

2.3.3. Medical devices subject to specific storage measures (e.g. cold chain products) should be immediately identified and stored in the appropriate conditions as required.

2.3.4. Medical devices should be stored under appropriate conditions to prevent contamination and deterioration by light, moisture, temperature or other adverse conditions. Records of the monitoring of the storage conditions should be maintained.

2.3.5. There should be designated areas for the orderly and segregated storage of various categories of goods such as those in quarantine, saleable stock, expired, rejected, recalled or returned medical devices. Alternative means of segregation may be considered, if they provide at least equivalent assurance to prevent mix-up.

2.3.6. The company should ensure appropriate stock rotation such that medical devices due to expire first are sold and/or distributed first (Earliest-Expiry-First-Out, EEFO). Where no expiry dates or shelf life for the device exists, First-In-First-Out (FIFO) should be applied. Deviations may, however, be permitted in exceptional cases where such deviation is appropriate and justified.

2.3.7. Medical devices beyond their expiry date or shelf life should be segregated from usable stock. They should be clearly labelled as “Not for Sale” or in other similar phrases/words. The expired medical devices should be disposed of in accordance with the requirements under Clause 2.8.

2.3.8. The records for receipt and distribution of the medical devices should be kept, stating the device name, date of transaction, invoice/delivery order number, name and address of purchaser/supplier, batch/lot number (or equivalent), expiry date/shelf life, quantity received/sold and stock balance. These records should be kept for a period of time in accordance with the requirements under Clause 2.15.

2.3.9. The company should ensure adequate provision for the security, storage condition and protection of the quality of medical devices during all transportation processes.

2.3.10. Medical devices requiring controlled temperature or other special control and conditions should be transported by appropriate or specialised means.

2.3.11. The vehicle for transportation should not be used as a store for medical devices.

2.4. Medical Device Complaints

2.4.1. Written work instructions should be in place describing the actions to be taken for the handling of all written and verbal complaints regarding a medical device.

2.4.2. The original details of the complaint, investigations and subsequent corrective and preventive actions taken, including medical device recall, if warranted, should be documented for each complaint. Such records should be maintained as required by the regulatory authority.

2.4.3. ~~A~~ designated personnel within the company should be available to handle complaints. This person should have the authority to initiate investigations.

2.4.4. Any report of adverse event received by the company that meets the regulatory reporting criteria should be reported to the regulatory authority promptly. Reporting criteria and specific timelines for reporting of adverse events are stipulated in the Health Products (Medical Devices) Regulations.

2.5. Field Safety Corrective Action (FSCA)

2.5.1. The company should establish written work instructions for the handling of FSCA. The responsibilities for planning, conducting and reporting of the corrective action should be described in the work instructions.

2.5.2. ~~A~~ designated personnel within the company should be available to handle FSCAs.

2.5.3. The regulatory authority should be informed prior to the execution of the FSCA. If the medical devices are exported, the overseas counterparts should also be informed of the FSCA. All notification and reports should be submitted in the manner as required by the regulatory authority.

2.5.4. Records of all actions taken in connection with the FSCA and their approval by the company and regulatory authority should be maintained.

2.5.5. Upon completion of each FSCA, a final report should be provided to the regulatory authority. Reconciliation should be made between delivered and recovered quantities of medical devices.

2.6. Medical Device Recall

2.6.1. Written work instructions should be in place describing the actions to be taken for the handling of a recall of a medical device in an effective and timely manner.

2.6.2. A responsible personnel or committee should be designated for the coordination and execution of all product recalls.

2.6.3. The regulatory authority should be informed of all product recalls. If the medical device is exported, the overseas counterparts and/or regulatory authorities should be informed of the recall. All customers or consignees to whom the product has been distributed should be

informed with the appropriate degree of urgency. All notification and reports should be submitted in the manner as required by the regulatory authority.

2.7. Returned Medical Devices

2.7.1. Records of all returned medical devices must be maintained.

2.7.2. The company should ensure that all returned medical devices are segregated from saleable stock and ~~to~~ prevent redistribution until a decision has been reached regarding their disposition.

2.7.3. The criteria for re-evaluation of the returned medical devices and the designated responsible person should be specified. Records of the re-evaluation and any subsequent action taken should be maintained.

2.8. Disposal of Medical Devices

2.8.1. Medical devices not immediately sent for disposal should be kept in a clearly segregated area and identified so that they will not be sold or distributed inadvertently, or contaminate other medical devices.

2.8.2. Records of the disposal of medical devices should be maintained.

2.9. Counterfeit, Adulterated, Unwholesome or Tampered Medical Devices

2.9.1. Written work instructions should be in place to handle counterfeit, adulterated, unwholesome or tampered medical devices found in the distribution network.

2.9.2. Such devices must be physically segregated from other medical devices to avoid any confusion. They should be clearly labelled as “Not for Sale” or in other similar words/phrases.

2.9.3. The company should inform the regulatory authority, registrant and product owner immediately. All reports should be submitted in the manner as required by the regulatory authority within 48 hours when

the company becomes aware of possession of possibly counterfeit medical devices.

2.10. Internal Review of QMS

2.10.1. The company should conduct regular internal reviews on the effective implementation of the QMS including the company's compliance with the licensing and/or regulatory requirements.

2.10.2. The outcome of review, including all observations made during the review and any subsequent corrective actions should be recorded.

2.11. Installation and Servicing

2.11.1. Where applicable, the company should establish and maintain adequate written work instructions on installation and inspection to ensure that the medical device will perform as intended after installation. The records of inspection and any test results to demonstrate proper installation should be maintained.

2.11.2. Where applicable, the company should establish written instructions on servicing. Records of servicing should also be maintained.

2.12. Packing

2.12.1. Where applicable, companies should establish written work instructions for planning and carrying out packing of class A medical devices under controlled conditions. Controlled conditions should include but are not limited to work instructions defining the work processes such as labelling and packaging of medical devices, in process control activities and line clearance. The release criteria to be met before approval for distribution should be established and documented.

2.12.2. The company should establish and maintain a batch packing record for each batch of medical devices packed. The record should carry the batch number, the quantity of medical devices packed and the

quantity approved for distribution. The batch record should be verified and approved by qualified personnel before the batch can be distributed.

2.12.3. The batch packing records should be kept for a period of time in accordance with the requirements under Clause 2.15.

2.13. Outsourced Activities

2.13.1. Where applicable, it is the company's responsibility to ensure that outsourced processes within the scope of the QMS are under control. The type and extent of control applied on the service provider should be dependent on the impact on meeting the requirements of the QMS.

2.13.2. The service provider should be audited as part of the regular internal review of the QMS by the company.

2.13.3. Depending on the nature of the activities performed, the service provider may be subjected to inspection by the regulatory authority.

2.13.4. Unless otherwise justified, a written agreement between the contract giver and contract acceptor should be established to define the respective responsibilities relating to the outsourced activities.

2.14. Cold Chain Medical Devices

2.14.1. Written work instructions should be available to ensure that medical devices requiring cold chain management are handled under the required storage conditions in compliance with the instructions stated on the product label. These include instructions for all activities related to the receipt, storage, packing and delivery that may affect the quality of these cold chain medical devices.

2.14.2. The company should ensure that incoming and outgoing cold chain medical devices are delivered under the specified storage conditions in compliance with the instructions on the product label. Cold chain

devices should be immediately identified upon receipt and held under the same conditions. The subsequent checks for signs of tampering, damage and non-compliance with cold chain storage condition as well as physically verifying the label description, and product quantity on these incoming medical devices should be carried out under these recommended storage conditions unless otherwise justified. Records of the checks performed should be maintained.

2.14.3. The temperature conditions for the cold room or refrigerator should be monitored and recorded on a continuous basis. The temperature probes/monitoring devices should be subjected to periodic calibration for the required operating range. A regular maintenance programme should be established and carried out for the air-conditioning system of the cold room and refrigerator. Adequate records of repair, maintenance and calibration activities for key equipment should be maintained.

2.14.4. Where applicable, the cold room, which is used for storage of cold chain products, should be subjected to temperature mapping studies in order to identify the suitable locations for placing the temperature probes.

2.14.5. The cold room or refrigerator should be installed with an alarm system to alert the staff to any temperature excursions. Action and alert limits should be established. The function of the alarm system should be subject to periodic testing.

2.14.6. Backup power should be available for the cold room or refrigerator to ensure that storage conditions and their monitoring would be maintained in the event of a power failure. Alternative back-up plans or arrangements that provide equivalent storage temperature conditions and monitoring system may be considered.

2.14.7. There should be written instructions established for handling temperature excursions that may occur during receiving, storage and delivery.

2.15. Written Work Instructions and Records

2.15.1. The company should ensure that all written work instructions are reviewed regularly and kept up-to-date.

2.15.2. The company should retain all records for a period of time as specified by relevant regulatory requirements, or at least equivalent to the lifetime of the medical device as defined by the product owner of the medical devices, or no less than two years from the date the medical device is shipped from the organisation, whichever is the longest. The retention period of essential records must be clearly defined.

3. REFERENCES

3.1. TS-01: Good Distribution Practice for Medical Devices – Requirements (Revision 2.1)

3.2. Health Sciences Authority Guidance Notes on Good Distribution Practice (August 2010)

3.3. Assessment Form for Class A Medical Device Dealers (FORM 31A)

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

Licensing & Certification Branch
Audit & Licensing Division
Health Products Regulation Group
Health Sciences Authority

150 Cantonment Road, Cantonment Centre, Block A
#01-02 Singapore 089762
www.hsa.gov.sg

T: 68663522
F: 6478 9068

HSA
Health Sciences Authority