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GUIDELINES ON GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES (GDPMD)

[Rule 10, Medical Devices Rules, 2015]

Regulatory Requirements for Medical Device Safety and Performance

PREFACE

Distribution is an important activity in the integrated supply-chain of medical devices. Various personnel and entities are generally responsible for the product sourcing, procurement, transportation, delivery, storage, device tracking, installation, commissioning, service and maintenance and calibration need to be appropriately managed and controlled to ensure the safety and performance of medical devices at the point of use. The Guidelines on Good Distribution Practice for Medical Devices (GDPMD) is developed to elucidate the requirements for an appropriate management and control of these activities. GDPMD specifies the requirements for a quality management system to be established, implemented and maintained by an establishment in carrying out activities in medical device supply-chain to comply with Pakistan medical device regulatory requirements as stipulated in Medical Device Rules, 2015 and DRAP Act, 2012 and to demonstrate its ability to maintain quality, safety and performance of medical devices in compliance with the regulatory requirement throughout the supply-chain. It is the responsibility of the establishment to ensure that they are in compliance with all applicable laws. This document provides general guidance for GDPMD. Although it has been tried that the accurate information be provided, however the authority does not warrant its accuracy and completeness and therefore does not accept any liability for any error or omissions in this document or for any action or decision taken or not taken as a result of using of this document. In the event of any contradiction between the requirements of GDPMD and any written law, the latter shall prevail.

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1. PRELIMINARY

1.1 Objective

The objective of this document is to ensure the quality, safety and performance of medical device during all aspects of medical device supply-chain, which include, but not limited to procurement, storage, transportation, delivery, installation, commissioning, service and maintenance, calibration and after sale service, tracking, documentation and record-keeping practices.

1.2 Scope and Application

This document is applicable to all parties involved in the supply-chain of medical device, covering authorized representatives of foreign manufacturers, importers or distributors of medical devices in Pakistan .

The design and implementation of GDPMD by an establishment is dependent on the types, categories and classification of medical device, size and structure of the establishment and the processes employed. If any requirement in GDPMD is not applicable due to the type, category and classification of the medical device and supply-chain activities, a justification has to be provided for exclusion from fulfillment of that particular requirement.

2. QUALITY MANAGEMENT SYSTEM

2.1 General Requirement:

The establishment shall establish, document, implement and maintain a quality management system in accordance to the requirements of GDPMD.

Where an establishment chooses to outsource any activity that may affect the quality of medical devices, the establishment shall ensure control over such processes.

The documentation required include:

(i) a site master file,
(ii) documented procedures required by the GDPMD,
(iii) documents needed by the establishment to ensure the effective planning, operation and control of its processes,
(iv) records required by the GDPMD, and
(v) any other documentation specified by the regulatory authority.

2.2 Control of Documents and Records

Documents required for GDPMD shall be controlled and records for each purchase and sale, showing the date of purchase and supply, name of medical device, quantity received and supplied and name and address of supplier or consignee shall be established and maintained to provide evidence of conformity to requirements of GDPMD. Record shall be legible, readily identifiable and retrievable.

A documented procedure shall be established for the identification, storage, protection, retrieval, retention time and disposal of record.

The establishment shall retain the record for a period of time:-

(i) specified by relevant regulatory requirements, or
(ii) at least equivalent to the lifetime of the medical device as defined by the product owner of the medical devices, whichever is the longest.

All documents shall be prepared, approved, signed and dated by an appropriate authorized person(s).

Documents shall be reviewed regularly and kept up-to-date. If a document has been revised, a control system shall be established to prevent the unintended use of the superseded version.

Where an electronic record system is used in place of a paper-based system, the system utilized should have built-in checks and balances to ensure the integrity of the record and to protect against unauthorized entries and the system should also incorporate audit trails for tracking changes.

Records providing traceability of medical devices from supplier and to the customers shall be maintained.

2.3 Complaints

The establishment shall establish a documented procedure for handling of all written and oral complaints regarding medical devices and record should be established.

The procedure for handling complaints shall ensure that the complaints received are investigated and followed through, and that corrective actions are taken to prevent repeated complaints, and, where a decision is made to recall the medical device, the details of the recall. Any report of adverse event which requires regulatory reporting shall be reported to the regulatory authority as per procedure and regulatory requirements.

Records of the complaint, investigation and any subsequent actions taken shall be maintained.

The investigation should take into consideration the condition and circumstances under which the medical device was distributed, stored and used.

2.4 Field Corrective Action (FCA) and Field Safety Notice (FSN)

"Field Corrective Action (FCA)" is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device.

"Field Safety Notice (FSN)" means a communication sent out by a manufacturer or its representative to the device users in relation to a FCA.

The establishment shall—

(i) establish documented procedures for handling of FCA and FSN
(ii) define the responsibilities for planning, conducting and reporting of corrective actions in the documented procedure;
(iii) establish in writing a recall or withdrawal procedure in consultation with manufacturer
(iv) inform the MDB prior to execution of FCA and FSN
(v) inform all customers to whom the medical device was distributed with the appropriate degree of urgency;
(vi) inform overseas counterparts on the FCA and FSN if the medical devices are exported;
(vii) request that the affected medical devices be removed immediately from usable stock and stored separately in a secure area until they are disposed of accordingly; and
(viii) maintain records of all actions taken in connection with the FCA and FSN.

The establishment shall establish documented procedure for incident/problem reporting to comply with the regulatory requirements, which include—

(i) the identification of the nature of the incident/problem;
(ii)the investigation;
(iii) the evaluation and analysis; and
(iv) the action to be taken.

Corrective actions as applicable shall be taken after final report.

2.5 Recall and Return

The establishment shall—

(i) establish a documented procedure to effectively and promptly recall and return medical device known or suspected to be defective;
(ii) ensure that the system comply with the regulatory requirements;
(iii) the manufacturer and/or authorized representative shall be informed in the event of a recall;
(iv) where a recall is instituted by an entity other than the manufacturer and/or authorized representative, consultation with the manufacturer and/or authorized representative should, where possible, take place before the recall is instituted;
(v) recall information shall be reported to the MDB.
(vi) All returned medical devices shall be segregated apart from saleable stock to prevent redistribution until a decision has been reached regarding their disposal and treated as nonconforming product.

Some criteria for medical devices to be returned to saleable stock are:-

(i) The medical devices are in their original unopened containers and in good condition;
(ii) It is known that the medical devices have been stored and handled under proper conditions;
(iii) The remaining shelf life period is acceptable; and
(iv) The medical devices have been examined and assessed by appropriate personnel. This assessment should take into account the nature of the medical device, any special storage conditions required, and the time that has elapsed since it was distributed. Special attention should be given to thermo-labile medical devices. Advice should be sought from the product owner as necessary.

The returned medical devices should only be formally released to saleable stock, following a satisfactory quality re-evaluation by a nominated, responsible person.

Medical devices returned to saleable stock should be placed in accordance with the stock rotation system established.

2.6 Disposal of Medical Devices

The establishment shall establish a documented procedure for the disposal of medical devices, keeping in view the regulatory requirements.

If the medical devices have not been immediately sent for disposal, they shall be kept in a clearly segregated area and identified so that they will not be sold inadvertently or contaminate other medical devices.

Control should be established to ensure that:-
(i) the status is clearly identified;
(ii) the products cannot re-enter the distribution system, and;
(iii) it is disposed of safely.

2.7 Internal Check System, Management Input and Output Review

The establishment shall establish internal check system to monitor the implementation of and compliance with the requirements of GDPMD.

Internal checking should normally be conducted once a year.

The result of the checking is usually stated in a written report indicating the nonconformities found. Timely action should be taken to eliminate the nonconformities and their causes. The checking results should be communicated to management for review.

The establishment top management should identify, review and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality system through the use of the quality policy, quality objectives, checking results, analysis of data, corrective and preventive actions and management review. This review shall include

assessing opportunities for improvement and the need for changes to the quality management system.

Records from management reviews shall be maintained.

The input to management review may also include information on:

(i) customer complaints/feedback;
(ii) surveillance and vigilance activities including field corrective actions, advisory notes, recalls and adverse event /incident reporting;
(iii) feedback from manufacturer;
(iv) feedback and directives from the authority;
(v) status of preventive and corrective actions;
(vi) changes that could affect the GDPMD regulatory compliance system; and
(vii) recommendations for compliance.

The output from the management review shall include any decision and action related to:-

(i) the corrective and preventive actions required; and
(ii) the effectiveness of the GDPMD regulatory compliance system and its compliance with the regulatory requirements.

Records of the management review should include the identity of those taking part in the review and all points of the review including description of any corrective or preventive action to be taken. For any action determined, the responsibility for such actions, the resources, target dates for completion, etc should be identified.

2.8 Corrective and Preventive Action

For corrective actions, The establishment shall—

(i) take action to eliminate the cause of nonconformities in order to comply with GDPMD and regulatory requirements; and
(ii) establish a documented procedure to define requirements for:

- reviewing nonconformities (including customer complaints);
- determining the causes of nonconformities;
- evaluating the need for action to ensure that nonconformities do not recur;
- determining and implementing action needed, including, if appropriate, updating documentation,
- recording of the results of any investigation and of action taken; and
- reviewing the corrective action taken and its compliance with GDPMD and regulatory requirements.

For preventive actions, The establishment shall—

(i) determine proactive action to eliminate the causes of potential nonconformities in order to comply with GDPMD and regulatory

requirements and preventive actions shall be appropriate to the effects of the potential problems; and

(ii) establish a documented procedure to define requirements for—

- determining potential nonconformities and their causes;
- evaluating the need for action to prevent occurrence of nonconformities;
- determining and implementing action needed;
- recording of the results of any investigations and of action taken;
- and reviewing preventive action taken and its effectiveness.

3 RESOURCE MANAGEMENT

3.1 Personnel

Personnel working at the premises shall be sufficient for complying GDPMD.
Qualified person shall possess the prescribed qualification.

3.2 Training

The establishment shall

(i) provide training to key personnel to satisfy needs, and
(ii) maintain training record.

Training for personnel will be tailored to the person's assignment. Typical training and education should cover the:

(i) nature of activities,
(ii) health, safety and environmental regulations and/or regulatory body related requirements,
(iii) establishment's policies,
(iv) function of the personnel, and
(v) procedures and instructions of relevance to personnel.
(vi) Special training may be necessary for personnel dealing with certain categories of substances/materials such as chemicals, biological, radiation emitting or energy source components and products.

3.3 Responsibility and Authority

The establishment shall ensure that responsibilities and authorities are defined, documented and communicated within the establishment. This should be documented in site master file as well.

3.4 Designated person

The establishment shall appoint designated person who, irrespective of other responsibilities, shall have the ultimate responsibility of:

(i) Ensuring that processes needed for the quality management system are established, implemented and maintained and reporting to top management on the performance of the quality management system and any need for improvement, and

(ii) Ensuring the promotion of awareness of regulatory and customer requirements throughout the establishment and liaising with external parties on matters relating to the quality management system and regulatory requirements.

3.5 Premises and Facilities.

The establishment shall ensure that the premises and equipment used are suitable and adequate to ensure proper conservation and distribution of medical devices. Fire extinguishers, smoke detector etc for control of fire shall be available. Storage areas should be cleaned and accumulated waste removed at regular intervals. The frequency and methods of cleaning the premises and areas should be recorded. No smoking, eating and drinking should be permitted in areas used for storage and handling of medical devices.

Buildings should protect medical devices from contamination and deterioration, including protection from excessive heat or undue exposure to direct sunlight.

Premises should be constructed, serviced and maintained regularly to protect stored medical devices from all potentially harmful influences such as undue variations of temperature and humidity.

3.6 Cleanliness and Pest Control

The establishment shall establish documented procedure for cleaning of premises including frequency and methods. Records of cleaning shall be maintained.

The establishment shall document and ensure a pest control mechanism to identify and prevent pest infestation.

Record of pest control mechanism shall be maintained.

3.7 Calibration

The instruments used for measuring and monitoring temperature and humidity shall be calibrated or verified for accuracy from accredited laboratories at defined intervals, or prior to use and the results of such calibrations or verifications shall be recorded and retained.

4 AUTHORIZATION

The establishment shall—

(i) obtain appropriate authorization to become authorized representative, importer or distributor of medical devices; and

(ii) establish and maintain written agreement with the relevant party regarding supply of information required for regulatory matters relating to medical devices it deals with.

5 SITE MASTER FILE.

The establishment shall establish and maintain a Site Master File as per format approved by the MDB.

6 STORAGE AND STOCK HANDLING, TRACEABILITY AND SUPPLY CHAIN MANAGEMENT

- The establishment shall provide suitable and adequate storage to ensure proper conservation of the medical devices and shall provide back up for electricity to ensure proper conservation of the medical devices during electric load shedding, wherever required.
- The establishment shall ensure proper receipt of medical devices.
- Medical devices requiring special storage conditions (e.g. temperature and/or humidity or narcotics requiring additional security measures) should be placed in separate areas equipped to provide the desired conditions. A list of such medical devices should be maintained and the medical devices properly identified. Storage conditions shall be monitored and recorded periodically and Records shall be maintained. During transportation special measure should be taken to maintain conditioned required to prevent effect on the integrity and quality of the medical devices.
- There should be adequate storage areas, and where applicable, physically separated zones for the orderly segregation of saleable stock, quarantined, expired, rejected/damaged, recalled and returned medical devices ensured, stored off the ground and suitably spaced having adequate lighting and ventilation.
- Appropriate and suitable storage conditions should be provided for hazardous, sensitive and dangerous materials such as combustible liquids and solids, pressurized gases, highly toxic and radioactive substances.
- Adequate precautions should be taken against spillage or breakage, attack by micro-organisms, contamination and cross-contamination.
- Where controlled environmental storage conditions are required, these conditions should be continuously monitored and documented. The actual storage temperature should be expressed quantitatively. Where the storage temperature is not expressed quantitatively or stated (in terms of a range) on the labels of the registered medical device.
- The establishment shall establish a system to ensure stock rotation with proper label information.
- The expired medical devices shall be disposed of as per procedure in this guidance document.
- Medical devices bearing an expiry date must not be received or supplied close to or after the expiry date such that this date is likely to occur before the consumer uses the medical devices.
- All labels and containers of medical devices should not be altered, tampered or changed.

- The establishment shall establish adequate methods of transportation and deliveries should be made only to authorized wholesalers, distributors or person to achieve safe and secure delivery of all medical devices from their point of collection to their point of delivery.

  Medical devices shall be transported in such a way that:-

  (i) their identification is not lost;
  (ii) they do not contaminate, and are not contaminated by, other medical devices or materials/substances;
  (iii) adequate precautions are taken against spillage, breakage or theft;
  (iv) they are secure and not subjected to unacceptable degrees of heat, cold, light, moisture or other adverse influence, or to attack by microorganisms and pests.

6.1 Installation and Servicing

The establishment shall where applicable—

(i) establish and maintain documented procedures, work instructions and reference materials, tools and test equipment and reference measurement procedures, for performing servicing activities including calibration, repair, maintenance and verifying that they meet the regulatory requirements and applicable standards;
(ii) establish documented requirements which contain acceptance criteria for installation, testing and commissioning of the medical device;
(iii) establish installation qualification and maintain adequate installation and inspection instructions for medical devices requiring specified installation requirements, and where appropriate, test procedures;
(iv) ensure proper installation, testing and commissioning;
(v) ensure equipment used for testing, maintenance and conservation of medical devices are calibrated or verified at specific intervals;
(vi) ensure the calibration and maintenance of test equipment conforms to the applicable standards; and
(vii) maintain testing and commissioning, installation, calibration and maintenance service records.

The establishment shall, as appropriate—

(i) establish an appropriate technical support which include maintenance service, training, calibration, management of spare parts, workshop setup and management;
(ii) establish maintenance management mechanism to support the customers;
(iii) ensure the technical and maintenance support services for active medical devices conform to the applicable regulatory requirements.

7. SEGREGATION OF COUNTERFEIT, ADULTERATED, MISBRANDED, SPURIOUS AND SUBSTANDARD MEDICAL DEVICES

Counterfeit, adulterated, misbranded, spurious and substandard medical devices, if found in the distribution network, shall be physically segregated from other medical devices to avoid any confusion. These shall be clearly labelled as "Not for Sale" or in other similar phrases/words.

Appropriate corrective measures should be undertaken for identified counterfeit, adulterate, misbranded, spurious or substandard medical device, which includes but are not limited to the following:-

(i) Segregation/quarantine of these medical devices,
(ii) Investigation of supply chain breach.

Communication is required to all affected wholesalers / distributors / retailers / consignees possibly supplied with these medical devices prior to notification to the regulatory authority for such communication

8. OUTSOURCE ACTIVITIES

Where the establishment outsources any process within the scope of the GDPMD, the establishment shall ensure control over such processes. Certain processes such as cleaning, pest control, transportation etc may be outsourced to third party service providers.

The establishment shall establish requirements to ensure that the outsourced activities conform to specified requirements.

ANNEX 1

SCOPE OF GDPMD CERTIFICATION

The GDPMD certificate shall specify the following—

(i) scope of activities performed by the establishment and category (s) of medical devices dealt by the establishment;
(ii) outsourced activities, if applicable;
(iii) any special storage and handling conditions, such as chill room or cold room for cold chain management; and
(iv) applicable rules of the Medical Device Rules, 2015.
(v) name, complete address and contact information of the establishment involved in performing activities.
(vi) issuing date and expiry date of the certificate.
(vii) particulars of CAB (if applicable) issuing the certificate which include the name and address, logo, registration number where applicable and/or accreditation number issued by Pakistan National Accreditation Council (PNAC) and the name and signature of the certification manager of the CAB; and
(viii) number, issuing date and expiry date of the certificate.

Scope of activities for establishment to be certified include anyone or combination of the following activities—

(i) import;
(ii) storage and warehousing;
(iii) distribution.
(iv) installation, testing & commissioning;
(v) servicing and maintenance; and

List of devices dealt by the establishment—

S.No	*Device Category

***List of device categories:**

01 Active implantable devices
02 Anesthetic and respiratory devices
03 Dental devices
04 Electro mechanical medical devices
05 Hospital hardware
06 In vitro diagnostic devices
07 Non-active implantable devices
08 Ophthalmic and optical devices
09 Reusable devices
10 Single-use devices
11 Assistive products for persons with disability
12 Diagnostic and therapeutic radiation Devices
13 Complementary therapy devices
14 Biologically-derived devices
15 Healthcare facility products and adaptations
16 Laboratory equipment
17 Medical software
18 Others: Please specify with justification for any additional categories

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