Medical Devices Storage Guideline

National Health Regulatory Authority (NHRA)

Kingdom Of Bahrain

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1. Introduction

Storage and distribution are important activities in the supply chain management of medical device that may be subjected to various risks at different stages in the supply chain, for example (purchasing, storage, repackaging, relabeling, transportation and distribution).

Various entities including (importers, AR, distributers and local manufacturers) are responsible for the handling, storage and distribution of medical devices.

The purpose of this guideline is to clarify requirements of the storage, handling and/or transportation of medical devices.

2. General Rules

- Authorized persons involved in the storage, handling and transport of medical devices must be aware of appropriate procedures for these activities and informed of existence of written procedures to be followed.
- The stored medical devices should be well organized or aligned to facilitate inspection and cleaning process.
- There should be written procedures for storing, transporting and handling of medical devices.
- There should be an emergency plan to be used in case of an electricity shutdown (power outage) in the storage area, if applicable.
- There should be a physically separate area for keeping damaged, expired or recalled medical devices.
- Parameters related to the required storage conditions should be recorded and monitored, if applicable.
- Precautions should be taken to prevent unauthorized persons from entering storage areas.

3. Storage area Requirements

1. Storage areas should be of sufficient capacity to allow the orderly storage of the various categories of medical devices.

2. It should be appropriately designed, constructed, maintained or adapted. They should be kept clean and there should be sufficient space and lighting.

3. The shelves should be made of / Coated with non-porous material for easy and safe cleaning.

4. Storage areas should be maintained within acceptable and specified temperature limits. Where special storage conditions are required on the label (e.g. temperature, relative humidity), these should be provided, controlled, monitored and recorded.

5. Medical devices should be stored off the floor and suitably spaced to permit 692 ventilation, cleaning and inspection.

6. Appropriate procedures should be available indicating the frequency of cleaning and the methods to be used to clean the premises and storage areas.

7. A generator should be installed OR an alternative plan should be implemented in case of electricity outage.

8. Certain materials and products such as highly active and radioactive materials, and other hazardous, sensitive and/or dangerous materials, as well as substances presenting special risks should be stored in a dedicated area that is subject to appropriate additional safety and security measures; and in accordance with national legislation.

9. Medical products should be handled and stored in such a manner as to prevent contamination, mix-ups and cross-contamination.

4. Storage Conditions

1. The storage of medical devices should be in compliance with their labelling.

2. Heating, ventilation and air conditioning systems (HVAC) should be appropriately designed, installed, qualified and maintained to ensure that the required storage conditions are maintained.

3. Temperature and relative humidity, as appropriate, should be controlled and monitored at regular intervals. Data should be recorded, and the records should be reviewed. The equipment used for monitoring should be calibrated and be suitable for their intended use. All records pertaining to mapping and monitoring should be kept for a suitable period of time.

5. Storage traceability

In case of recalling medical devices from Bahrain market, authorized representative should be able to trace the defected medical devices by serial number / batch number/ lot number and determine the quantity in the store and submit the form of recall and required documents to NHRA.

Recalled and expired products should be kept in separate / isolated area. This area should be clearly monitored to prevent the use of these devices until the final decision is taken to get rid of them by either destruction or return back to manufacturer.