nhra BAHRAIN
الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

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Policies and Procedures Guideline for Medical Devices Authorized Representatives.

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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1. Introduction

This guideline is intended to guide all importers and medical devices companies to the importance of having appropriate policies that address all elements related to medical devices. As per international standard **ISO 13485, Clause 4** every company should have a quality management system (QMS) for medical devices so that procedures are documented, controlled and effectively implemented and maintained.

Each procedure should clearly define a sequence of steps to be followed and implemented and should be incompliance with the regulatory authority. **NHRA** strictly recommended to have a documented policy which is one of the main requirements to register the Authorized Representative.

2. Documentation Requirements

As per international standard **ISO 13485, Clause 4.2,** policies and procedures should be documented in a way that ensures confidentiality and easy retrieval of information.

Documents Required are:

- Written quality policy with clear Scope of the QMS.
- Defined procedures and processes.
- Forms

3. Roles and Responsibilities

The main responsibility of the management is to ensure:

1. Responsibilities and authorities are defined, documented.
2. Quality policy is being reviewed at planned intervals to ensure is continuing suitability, adequacy and effectiveness.
3. Appropriate communication processes are established within the organization.
4. Monitoring and evaluating of implementing policies and procedures.

It is the responsibility of each individual employee to ensure that:

1. They are aware of the content of this policy.
2. Appropriately trained and competent to handle the medical devices as part of their duties.

4. Elements of Policy

The main objective of policy is to provide an organization wide framework for the management of Medical Devices and the highest standards of device safety, risk management and financial efficiency are realized in the management of the device. The policy aims to minimize related hazards, to ensure that employees are properly trained and competent to handle Medical Devices, and devices are maintained in a safe and reliable condition, are quality assured and subjected to asset management that is inclusive of device history and tracking.

- **Distribution:**

Records of distribution including (invoices, LPO, service reports…etc), should be kept and maintained in a tracing system (software) including all details related to the imported and marketed medical devices in Bahrain market.

Tracing system should include the below information about each medical device:

1. Medical device Name.
2. Model.
3. Serial number.
4. Batch number.
5. Lot number.
6. Manufacturer name.
7. Country of origin.
8. Quantity.
9. Price.
10. End user details.
11. Recall /Complaints /Adverse event history.
12. Service reports/PPM.

Please note that (Excel sheet is not accepted)

- **Importation:**

Documentation of the internal process implemented by the AR in importation phases starting from the order confirmation where the phase must highlight the responsible person designation and the roles.

The policy must include the AR understanding of NHRA import permit in phases and how the documentation is managed internally to avoid rejection and/or violation.

- **Complaint Handling:**

A documented process describing the sequence followed for handling complaint starting from receiving the complaint via email, phone call or online contact form passing through investigation process and root cause analysis until the corrective action taken to solve and close the complaint to eliminate the risks associated with the concerned medical device.

A **complaint form** should be filled with all details related to the concerned medical device including:

- Medical device details (device name, model, serial number, manufacturer,..).
- End user details.
- Complaint details.
- Authorized representative details.
- Corrective action taken to solve the complaint.

Critical Complaints should be reported to NHRA to take the necessary action.

- **Adverse Events:**

A documented process describing the sequence followed to receive the adverse event related to the use of a medical device including investigating and defining the main causes of the adverse even at the corrective action taken by the authorized representative to prevent the recurrence of the adverse event.

An **Adverse event form** should be filled including details about:

1. Medical device.
2. Healthcare facility.
3. Description of the adverse event.
4. Details about the persons involved in the AE (patient, doctor, nurse….).
5. Corrective action taken to eliminate the risks associated with medical device.

Adverse events should be reported to NHRA with supportive documents (pictures, reports…) in order to take the necessary action.

- **Recalls:**

A documented process describing the sequence followed starting from receiving the field safety notice from the manufacturer, withdrawal of the defected medical device from Bahrain market until the destruction OR return back of the defected medical device to the manufacturer.

When the authorized representative receives a FSN from the manufacturer related to a defected medical device, NHRA recall form available on NHRA website should be filled and submitted to NHRA with required documents as per guideline and checklist and as per the time frame set in the guideline.

- **Alerts and modifications:**

A documented process describing the sequence followed in case of modification of medical devices including (changes in manufacturing process of the medical device or the design, the materials, changes in sterilization that may unintentionally affect device performance, or software upgrading or releasing a new model or updated version of medical device).

Modifications of a medical device that could affect significantly the safety and effectiveness of a device, or change the device's intended use, require the submission of full details about the medical device and reasons of modification to NHRA.