The officer's guidance for dealing with the National Center of medical devices

Introduction

The aim of this guidance is to explain how to deal with any recalls and field safety notices received from the national center of medical devices reporting

Definitions

National center of medical devices reporting	An organization managing a database of information on safety and performance related to aspects of medical devices and employing staff capable of taking appropriate action on any confirmed problems.
Field safety notices	A notification from the SFDA to relevant medical devices users in relation to a field safety corrective action plan
Adverse events	Any malfunction or deterioration in the characteristics or performance of the medical device, including an inadequacy in its labelling or the instruction for use which may lead compromise the health or safety of the patient s, users or third parties
Corrective action	An action to eliminate the cause of potential nonconformity or other undesirable situation
National Center for Medical Devices Repotting Officer (NCMDR- Officer)	A contact peroneal between SFDA and the healthcare providers

Role of NCMDR officer:

In order to that Saudi Food and Drug Authority play role in fullest as well as achieve its goal to ensure safety, effectiveness, and quality of medical devices and their performance according to their intended purpose, and to ensure the safety of related electronic products, It should that Contact Officer of National Center for Medical Devices Reporting, shows initiative and carry out the following tasks:

- Receiving the weekly reports of Field Safety Notes and National/International Recalls from NCMDR then Disseminate and share the information with other Departments within healthcare facility.
- Ensuring that the healthcare facility is free of any affected device/product mentioned in the FSNs/Recalls.
- Communicate with NCMDR Team and Authorized Representative of the manufacturer to ensure the implementation of the necessary corrective actions, in case the healthcare facility has affected device/product.
- Report any adverse event/incident happen in the healthcare facility associated with medical device to NCMDR.
- Visiting NCMDR website for latest published Recalls/Alerts (http://ncmdr.sfda.gov.sa/Default.aspx).