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Saudi FDA reporting system - NCMDR

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Since 2008 medical devices sector within Saudi Food and Drug Authority lunch first of its kind in the region an on line reporting system works as an organization managing a database devoted to receive adverse event reports about any medical devices malfunction from hospital and healthcare facilities all around Kingdom of Saudi Arabia, studying them and working together with manufacturers, authorized representatives, importers and distributors to take the appropriate action and assuring the safe performance of those medical devices placed on KSA market or put in service .

The goals behind establishing this national center are to:

- Improve protection of the health and safety of patients, users and others.
- Disseminate relevant device related information which may reduce the likelihood of, or prevent repetition of adverse events, or alleviate consequences of such repetition.
- Encourage collaboration between manufacturers and healthcare providers to identify and investigate adverse events associated with medical devices and take appropriate action to execute a key aspect of SFDA's post market activities "surveillance".

NCMDR has full leverage membership of GHTF NCAR currently IMDRF which are among USA, Canada, EU, Australia, Japan, China and Brazil.

Also NCMDR has membership of AHWP SADA which includes in its membership more than 22 member economies.

This paper will address the importance of NCMDR, who makes the recall / FSN, what should be reported, some snap shot from the system and some statistics.

Biography

Essam M. Al Mohandis has completed his B.Sc. from Kind Saud University and he works for a tertiary healthcare and research center for 12 years then he joined SFDA for more than six years, currently he is appointed as Executive Director of Surveillance and biometrics. He is chair and member of many working groups related to medical devices regulation in AHWP as well as GHTF/IMDRF. He has been a speaker in many national, regional and international events.

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