Medical Devices

Industry Obligations

Medical Device product registrants must also consider the following compliance obligations:

- **Causality** is **not** a prerequisite for tracking and reporting adverse events associated with the use of pesticides registered with either the EPA or PMRA.
- When considering the MDR reporting requirements for medical devices, manufacturers of diagnostic testing devices, such as glucometers, must evaluate each report of an inaccurate measurement to determine if the inaccuracy may have indirectly resulted in serious injury.

SafetyCall Medical Device Product Services

An important regulation applicable to the Medical Device Industry that is a focus of SafetyCall services is highlighted below:

US Food & Drug Administration: 21 CFR 803:
Upon becoming aware of an Medical Device Reporting (MDR) event that is serious or resulted in fatality, the manufacturer must report the MDR event to the FDA within 30 calendar days. Upon becoming aware of an MDR event that is not serious but could result in serious injury should the malfunction recur, the manufacturer must report the MDR event to the FDA within 30 calendar days. Upon becoming aware of an MDR reportable event that needs remedial action to prevent an unreasonable risk of substantial harm to public health, the manufacturer must report the event to the FDA within 5 calendar days.

The health care professionals at SafetyCall have over 15 years of experience responding to issues related to medical device products. All adverse events are reported, documented and stored in SafetyNotes, our proprietary case management software application. Clients have access to their incident data 24/7 utilizing SafetySearch, a secured password protected web-based search engine.

Contact SafetyCall today to learn more about services we provide to the Medical Device industry.

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