



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 over the counter drugs.
- Understand that consumers will most likely report adverse events directly to the manufacturer. This means that manufacturers need to implement additional processes for differentiating between those adverse effects which may represent a potential safety concern from those having nothing to do with the use of the product.
- Be aware of background noise involving adverse events not related to product use.

SafetyCall Nonprescription (OTC) Drug Services

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

US Food & Drug Administration: 21 CFR 803:

Under federal law distributors, manufacturers and packers of dietary supplements in the United States must report medical problems that are associated with their products.

Firms are required to document and assess adverse events based on "reasonable medical judgment." Adverse events meeting the FDA defined criteria for **serious** must be reported to the FDA within 15 days using the FDA form 3500A and its accompanying data elements.

Serious Adverse Events may include but are not limited to the following: "death," "a life-threatening experience," "inpatient hospitalization," "a persistent or significant disability or incapacity" or "a congenital anomaly or birth defect."

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.