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Need to Know Facts about Medical Device Reporting For Manufacturers

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Each year, the FDA gets several hundred thousand medical device reports of suspected device-related deaths, brutal injuries and malfunctions. Medical Device Reporting (MDR) is one of the post market surveillance tools the FDA uses to monitor performance of the device, detect potential device-related safety issues, and contribute to benefit medical devices risk assessments. Here are a few must know facts about Medical Device Reporting For Manufacturers.

1. Reports to be submitted to FDA by Manufacturers

Device Manufacturers need to submit certain types of reports for adverse events and product issues to the FDA in a very short time. If you are the manufacturer of a medical device, you are considered to be aware of an event when any of your workers becomes aware of a reportable event that needs to be reported within 30 calendar days or that is required to be reported within 5 working days because the FDA requested reports in agreement with 803.53(b).

2. Reports to be submitted to FDA by Experts, patients, consumers and caregivers

The FDA expects healthcare experts, patients, consumers and caregivers submit voluntary reports about serious adverse events that may be associated with a medical device, product quality issues, as well as use errors and therapeutic failures. The overall purpose of this plan, just like the FAA for passenger safety, is to offer significant information that helps improve patient safety.

3. Requirements for Mandatory Medical Device Reporting

The Medical Device Reporting (MDR) regulation (21 CRF 803) contains obligatory requirements for importers, manufacturers and device user facilities to report certain device-related unfavorable events and product problems to the FDA. Importers: Importers need to report to the FDA and the manufacturer on learning that one of their components that are used to produce or assemble the final device may have caused or contributed to a death or brutal injury. The importer should report only to the manufacturer if their imported devices have malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to reoccur.

4. When to report to the FDA

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Manufacturers of Medical Devices need to report to the FDA when they learn that any of their devices may have caused or contributed to a death or severe injury. Manufacturers also need to report to the FDA when they come to know that their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to reoccur.

5. Voluntary Medical Device Reporting

The FDA encourages healthcare professionals, caregivers, patients and consumers submit voluntary reports of significant adverse events or product issues with medical products to MedWatch, the FDA's Safety Information and Adverse Event Reporting Program.

6. How to Report a Medical Device Problem

Medical device reports are presented to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters (health care professionals, caregivers, patients, and consumers).

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