



Demystifying MDR: Your Questions Answered

Confused about medical device reporting? You're not alone – many manufacturers struggle to interpret the definitions outlined in CFR 803. The imprecise nature of these requirements – coupled with manufacturers' reluctance to report device malfunctions to the FDA – leads many companies to file to late, inaccurate, or incomplete reports.

Failure to perform comprehensive MDR can lead to major problems for your company, including financial losses and severe FDA penalties. Knowing these MDR basics will help you avoid these consequences and perform mistake-free reporting.

Who do MDR requirements affect? All domestic and foreign manufacturers of medical devices and ready-for-use device components sold in the United States are required to comply with MDR requirements. An MDR must be filed when a manufacturer receives information that one of its marketed devices “has or may have caused or contributed to a death, serious injury, or has malfunctioned, and that the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.” A “serious injury” is defined as one that is life-threatening, results in permanent impairment to a body function or body structure, or necessitates medical or surgical intervention to preclude permanent damage to a body structure. Your device has “caused or contributed” to an event if it may have been a factor as a result of failure, malfunction, improper or inadequate design, or mislabeling. A company also has the responsibility to report if a device has malfunctioned and a similar device made by the manufacturer would likely cause or contribute to a death or serious injury if that malfunction were to recur.

There is often confusion about the distinction between CFR 803, Medical Device Reporting, and CFR 806, Medical Device Corrections and Removals. Under 21 CFR 806, Medical Device Corrections and Removals, manufacturers and importers are required to make a report to the FDA about any correction or removal of a medical device if the action was initiated to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health. If companies have already provided the required information in a medical device report under 803, they are not required to file under 806.

What is the required documentation? When reporting a significant incident, manufacturers must file a **3500A report**.

The first time a manufacturer reports an event involving a device model or device family, a **baseline report** is required.

A **supplemental report** is required when a manufacturer receives additional information that was unknown or unavailable on the original MDR report.

Annual certification is required once a year from all manufacturers. Manufacturers are required to provide a numerical summary of the MDRs they filed that year. If they did not file any, they are required to certify that they did not receive any reportable events during the reporting period.

When should my company file an MDR? MDRs should be filed within **30 days** after a manufacturer becomes aware of a significant adverse event. If a **remedial** action is required – such as a recall or other action other than routine maintenance or servicing of a device – the manufacturer is required to submit the report within **5 days** of determining that such an action is required.

Where should I send the forms? The necessary forms can be downloaded at the site and sent to the FDA through the mail. At present, if companies want to file electronically they need to receive permission from the FDA. However, the FDA is currently developing an electronic filing system that will simplify the transmittal of adverse event reports for all manufacturers.

Why file? In some cases, manufacturers may wonder whether an MDR is necessary for an adverse event. It may seem doubtful that the product in question is actually at fault, or that the event in question is “significant” enough to warrant mandatory reporting. Reluctance to file is understandable – MDRs can be damaging to a company’s reputation, and could lead to an extensive FDA investigation. However, the risks of failing to file an MDR include severe penalties, such as seizure, injunction, criminal fines and imprisonment. It is always better to err on the side of caution – file a report even if you have the slightest bit of uncertainty about an incident.

How do I prevent the need to file MDRs? Prevention involves performing consistent corrective and preventive actions, analyzing risks, and evaluating customer complaints. Focus your attention on streamlining these quality processes and you may never have to face the dreaded MDR again.



