

How to Avoid an MDR Disaster: Set Up An Effective Reporting System

It is essential that device manufacturers understand their medical device reporting obligations and how to fulfill them.

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In June 2003, Endovascular Technologies Inc. (Palo Alto, CA), a manufacturer of medical devices used to treat abdominal aortic aneurysms, pled guilty in federal court to 10 felonies. The company agreed to pay \$92.4 million to settle criminal and civil charges. Nine of the 10 charges stemmed from the company's failure to report to FDA more than 2000 adverse events associated with its devices.¹ Endovascular Technologies' experience shines a spotlight on the potential consequences of failing to comply with FDA's medical device reporting (MDR) regulation (21 CFR Part 803), which requires device manufacturers to report to FDA any deaths, any serious injuries, and certain malfunctions associated with their devices.

According to FDA's Sharon Kapsch, "The goal of the MDR regulation is to provide signals to both FDA and the manufacturer that a device may present a potential public safety problem, and that corrective action may need to be taken to protect the public health." Kapsch is the branch chief in the Reporting Systems Monitoring Branch in CDRH's Office of Surveillance and Biometrics. FDA focuses significant enforcement attention on compliance with MDR requirements. Indeed, in 2004, approximately one-quarter of the warning letters issued by CDRH cited MDR-related violations. Thus, it is critical that device manufacturers understand their MDR obligations and



how to fulfill them. This article discusses the meaning of key terms in the MDR regulation and addresses how to set up an MDR system. In addition, it identifies common MDR pitfalls and explains how to complete the MDR form.

Key Terms and Definitions

FDA requires that manufacturers report device-related adverse events if the event meets the definition of an *MDR reportable event*. Determining whether an event constitutes an MDR reportable event, however, is far from straightforward, because FDA's definition of this term is complex and open to interpretation. FDA defines an MDR reportable event as:

An event about which manufacturers or importers have received or become aware of information that reasonably suggests that one of their marketed devices:

- (i) May have caused or contributed to a death or serious injury; or
- (ii) Has malfunctioned and . . . the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.²

This definition raises several important questions: When does a manufacturer "become aware" of an adverse event? What does it mean for a device to "cause or contribute" to a death or serious injury? What constitutes a "serious injury," and what does FDA consider to be a "malfunction"? The definition of each of these terms is found in the MDR regulation. However, FDA's meaning of these terms sometimes differs significantly from how someone outside the agency would define them.

Become Aware. Manufacturers often miss MDR deadlines because they do not understand the definition of *become aware*. Generally speaking, manufacturers are considered to have become aware of an MDR reportable event when any employee becomes aware of it.³ MDR reports are typically due to the agency within 30 days of the "become aware" date.⁴ Therefore, the MDR clock does not wait to start ticking until information about the

event makes its way to the company's regulatory department; rather, it generally starts ticking at the moment the event is brought to the attention of any company employee. This highlights the importance of training all personnel on MDR principles and ensuring that employees understand the importance of quickly routing potentially MDR reportable information to the regulatory department for analysis.

Caused or Contributed. Under the MDR regulation, *caused or contributed* means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury.⁵ The regulation goes on to list device failure, malfunction, improper or inadequate design, manufacture, labeling, and user error as examples of factors that could result in a device having caused or contributed to a death or serious injury.⁵

FDA's Kapsch says that "manufacturers often overlook the need to analyze the 'contributed' portion of 'caused or contributed.'" As a result, manufacturers may incorrectly determine that an event is not reportable because the device did not directly cause the patient's injury—even though the information reasonably suggests that the device may have been a contributing factor. For example, a device that failed out of the box and was never actually used on a patient may have "contributed" to a death or serious injury, if the time delay the clinician experienced in trying to locate a functioning device was in part responsible for the adverse event.

Serious Injury. To most people, *serious injury* means being badly hurt. FDA's definition incorporates this notion—and more. According to the MDR regulation, serious injury means an injury or illness that meets one of the following three criteria:

- It is "life-threatening."
- It "results in permanent impairment of a body function or permanent damage to a body structure."
- It "necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure."⁶

Manufacturers sometimes neglect the third criterion, instead focusing exclusively on whether the patient or user died or was badly hurt. However, under the MDR regulation, an event also is reportable as a serious injury if medical or surgical intervention was done to prevent a death or serious injury.

Malfunction. FDA considers a device to have *malfunctioned* if it "fail[ed] . . . to meet its performance specifications or otherwise perform as intended."⁷ Performance specifications encompass more than technical operating specifications; they also include all claims made in the labeling for the device.⁷ For example, if a device's labeling states that it will have the desired therapeutic effect within a certain amount of time, and it does not, this would constitute a malfunction.

How to Set Up an MDR System

As noted above, generally speaking, device manufacturers must report an MDR reportable event within 30 days of becoming aware of it.⁸ However,

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a manufacturer is required to report an MDR reportable event within five workdays if the event "necessitates remedial action to prevent unreasonable risk to the public health," or if FDA has requested in writing that a "five-day" report be submitted for the type of event in question.⁹ If, after reporting an event to FDA, a manufacturer obtains information about the event that was required to be reported (but was unavailable or unknown at the time of the initial report), the manufacturer must, within one month of obtaining the additional information, submit a supplemental report to the agency.¹⁰

The first time a manufacturer submits an MDR report for a particular device model or family, the manufac-

turer also must submit a baseline report (Form FDA-3417). The baseline report provides basic device identification information (e.g., brand name, date the device was initially marketed) and must be updated annually if changes in the baseline information have occurred.^{11,12}

Information about MDRs must be maintained in "MDR event files."¹³ Specifically, MDR event files must contain documentation of a manufacturer's deliberations and decision-making processes regarding the reportability of an event. These files must also include copies of all MDR forms and other information related to the event submitted to FDA.¹³ Manufacturers may maintain MDR event files as part of their complaint files, provided that the files are prominently identified as MDR reportable events.¹²

An often-neglected, but extremely important, part of the MDR regulation is the requirement that manufacturers develop and follow written MDR procedures. MDR procedures must, among other things, establish a system for identifying events that may be MDR reportable. Procedures must also create a standardized review process for determining whether an event is reportable and ensure that MDR reports are submitted to FDA in a timely fashion.¹⁴ FDA frequently cites manufacturers for failure to have in place adequate written MDR procedures.

Avoiding Common MDR Pitfalls

As Endovascular Technologies' experience demonstrates, the consequences of failing to report MDR reportable events can be disastrous. In most cases, the roots of a manufacturer's noncompliance with MDR requirements can be traced to one or a combination of the following factors: problems with its complaint-handling system, deficiencies in its MDR procedure, insufficient documentation of its MDR decision-making process, and/or inadequate training of personnel on MDR principles.

Proper Complaint Handling Is Critical. A manufacturer's complaint-handling system is the primary gateway through which information that may constitute an MDR reportable

event is brought to the company's attention. FDA's complaint files regulation requires that all complaints be reviewed and evaluated to determine whether they constitute MDR reportable events. Complaints involving MDR reportable events must be promptly investigated.^{15,16}

FDA's Kapsch finds that "one of the most common problems is that manufacturers often do not investigate complaints thoroughly enough to determine whether they are MDR reportable." Indeed, failure to properly identify complaints as MDR reportable is a frequent FDA inspectional observation and warning letter allegation. Therefore, it is critical that complaint-handling personnel be trained to conduct comprehensive investigations so that the company can carefully document the decision-making process used to determine whether an event is reportable.

Assume Malfunctions Will Recur. FDA requires that an event be reported if a device has "malfunctioned and . . . the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." A common MDR pitfall is determining that a malfunction is not reportable because it seems unlikely that the malfunction will recur. However, assessing the likelihood that a malfunction will recur is inconsistent with the MDR regulation. Rather, the regulation directs manufacturers to assume that a malfunction will recur and to analyze whether the malfunction would be likely to cause or contribute to a death or serious injury when it recurs. This underscores the importance of having a written MDR procedure that thoroughly incorporates the concepts of FDA's MDR regulation, as well as a written complaint-handling procedure that includes the MDR principles necessary for determining whether an event is reportable.

Do Not Disregard User Error. Incorrect MDR reporting decisions often result from a misunderstanding of what it means for a device to have "caused or contributed to a death or serious injury." A common mistake manufacturers make is deciding that a death or serious injury is not re-

portable because, although their device was involved in the incident, the clinician used the device improperly. However, FDA's definition of caused or contributed specifically includes events occurring as a result of user

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error. FDA's reasoning behind this is that reports of adverse events resulting from user error may alert the agency to the need for improved labeling to prevent future injuries.¹⁶

Be Consistent. Another common MDR pitfall is inconsistent reporting of adverse events. For example, a manufacturer of cardiac catheters may receive 10 complaints stating that the tip broke off of a catheter inside a patient during surgery. Submitting MDR reports for only five of these events will likely attract the scrutiny of an FDA investigator, particularly if there is no documentation of the manufacturer's rationale for not reporting the other five events. Indeed, from the agency's perspective, such action may look like an attempt to cover up a pattern of recurring device problems.

A manufacturer can help prevent inconsistent MDR reporting by maintaining a summary log of the types of events that have and have not been reported and by ensuring that the same highly trained personnel are responsible for making MDR decisions. In addition, MDR training should emphasize the importance of documenting all deliberations and decision-making processes regarding the reportability of an event.

Filling Out the Forms

Once the decision to report an event is made, the next challenge is to prop-

erly fill out the MDR form. Thirty-day and five-day MDR reports, as well as supplemental reports, are submitted on FDA's MedWatch form (Form FDA-3500A). Important information on how to complete the MedWatch form is contained in FDA's "Instructions for Completing the MedWatch Form 3500A."¹⁸

Stick to the Facts. As a general rule, MedWatch forms should be completed using factual, nonspeculative language. Pursuant to FDA regulations, MedWatch forms contain the disclaimer, "Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer, or product caused or contributed to the event."¹⁹ This disclaimer can be beneficial to a manufacturer from a product liability perspective. However, any benefit is likely to be significantly diminished if a manufacturer makes unnecessary admissions of wrongdoing in its description of the event.

Check for Inconsistencies. Personnel responsible for completing MedWatch forms should be trained to review the forms for internal consistency as well as for consistency with underlying complaint documents before submitting them to FDA. For example, Sections D10 and H3 of the MedWatch form ask essentially the same question, i.e., whether the device was available for evaluation by the manufacturer. Responding inconsistently to these sections may attract FDA's scrutiny.

Similarly, characterization of an event in a MedWatch form should be consistent with the findings of the complaint investigation that was the basis for the MDR report. For example, if a complaint investigation demonstrates both that a device had malfunctioned and that it had caused or contributed to a serious injury, then the corresponding MedWatch form also must contain this information. Specifically, in Section B1, both boxes ("adverse event" and "product problem") should be checked, and Section B5, which asks for a description of the event or problem, should discuss both the malfunction and the serious injury. Inconsistencies, while most often simply the result of an administrative oversight, may appear to FDA to be an attempt to withhold MDR reportable information.

Don't Say Remedial Action Was Initiated if It Wasn't. Another common pitfall is incorrectly completing Section H7, which asks whether remedial action was initiated. Manufacturers frequently respond affirmatively, when, in fact, no remedial action was undertaken, as that term is interpreted by FDA. The MDR regulation defines remedial action as "any action other than routine maintenance or servicing of a device where such action is necessary to prevent recurrence of a reportable event."²⁰ FDA's policy is that action taken to fix a single device is not "remedial action;" rather, remedial action is an action undertaken in response to a systemic problem affecting multiple devices.¹² Therefore, while a device recall would constitute remedial action, repairing or replacing a single device would not.

Conclusion

It is critical that device manufacturers have an effective system for identifying potentially reportable MDR events, analyzing in a consistent manner whether events are reportable, and submitting accurate and timely MDR reports to FDA. The foundation for building an effective MDR system is a set of written procedures that incorporate the principles of FDA's MDR and complaint files regulations. A manufacturer that lacks such a system may expose itself to FDA enforcement action, as well as increased product liability risk.

References

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