

Overview of Medical Device Reporting

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Hello, my name is Anike Freeman and I am a Senior Consumer Safety Officer for the Division of Industry and Consumer Education. In this module, I will provide an overview of Medical Device Reporting, a key postmarket activity monitored by FDA.

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Before we begin, it is important to highlight the value of medical device reports. Information on medical device adverse events benefit everyone. Consumers can be empowered to make educated decisions about their healthcare and Industry may use this information to improve the design and safety of their products over time. As a regulatory agency, FDA is particularly interested in understanding how medical devices perform once they enter the market. This allows the agency to monitor device safety and determine when regulatory intervention may be necessary to mitigate serious concerns.

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Our learning objectives for today are as follows. First, we will establish FDA's regulatory authority for medical device reporting. We will then define an MDR reportable event and identify who reports to FDA and how those reports are submitted. Afterwards, we will explain how FDA uses medical device reports and demonstrate how you can independently search for MDRs.

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Let's establish FDA's regulatory authority over medical device reporting

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FDA's regulatory authority stems from the United States Food, Drug, and Cosmetic Act. Section 519 pertains specifically to records and reports on medical devices. It grants FDA the authority to require medical device reports from manufacturers, importers, and device user facilities. We will discuss these groups later on in the presentation.

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The medical device reporting regulation is found in Title 21 of the Code of Federal regulations (or CFR), part 803. It establishes how adverse events involving medical devices can be reported to FDA. It also defines important reporting roles, responsibilities, and deadlines.

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So what is an MDR Reportable Event?

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The regulation states MDR reportable events reasonably suggest a marketed device may have caused or contributed to a death or serious injury OR

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That a marketed device malfunctioned and the malfunction likely would have caused or contributed to death or serious injury if it recurred. This is an important distinction that helps FDA hone in on events that are especially serious or harmful to the public.

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Now we will talk about who reports this information. There are two categories. mandatory and voluntary reporters. First, we will discuss mandatory reporters.

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Mandatory reporters are medical device manufacturers, importers, and device user facilities. Examples of user facilities are hospitals and nursing homes. You may refer to the regulations linked here for a complete description of each of these roles.

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Manufacturers and importers may only submit their reports electronically through the Electronic Submissions Gateway. This is the result of the electronic medical device reporting (or eMDR) final rule which was issued in August of 2015. For more information on this requirement, you are welcome to refer to the eMDR guidance document.

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User facilities, however, while encouraged to report electronically, are not required to do so. They still have the option to submit written reports to FDA by mail using Form 3500A. Please refer to the guidance document on medical device reporting for user facilities for more information.

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Next we will discuss voluntary reporters.

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Voluntary reporters are, essentially, everyone else. They do not have a regulatory obligation to submit MDRs but their input will always be welcomed and encouraged by FDA. Most voluntary reporters are patients, healthcare professionals (such as doctors and nurses), and consumers who may be serving as caretakers.

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Voluntary reporters may report adverse events online through the MedWatch portal linked here. They may also download the report form from the FDA website and submit it by postal mail. All voluntary reporters may use Form 3500, however, Form 3500B serves as a more consumer-friendly option.

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Now that we've established who reports and how that information is delivered to FDA, let's talk about how FDA uses medical device reports.

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Proper information analysis is really the key to effectively understanding reported information and its potential implications. CDRH values adverse event data collection and management and is responsible for maintaining the database that houses this information. The Center also provides eMDR technical support. This is to ensure timely communication of these events to FDA by mandatory reporters.

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On average, FDA receives over 800,000 adverse event reports each year. These reports are read and reviewed by FDA analysts who have years of professional and technical experience. Many of these individuals have backgrounds in nursing, medicine, engineering, and science and may specialize in certain device product areas, such as dental or orthopedic devices.

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When reviewing reports, analysts seek to identify trends. They determine which types of device problems are common and make note of unique or novel events. They also monitor the frequency and severity of a product problem as they may indicate an emerging safety issue in need of correction. Combined, all this information contributes to FDA's assessment of potential risks to public health.

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MDRs are also used to identify possible actions to be taken. If an analyst determines a trend is particularly concerning, they may escalate the issue to Center management. This may then prompt FDA to take regulatory action in response to these reports and trends such as-- inspecting the manufacturer, recommending changes to device labeling, issuing public health notices, or possibly recalling the device. The information you provide FDA helps make this possible.

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Previously, I mentioned that CDRH maintains a database of this reported information. Let's discuss this tool and how you can search for medical device reports.

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MAUDE stands for manufacturer and user facility device experience. It is a publicly searchable database containing medical device adverse event reports from as far back as the early 90s. Both industry and consumers may refer to this database when seeking information on specific medical devices.

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Here, you will find a screenshot of the database. You will notice it allows you to search by a variety of terms such as product problem, brand name, or manufacturer. Of course, you do not need to enter information in all of fields to complete a search. Simply enter your known search terms to obtain results. This search engine caps the number of results per search to 500, so bear this in mind if you are in need of large sets of data.

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Another point to remember is that reports are redacted to protect patients and any other confidential information. When reading a report, you may notice certain words are missing. This redaction is part of the MDR review process before anything is uploaded into the database. Additionally, reports more than 10 years old are best accessed by using the "download files" feature. Clicking this link takes you to a supplemental webpage which contains a series of downloadable zip files. These files contain adverse event reports for each reporting year as far back as 1995.

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Having a general understanding of the database and its features, let's do an example search.

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Here, I have decided to search for event types documented as malfunctions. I've narrowed the search further by setting the dates to go from March 1st of 2015 to the end February, 2019. If I do not change these dates, the database defaults to providing results from the previous month. I have also identified product code DZE, which is for dental implants. Product codes may be found by searching the product classification database. If you do not know the product code for a device, you may use a different search criterion such as the brand name or model number.

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When I click search, I receive a series of results spanning multiple pages.

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You will notice my search terms yielded over 500 reports. The database is letting me know the results displayed are incomplete and that I may need to narrow my search further. If I absolutely must collect all of this information, I can utilize the download files function instead, as I mentioned earlier.

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You will also notice report results will be listed by date, with the most recently received reports appearing first, followed by older records.

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When I click one of the results, it takes me to a page which provides more detail. Here, I can see the model number and review the specific device problem and event description. Remember, reports contain as much information as is reasonably available to the individual filing the report. This means certain details, such as model numbers, may not always be available. However, careful compilation and review of multiple reports on a specific device type may help you better understand common issues people experience with that product.

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In summary, medical device reports are critical to public health and safety. The information provided by mandatory and voluntary reporters generates robust medical device performance data. FDA uses all data to monitor device performance and safety and inform its regulatory decision-making. This information is not only available to the Agency, but also the public through the MAUDE database. You, too, may use these reports to make informed decisions.

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We hope you found this information useful. The following slides contain links to additional, relevant resources. For assistance with more nuanced or complex questions involving the interpretation of MDR policies, please contact the MDR Policy Group.

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If you have general MDR questions please contact the Division of Industry and Consumer Education. We also encourage you to refer to CDRH Learn and Device Advice which contain additional educational materials for your benefit. We hope you continue to educate yourself on these important regulatory activities.

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In closing, here is your call to action. Take time to properly understand your reporting responsibilities. Notify FDA of reportable events when you become aware of them. And finally, try using the MAUDE database and other educational resources FDA has provided. I hope you have found this presentation to be helpful. Thank you for watching.
