MDR: Medical Device Reports

2018 AMDM Annual Submission Workshop

North Bethesda, Maryland

Patrick Weixel

Acting Deputy Director of Patient Safety and Product Quality

Center for Devices and Radiological Health

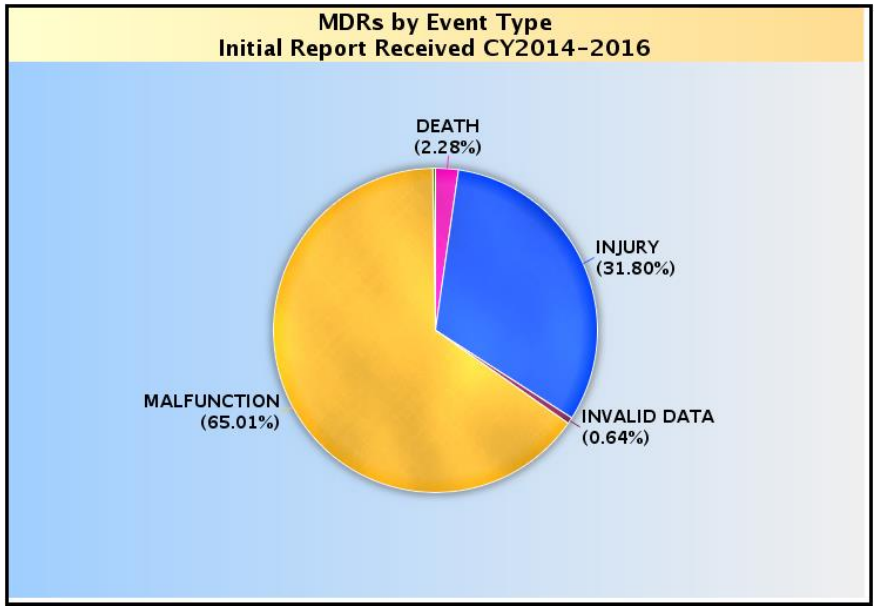
U.S. Food and Drug Administration

Objectives

- Overview of MDR data
- Understanding Reporting Requirements
- How MDRs can be submitted
  - Discussion of MDR form fields
- MDRs and Universal Device Identifiers (UDI)
- Description of available MDR resources, including publicly available data

MDRs by the numbers (Received CY2014-2016)

- Receive ~700k initial reports & ~300k follow up reports per year
- ~98 percent of reports are received from the manufacturer



What is reportable?

21 CFR Part 803.3(o) states a MDR reportable event is:

- An event that user facilities become aware of that reasonably suggests that a device has or may have caused or contributed to a death or serious injury or
- An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices:
  - May have caused or contributed to a death or serious injury, or
  - Has malfunctioned and that 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.

Manufacturer & Importer Reporting

Summary of Mandatory Reporting Requirements for Manufacturers and Importers

REPORTER	WHAT TO REPORT	REPORT FORM #	TO WHOM	WHEN
Manufacturers	30 day reports of deaths, serious injuries and malfunctions	Form FDA 3500A *	FDA	Within 30 calendar days of becoming aware of an event
	5-day reports for an event designated by FDA or an event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health	Form FDA 3500A *	FDA	Within 5 work days of becoming aware of an event
Importers	Reports of deaths and serious injuries	Form FDA 3500A *	FDA and the manufacturer	Within 30 calendar days of becoming aware of an event
	Reports of malfunctions	Form FDA 3500A *	Manufacturer	Within 30 calendar days of becoming aware of an event

* Or electronic equivalent

Source: "**Mandatory Reporting Requirements: Manufacturers, Importers and Device User Facilities"; www..fda.gov**

User Facility Reporting

Summary of Mandatory Reporting Requirements for User Facilities

REPORTER	WHAT TO REPORT	REPORT FORM #	TO WHOM	WHEN
User Facility	Device-related Death	Form FDA 3500A	FDA & Manufacturer	Within 10 work days of becoming aware
User Facility	Device-related Serious injury	Form FDA 3500A	Manufacturer. FDA only if manufacturer unknown	Within 10 work days of becoming aware
User Facility	Annual summary of death & serious injury reports	Form FDA 3419	FDA	January 1 for the preceding year

Source: "**Mandatory Reporting Requirements: Manufacturers, Importers and Device User Facilities"; www..fda.gov**

- ✓ Distributors are required to maintain records but not report
- ✓ Anyone (including healthcare professionals, patients, caregivers and consumers) can submit a MDR voluntarily

How Are MDRs Submitted?

- Manufacturers and importers are required to submit MDRs electronically (as of 8/13/2015)
- User facilities have the option of submitting electronically or via paper reports.
- Voluntary reports can be submit via MedWatch (FDA's Safety Information and Adverse Event Reporting Program). It can be accessed via fda.gov or mobile app (Android/iOS).

Form 3500A

- Most reports are submitted via this form
- Submitters are encouraged to read the instructions and definitions/descriptions of the form elements
  - "Consistency" and "content" should be considered when completing
    - Consistency Example- Brand name is entered in a consistent manner over time for all applicable reports
    - Content Example- Fields such as event problem codes, event description and manufacturer narrative accurately and completely capture event
- Numerous resources are available on fda.gov that can provide additional insight and best practices.

MDRs and UDI

- Unique Device Identifier (UDI) designed to adequately identify devices through distribution and use
- Now part of Form 3500A (not currently on Form 3419)
- UDI should be entered on MDR report for applicable devices
- See *Unique Device Identifier System: FAQ Vol. 1* or "Compliance Dates for UDI Requirements" on fda.gov for more information

Publicly Available MDR data

- Publicly releasable MDR Data between 1984 and present available on fda.gov via zip files, as well as an online search option. Updated monthly.
- Another option is the OpenFDA Adverse Event API, which is updated weekly. There are many examples that can be found online using this API.

Recommended Guidance Documents

- *Medical Device Reporting for Manufacturers* (updated 11/8/2016)
- *Questions & Answers about eMDR-Electronic Medical Device Reporting*
- *Medical Device Reporting for User Facilities*

Questions?