Medical Device Reporting: Viewing Adverse Events as Opportunities for Transformation

FDA Small Business Regulatory Education for Industry (REdI) Annual Conference

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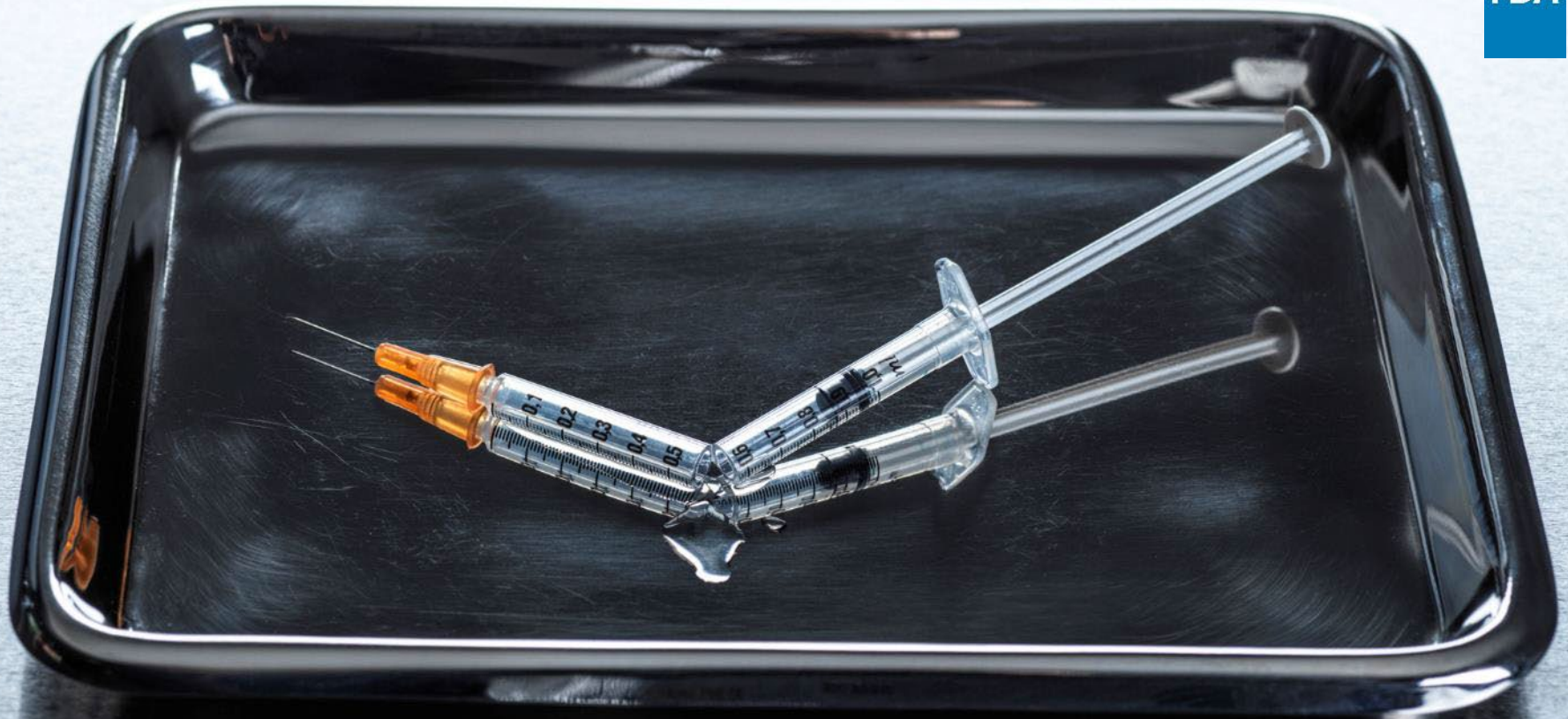
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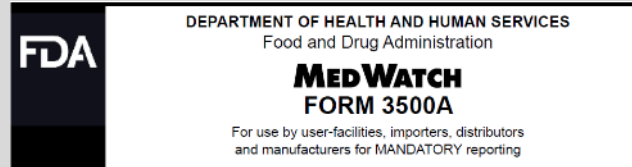
Learning Objectives

- Review requirements for Medical Device Reporting for Mandatory Reporters

- Discuss potential outcomes of Medical Device Reporting

- Describe elements of an effective reporting system

- Identify potential strategies to optimize a reporting system

Regulatory Requirements for Mandatory Reporters

Key Terms

MDR

Medical Device Report

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
MEDWATCH
FORM 3500A
For use by user-facilities, importers, distributors
and manufacturers for MANDATORY reporting

[21 CFR 803.3(n)](#)

Key Terms

FDA

MDR Reportable Event

An event that reasonably suggests a marketed device:

- May have caused or contributed to a death or serious injury, or

- Has malfunctioned and is likely to cause or contribute to death or serious injury if the malfunction were to recur

21 CFR 803.3(o)

Key Terms

Serious injury

An illness or injury that:

- Is life-threatening

- Results in:

  ❑ Permanent impairment of a body function or permanent damage to a body structure or,

- Necessitates medical or surgical intervention

21 CFR 803.3(w)

Key Terms

Malfunction

The failure of a device to meet its performance specifications or otherwise perform as intended.

21 CFR 803.3(k)

Key Terms

Device User Facility

Means:

- A hospital,
- Ambulatory surgical facility,
- Nursing home,
- Outpatient diagnostic facility, or
- Outpatient treatment facility

It is *not* a physician's office.

21 CFR 803.3(d)

Reporting Requirements for Manufacturers and Importers

FDA

| 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

Reporting Requirements for Device 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

How to Submit MDRs

- Electronically through the Electronic Submissions Gateway (ESG)

  - ❑ Mandatory for Manufacturers and Importers

  - ❑ Encouraged for Device User Facilities

- By mail (Device User Facilities only)
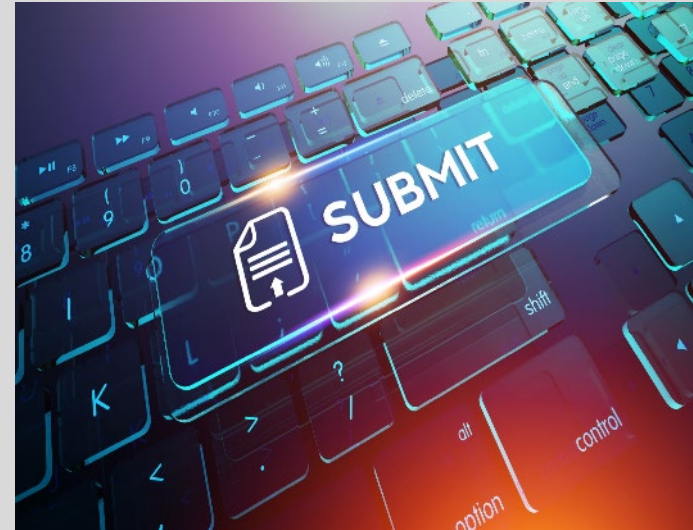
Knowledge Check

If you are a *manufacturer* or *importer*, when should reports of deaths, serious injuries, and malfunctions be reported?

A. Within 5 days of becoming aware of the event.

B. Within 30 days of becoming aware of the event.

C. They do not need to be reported. Internal documentation is appropriate.

FDA

Potential Outcomes of Medical Device Reporting

Outcomes of Medical Device Reporting

Protect public health

- Detect potential device-related safety issues

- Contribute to risk-benefit analysis of devices

- Potentially Initiate actions

  - ❑ FDA inspection of manufacturer

  - ❑ Changes to device labelling

  - ❑ Require device recalls

Effective Reporting System Elements

Effective Reporting System Elements

- Adverse event detection

- Documentation and Maintenance of MDR Event Files

- Investigation

- Reporting

Effective Reporting System Elements

- **Adverse event detection**
- Documentation and Maintenance of MDR Event Files
- Investigation
- Reporting

Effective Reporting System Elements

Adverse event detection

- Internal systems that provide for timely and effective identification of reportable events

  - ❑ Timely and effective identification and evaluation of events for reportability

  - ❑ Standardized review process for determining when an event is reportable

  - ❑ Timely transmission of complete MDRs

Effective Reporting System Elements

- Adverse event detection

- **Documentation and Maintenance of MDR Files**

- Investigation

- Reporting

Effective Reporting System Elements

Documentation:

- Information evaluated for reportability

- MDRs submitted to FDA and/or Manufacturer

- Information evaluated to prepare the submission of annual reports

- Systems to ensure access to information that facilitates timely followup and inspection by FDA

21 CFR 803.17(b)

Effective Reporting System Elements

Maintenance of MDR Event Files:

- Retention period:
    - □ User Facility: 2 years from date of event
    - □ Manufacturer or Importer:
        - ➢ 2 years from date of event *or*
        - ➢ Period of time equivalent to the expected life of the device, whichever is greater

21 CFR 803.17(b)

Effective Reporting System Elements

- Adverse event detection
- Documentation and Maintenance of MDR Event Files
- **Investigation**
- Reporting

Effective Reporting System Elements

Investigation

- Completed by technical experts qualified to make medical judgments
- To determine:
  - ❑ If the device failed to meet specifications;
  - ❑ Whether the device was being used for treatment or diagnosis; and
  - ❑ The relationship, if any, of the device to the reported incident or adverse event
  - ❑ The cause of the adverse event

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Effective Reporting System Elements

- Adverse event detection
- Documentation and Maintenance of MDR Event Files
- Investigation
- **Reporting**

Effective Reporting System Elements

Reporting

- Submit MDRs using the appropriate forms by the deadline
- Submit all required information on the form
  - ❑ If required information is not available, submit a statement of why the information is missing and attempts to obtain the information
  - ❑ If required information becomes available later, submit using a supplemental report

Knowledge Check

FDA will not accept incomplete medical device reports.

1. True

2. False

Potential Strategies to Optimize a Reporting System

Optimizing a Reporting System

Strategies for optimizing a reporting system:

- Innovative technology

- Continuous improvement initiatives

Optimizing a Reporting System

Innovative technology

- Technology tool
    - ❑ Real-time surveillance
        - ➢ Software as a Medical Device (SaMD) that allows reporting of "bugs" as they occur

Optimizing a Reporting System

Continuous improvement initiatives

- Internal Audits

- Routinely scheduled training sessions

Optimizing a Reporting System

Continuous improvement initiatives

- **Internal Audits**
    - ❑ Regularly scheduled and spontaneous
    - ❑ Standard operating procedures (SOPs)
    - ❑ Data collection (complaints and forwarded reports)
    - ❑ Documents and recordkeeping
    - ❑ Employee training programs
- Routinely scheduled training sessions

Optimizing a Reporting System

Continuous improvement initiatives

- Internal Audits

- **Routinely scheduled training sessions**
    - ❑ Review the process for handling MDR event files
        - ➢ Documentation and maintenance
    - ❑ Explain reporting requirements
        - ➢ Key terms, appropriate forms, reporting deadlines, where and how to submit MDRs

MDR Resources and Links

FDA

Slide Number	Cited Resource	URL
10-12	Mandatory Reporting Requirements: Manufacturers, Importers, and Device User Facilities	www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities
5-9, 18-25	Electronic Code of Federal Regulations (eCFR) 21 CFR 803 (Medical Device Reporting)	www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-803?toc=1
24	21 CFR 820 (Quality System Regulation)	www.ecfr.gov/current/title-21/part-820

Summary

- Medical Device Reporting is critical to ensuring that devices continue to be safe and effective

- An effective reporting system allows for timely and accurate reporting of adverse events and malfunctions

- Continuous optimization of reporting systems is encouraged

Questions

Your Call to Action

- Know your Medical Device Reporting requirements

- Challenge your organization to continuously improve your reporting system

- Stay current on regulations and policies by visiting and subscribing to CDRH resources:

  - [Device Advice](#) webpages

  - [CDRH Learn](#): Multi-Media Industry Education

  - [CDRH New](#) for news and updates