

# **Medical Device Reporting: Viewing Adverse Events as Opportunities for Transformation**

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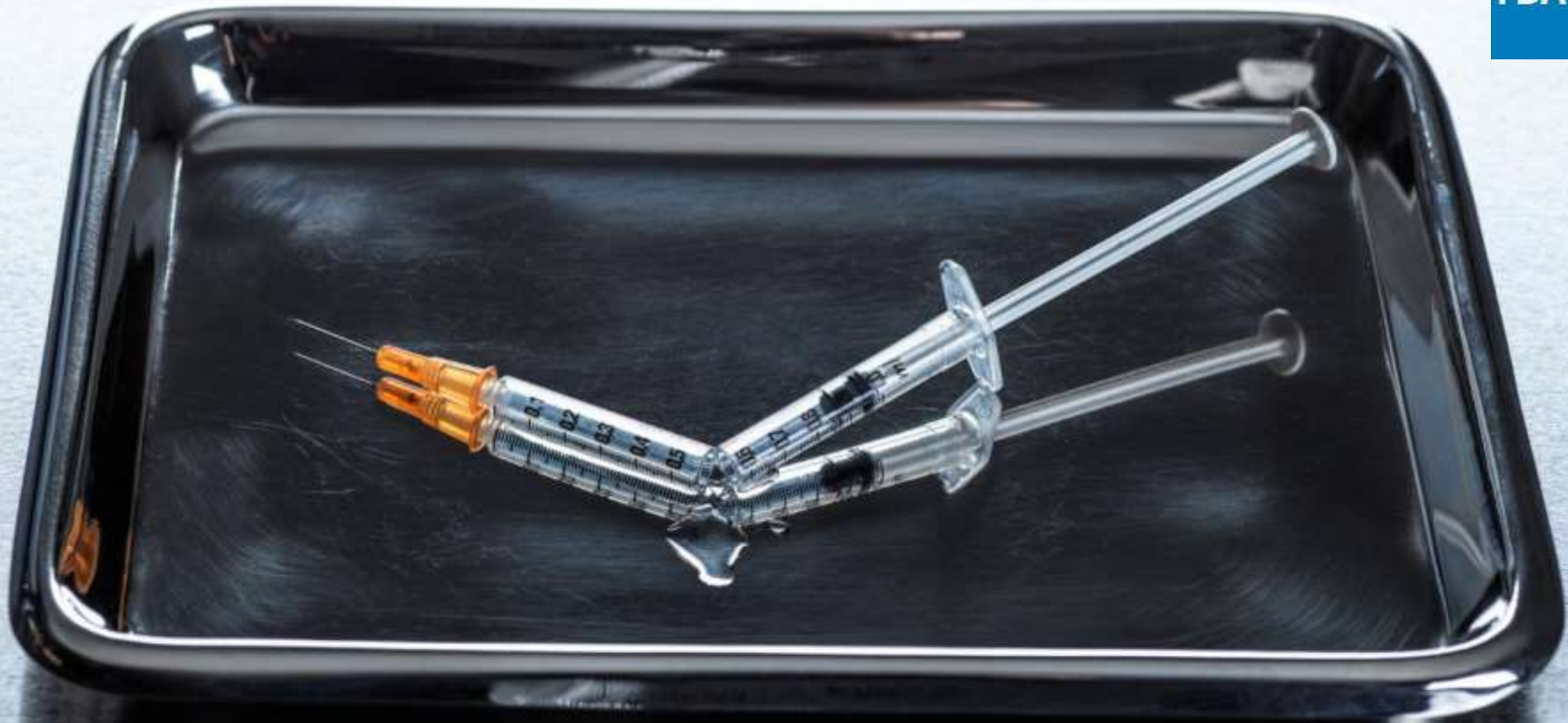
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U.S. Food and Drug Administration



# 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



[21 CFR 803.3\(n\)](#)

# Key Terms

## 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

# 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

# Key Terms

## Malfunction

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



# 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



REPORTER	WHAT TO REPORT	REPORT FORM #	TO WHOM	WHEN
Manufacturers	30 day reports of deaths, serious injuries and malfunctions	<a href="#">Form FDA 3500A</a> *	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	<a href="#">Form FDA 3500A</a> *	FDA	Within 5 work days of becoming aware of an event
Importers	Reports of deaths and serious injuries	<a href="#">Form FDA 3500A</a> *	FDA and the manufacturer	Within 30 calendar days of becoming aware of an event
	Reports of malfunctions	<a href="#">Form FDA 3500A</a> *	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	<a href="#">Form FDA 3500A</a>	FDA & Manufacturer	Within 10 work days of becoming aware
User Facility	Device-related Serious injury	<a href="#">Form FDA 3500A</a>	Manufacturer. FDA only if manufacturer unknown	Within 10 work days of becoming aware
User Facility	Annual summary of death & serious injury reports	<a href="#">Form FDA 3419</a>	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.

# 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

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# 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

# 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

# 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



# 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

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

# 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