Medical Device Reporting for Manufacturers

FDA Small Business
Regulatory Education for Industry (REdI)
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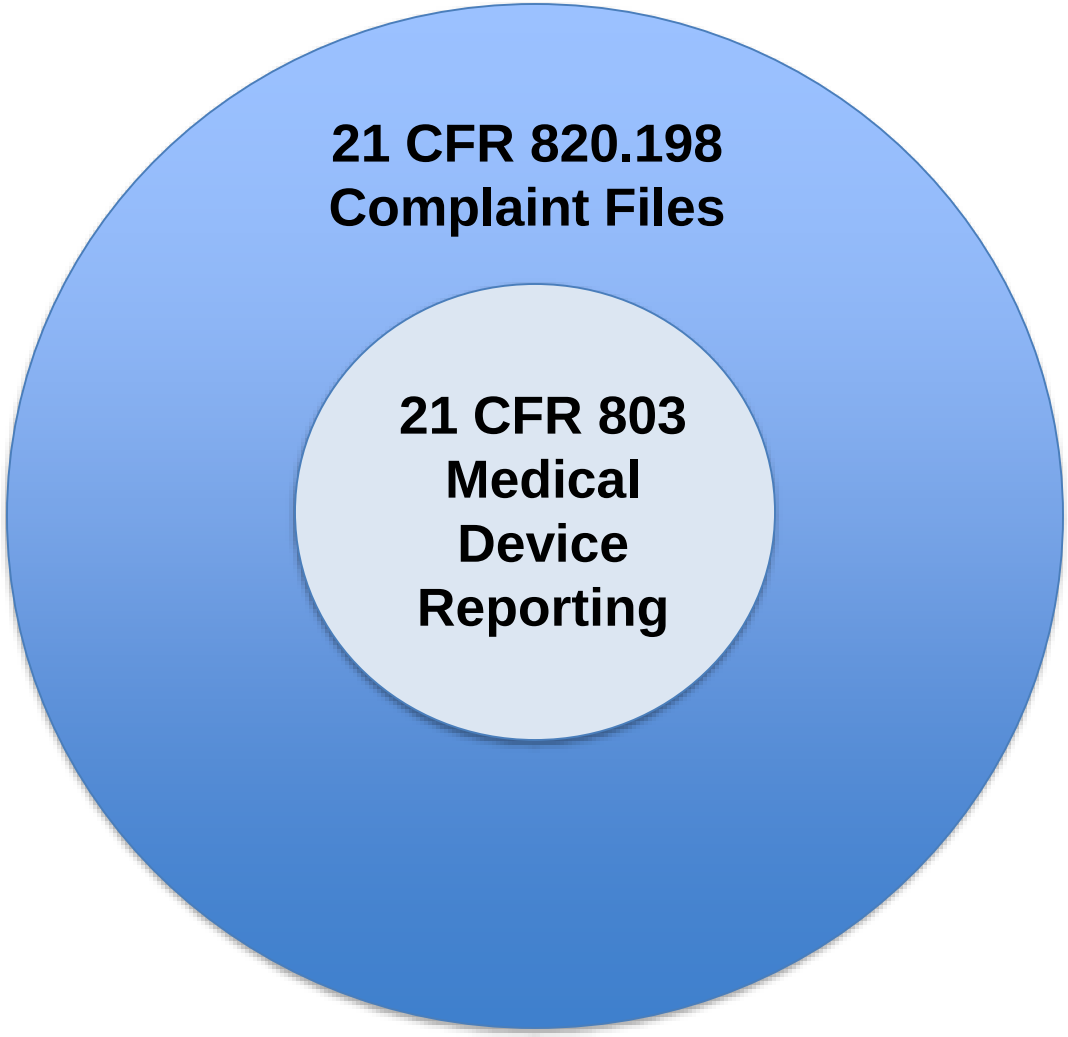
Learning Objectives

- Learn the Purpose of 21 CFR 803
- Know basic reporting requirements
- Understand the recent Final Guidance for Manufacturers
  - Clarify existing requirements

Complaint Files in Relation to MDR



Why Report?

Medical device reports are valuable to:

- Industry
- FDA
- Consumers

Public health, safety, and product quality are of utmost importance to the FDA

Medical Device Reporting (MDR)

21 CFR 803

- Supplements provisions of 21 CFR 820
- Establishes requirements for firm's medical device reporting system
  - Standardized complaint review process
  - Timely, effective identification and communication of adverse events
  - Documentation and recordkeeping

21 CFR 803.17

Mandatory Reporting

Reportable Events reasonably suggest a marketed device:

- May have caused or contributed to a death or serious injury, or
- Malfunction was likely to cause or contribute to death or serious injury were it to recur

21 CFR 803.1, 21 CFR 803.3

Who Reports?

Mandatory Reporters:

- Manufacturers
- Importers
- Device User Facilities

Voluntary Reporters:

- Patients
- Healthcare Professionals
- Consumers

www.stanford.edu

When to Report

Reporter:	What to Report:	Reports to:	When:
Manufacturers	Deaths, serious injuries, or certain malfunctions	FDA (3500A)	30 days
	Events requiring remedial action*	FDA (3500A)	5 days
Importers	Deaths or serious injuries	FDA (3500A) Manufacturer	30 days
	Certain malfunctions	Manufacturer	30 Days
User Facility	Deaths or serious injuries	FDA (3500A)	10 days

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How are MDRs Reported?

Mandatory Reporters (Manufacturers):

- Electronic submission ***only***
  - eMDR Final Rule issued August 14, 2015
  - Use Electronic Submissions Gateway (ESG)

Voluntary Reporters:

- Online via MedWatch (Form FDA 3500)
- Mobile app
- Download and submit via postal mail

Guidance:
Medical Device Reporting for Manufacturers

Guidance Document Overview

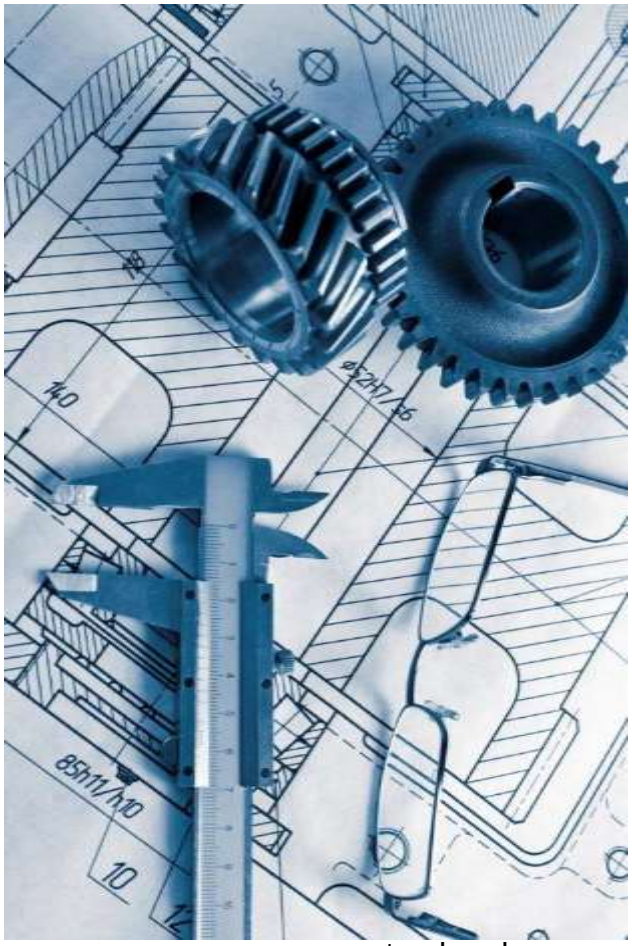
- Manufacturer focused & published November 8, 2016
- Reiterates and clarifies reporting expectations:
  - Meaning of “Becomes Aware”
  - 5-day reports and remedial actions
  - Foreign adverse events
  - MDRs for devices used in IDE studies

“Becomes Aware”

FDA considers a firm to be aware whenever:

- Any employee becomes aware of the reportable adverse event
- Any supervisory employee becomes aware the event requires remedial action

21 CFR 803.3(b)



www.mentorchamber.org

“Becomes Aware”

www.askthedentist.com

Example :

- Receive complaint from dentist about implant on April 1st
- Complaint handling team receives additional information on April 3rd and determines it is a reportable event

Quiz

www.askthedentist.com

When did the company "become aware"?

A. April 1st
B. April 3rd
C. April 4th
D. Never, it was reported on April Fool's Day

“Becomes Aware”

www.askthedentist.com

Example:

- Became Aware: April 3rd
- Clock Starts (Day 1): April 4th

5-day Reports & Remedial Actions

The “5-day Report” is:

- For MDR reportable events requiring remedial action to protect public safety
- Begins day after supervisory employee becomes aware
- Also required when requested by FDA

Remedial Action

- Prevent unreasonable risk of substantial harm to the public health

Reporting Foreign Adverse Events

Firm Location	Cleared/Approved to Market in US	Market Status OUS	Report Foreign Event?
US	Yes	Yes	Yes
OUS	Yes	Yes	Yes
OUS	Under Study	Yes	No

OUS – Outside the United States

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Reporting Foreign Adverse Events

U.S. based companies selling devices OUS must report:

- If a similar version is sold in the U.S.
  - See Section 2.14 of guidance, page 12
- If it is a 510(k) exempt device listed in the U.S. for a U.S. registered manufacturer.

Foreign Companies marketing a device solely OUS:

- Not required to report if not FDA-cleared/approved and no similar version sold in U.S.

IDE Reporting

Legally Marketed or Cleared/Approved	Investigational Use	Report per 21 CFR 803	Report per 21 CFR 812
✓	✗	✓	✗
✗	✓	✗	✓
✓	✓	✓	✓

Example

A manufacturer learns their blood pressure cuff burst upon inflation while recording a patient's vitals during an IDE study.

Should this be reported?

If yes, how?

It depends…

Keys to Analyzing an Event

- Determine if complaint meets reportability criteria
  - Request additional information from reporter
- Assess what happened AND *could* have happened
- Recognize reporting requirements vary
  - User Facility vs. Manufacturer
- Promptly take action to report a problem

Summary

- 21 CFR 820.198 points to 21 CFR 803
- MDRs are critical to public safety and product quality
- You must understand your reporting obligations
- You must comply with reporting obligations
- MDR Guidance is a helpful resource

Resource Websites

- Medical Device Reporting (MDR)
- Guidance Document: Medical Device Reporting for Manufacturers
- eMDR Final Rule
- How to Enroll in eMDR Program
- Setting up a Web Trader Account Checklist
- eSubmitter Download and Installation
- Health Level Seven (HL7) Individual Case Safety Reporting
- CDRH Learn

Questions?

- **General MDR questions: Division of Industry and Consumer Education (DICE)**

  Email: **DICE@fda.hhs.gov**

  Phone: (800) 638-2041

- **Interpretations of MDR policy: MDR Policy Group**

  Phone: (301) 796-6670 (voice message)

  Email: **MDRPolicy@fda.hhs.gov**

Questions

Please complete the session survey:

surveymonkey.com/r/DEV-D2S06

Call to Action

- Understand and comply with 21 CFR 803
- Be eMDR ready!
- Read the MDR for Manufacturers Guidance
  - Understand existing reporting requirements
  - Remain informed of existing MDR policies


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