Medical Device Reporting

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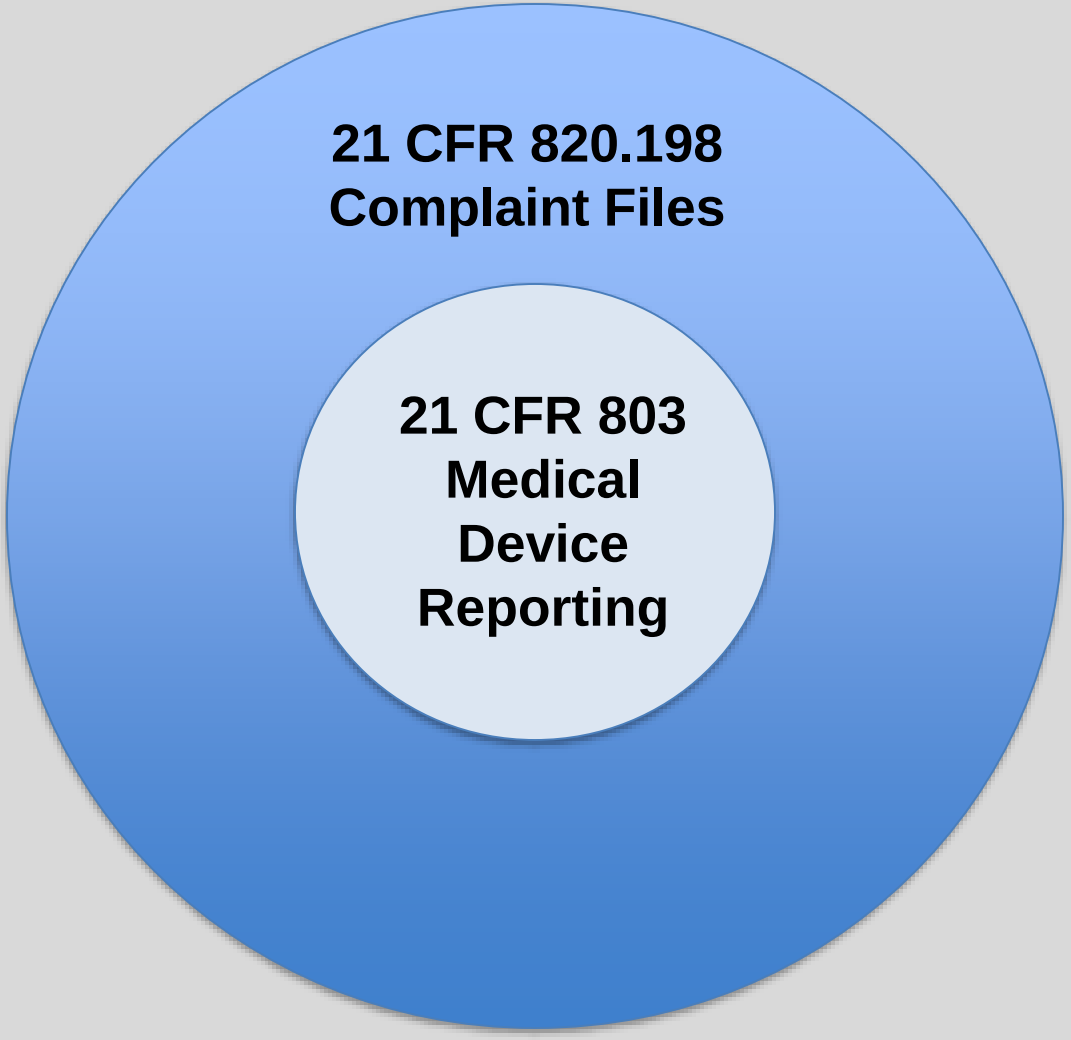
Learning Objectives

- Establish the intent of 21 CFR 803
- Identify basic reporting requirements
- Discuss harmonized adverse event codes
- Understand how FDA utilizes MDRs

MDRs Stem from Complaint Files



Value of Medical Device Reports

Consumers and Industry:

- Device safety and performance
- Design improvement

FDA:

- Monitor device safety and performance
- Assess need for regulatory action

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

How are MDRs Submitted?

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

Adverse Event Codes: Harmonization with IMDRF*

*IMDRF = International Medical Device Regulators Forum

Adverse Event Coding Working Group

FDA is participating in IMDRF working group

- IMDRF Adverse Event Terminologies
- Developing coding schemes
  - Device Problem Codes
  - Device Evaluation Codes
  - Patient Problem Codes
  - Component Codes

FDA Harmonization Efforts

- Released two code lists in November 2017
  - Device Problem and Manufacturer Evaluation Codes
  - Retires FDA terms not included in the IMDRF lists
  - Adds IMDRF terms not previously in FDA lists
  - New FDA and NCIt codes assigned to new terms

FDA Harmonization Efforts

- New code lists go live July 5th, 2018
- Retired codes will no longer be accepted
- Plan accordingly

Future Coding Efforts

- Currently under development by IMDRF
  - Patient Problem Codes and Component Codes
  - FDA plans to harmonize with those coding sets
- Once harmonization is complete
  - Update internal systems to accept IMDRF alphanumeric codes
  - Continue to accept FDA and NCIt codes

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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Poll:
What happens to submitted MDRs?

A. Reviewed, analyzed, and redacted by FDA

B. Entered in MAUDE database

C. A and B

D. Nothing, ESG connects directly to a black hole

Statistics

- FDA receives ~855,000 reports per year
  - 936,508 reports in 2017
  - Majority from Mandatory Reporters
  - 7,200 from Voluntary Reporters
- Each report is reviewed by an analyst
- Analysts are medical and technical professionals
  - Nurses, engineers, scientists etc.

Analyst Medical Subject Areas

Product Evaluation Branch I	Product Evaluation Branch II	Product Evaluation Branch III
• Cardiovascular • Gastroenterology • Renal/Urology • OB/GYN	• General Hospital • General/Plastic Surgery • Orthopedics • Infection Control • Physical Medicine	• Respiratory • Anesthesia • Neurology • Ear/Nose/Throat • Dental • Ophthalmology

What are Analysts looking for?

Trends:

- Common vs Novel
- Frequency
- Severity
- Risk

Information Analysis Branch

- CDRH's adverse event data management team
- Maintains MAUDE database and data files
- Provides eMDR Support
  - Houses eMDR Help Desk (eMDR@fda.hhs.gov)

Possible Actions

- Contact the reporter
- Escalate the signal within CDRH
- Make recommendations
  - FDA inspection of manufacturer
  - Changes to device labeling
  - Public health notifications
  - Device recall

Other Uses of MDR Data

- Educate premarket review staff
- Refining premarket review
- Response to congressional inquiries

Summary

- MDRs are a regulatory requirement per 21 CFR 803
- You must understand your reporting obligations
- You must comply with reporting obligations
- MDRs are critical to public health and safety

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

Resource Websites

- MDR Adverse Event Codes
- How to Code
- Coding Resources
- Coding FAQs
- eMDR Help and FAQs

Resources

- **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)

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

Questions

Please evaluate this session:

surveymonkey.com/r/DEV-D2S07

Your Call to Action

- Understand and comply with 21 CFR 803
- Utilize harmonized adverse event codes
- Remember your reports support public health


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