Medical Device Reporting for Mandatory Reporters

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Learning Objectives

- Describe FDA's regulatory authority for medical device reporting
- Define medical device reporting terms
- Identify mandatory reporters and their responsibilities
- Determine how, when, and where to report
- Explain the Voluntary Malfunction Summary Reporting Program

FDA's Regulatory Authority

Regulatory Authority

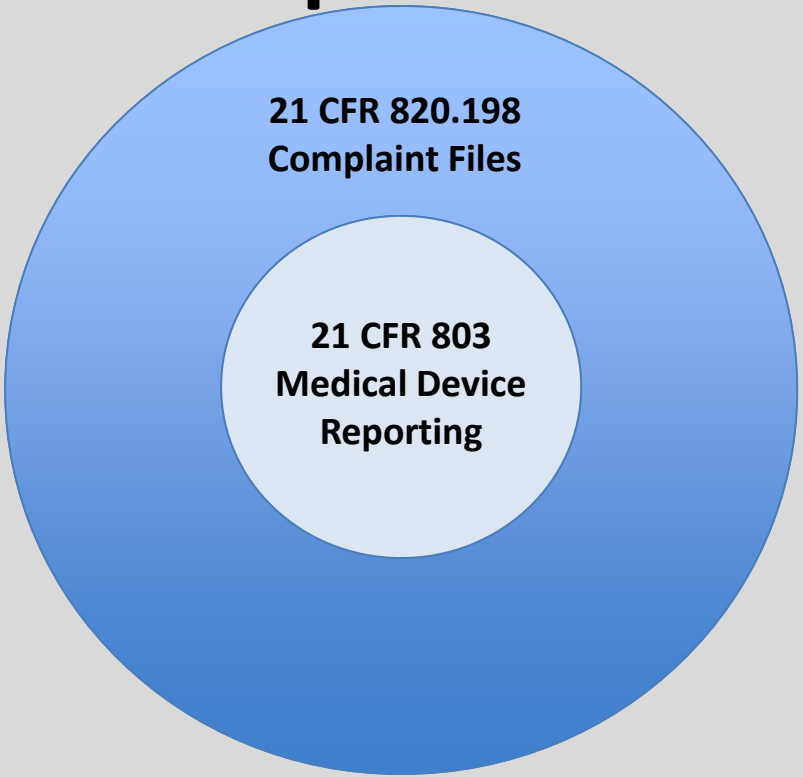
- Section 519 of the Food, Drug, and Cosmetic Act
  - Pertains to records and reports on medical devices
  - Grants FDA authority to require mandatory medical device reports from manufacturers, importers, and device user facilities
  - Reporting requirements found in 21 CFR 803

Medical Device Reporting: 21 CFR 803

- In addition to provisions of the Quality System Regulation
  - 21 CFR 820
- Establishes requirements for firm's medical device reporting system
  - Standardized complaint review process
  - Timely, effective identification and communication of reportable events
  - Documentation and recordkeeping

21 CFR 803.17

Medical Device Reports (MDRs) and Complaint Files



Medical Device Reporting Terms

MDR Reportable Event

An MDR reportable event reasonably suggests a marketed device:

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

21 CFR 803.3(o)

MDR Reportable Event

An MDR reportable event reasonably suggests a marketed device:

- Malfunctioned, and
- Likely to cause or contribute to death or serious injury were it to recur

21 CFR 803.3(o)

Malfunction

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

- Performance specifications include all claims made in labeling for the device

(21 CFR 803.3(k))

Serious Injury

Refers to an injury or illness that:

- Is life-threatening
- Results in permanent impairment of a body function
- Results in permanent damage to a body structure
- Necessitates medical or surgical intervention

(21 CFR 803.3(w))

Mandatory Reporters and Their Responsibilities

Mandatory Reporters

- Manufacturers
  - 21 CFR 803.3(l)
- Importers
  - 21 CFR 803.3(j)
- Device User Facilities
  - 21 CFR 803.3(d)

Common Responsibilities

- Establish and maintain MDR procedures
  - (21 CFR 803.17)
- Establish and maintain MDR event files
  - (21 CFR 803.18)
- Clearly identify MDR event files in their records
  - (21 CFR 803.18)
- Permit FDA employees to access, copy, and verify records

Mandatory Reporters

- **Manufacturers**
  - 21 CFR 803.3(l)
- Importers
  - 21 CFR 803.3(j)
- Device User Facilities
  - 21 CFR 803.3(d)

Manufacturer

- Any person who manufactures, prepares, propagates, compounds, assembles, or processes a device

(21 CFR 803.3(l))

Manufacturer

Includes those who:

- Repackage a device
- Initiate specifications for a device
- Manufacture components or accessories that are ready to be used

(21 CFR 803.3(l))

Other Responsibilities of Manufacturers

- Investigate each event
- Obtain and submit missing information from other reporters
- Provide all information reasonably known

(21 CFR 803.50(b))

Other Responsibilities of Manufacturers

Information reasonably known:

- Obtained by contacting the reporter
- Obtained through analysis, testing, or other evaluation
  - Such as professional, scientific, or medical facts, observations, or opinions
- In the manufacturer's possession

(21 CFR 803.50(b))

Mandatory Reporters

- Manufacturers
  - 21 CFR 803.3(l)
- **Importers**
  - 21 CFR 803.3(j)
- Device User Facilities
  - 21 CFR 803.3(d)

Importers

- Any person who imports a device into the United States

AND

- furthers the marketing of a device to the person who makes final delivery or sale to the ultimate user

(21 CFR 803.3(j))

Importers

- Do not repackage or change the container, wrapper, or label of a device or device package

(21 CFR 803.3(j))

Other Responsibilities of Importers

- Responsibilities do not extend further than those required of all mandatory reporters

Mandatory Reporters

- Manufacturers
  - 21 CFR 803.3(l)
- Importers
  - 21 CFR 803.3(j)
- **Device User Facilities**
  - 21 CFR 803.3(d)

Device User Facilities

- Hospital
- Ambulatory surgical facility
- Nursing home
- Outpatient diagnostic facility
- Outpatient treatment facility

(21 CFR 803.3(d))

Device User Facilities

Are not:

- Physician's offices
- School nurse offices
- Employee health units

(21 CFR 803.3(d))

Other Responsibilities for Device User Facilities

- Submit annual reports to FDA (21 CFR 803.33)
  - Form FDA 3419
  - Form FDA 3419 instructions

How, When, and Where to Submit MDRs

How to Report: Mandatory Reporters

Manufacturers and Importers:

- Electronic submission ***only***
- Electronic Medical Device Reporting (eMDR) Final Rule
  - Issued August 14, 2015
- Use Electronic Submissions Gateway (ESG)
  - eMDR Guidance

How to Report: Mandatory Reporters

User Facilities:

- Electronic submission encouraged
- eMDR Final Rule permits written reports
  - Use Form 3500A
- Guidance: Medical Device Reporting For User Facilities

When to Submit

- After “becoming aware” of reportable adverse events and certain malfunctions
  - Within 30 calendar days
  - Within 10 work days
  - Within 5 work days

Becoming Aware

FDA considers a firm to be aware whenever:

- Any employee (or medical personnel) becomes aware of the reportable adverse event
- Any supervisory employee becomes aware the event requires remedial action to prevent harm to public health

21 CFR 803.3(b)

Remedial Action

- Any action other than routine maintenance or servicing of a device where such action is necessary to prevent recurrence of a reportable event

21 CFR 803.3(v)

When and Where to Report

Reporter:	What to Report:	Where to:	When:
Manufacturers	Deaths, serious injuries, or certain malfunctions	FDA (3500A)	30 calendar days
	Events requiring remedial action	FDA (3500A)	5 work days
Importers	Deaths or serious injuries Certain malfunctions	FDA (3500A) Manufacturer Manufacturer	30 calendar days 30 calendar days
Device User Facilities	Deaths or serious injuries	FDA (3500A) Manufacturer	10 work days

5-day Reports

- For events requiring remedial action to prevent an unreasonable risk of substantial harm
- When FDA has made a written request

21 CFR 803.53

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Voluntary Malfunction Summary Reporting Program (VMSRP) for Device Manufacturers

VMSRP for Device Manufacturers

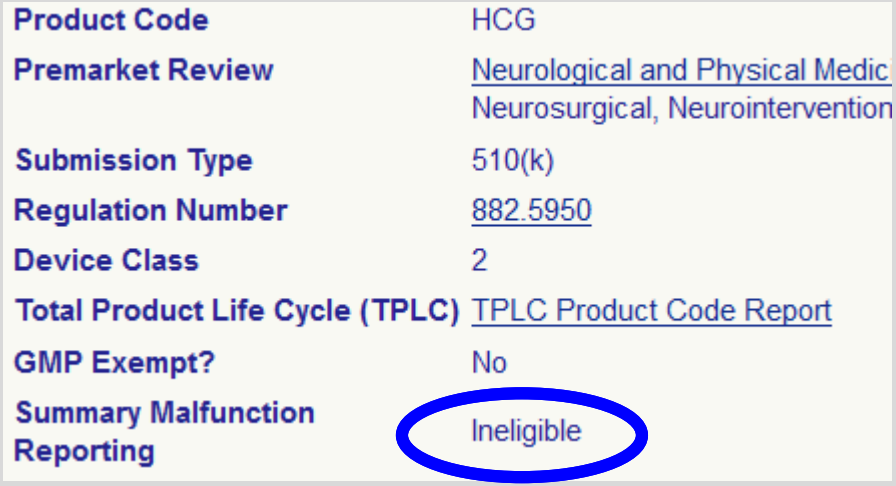
- Final Rule issued August 17, 2018
- Grants an alternative for certain manufacturers to report certain malfunctions in summary format
- Reports are submitted electronically on quarterly basis
- Applies to malfunctions manufacturers become aware of after August 17, 2018

VMSRP Conditions

Summary reporting cannot be used if a reportable malfunction:

- Is associated with a 5-day report
- Is the subject of certain device recalls
- Involves a device deemed ineligible

– See Product Classification Database



Product Code	HCG
Premarket Review	Neurological and Physical Medic Neurosurgical, Neurointervention
Submission Type	510(k)
Regulation Number	882.5950
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible

VMSRP Conditions

Summary reporting cannot be used:

- If FDA has determined individual reporting is necessary
  - Typically for public health reasons
- If FDA has determined a device manufacturer may not report in summary format
- If it is a new type of reportable malfunction for a device

VMSRP Reporting Schedule

Timeframe*:	Submit to FDA by:
January 1 – March 31	April 30
April 1 – June 30	July 31
July 1 – September 30	October 31
October 1 – December 31	January 31

*Events manufacturers become aware of during this timeframe

Summary

- MDRs are required by FDA per 21 CFR 803
- Mandatory Reporters must understand and comply with reporting requirements
- MDRs are critical to public health and safety

Contact Information

Interpretations of MDR policy: MDR Policy Group

- Phone: (301) 796-6670 (voice)
- Email: **MDRPolicy@fda.hhs.gov**

Industry Education: Three Resources for You

1. **CDRH Learn: Multi-Media Industry Education**
   - Over 125 modules
   - Videos, audio recordings, power point presentations, software-based "how to" modules
   - Mobile-friendly: access CDRH Learn on your portable devices

   www.fda.gov/CDRHLearn

2. **Device Advice: Text-Based Education**
   - Comprehensive regulatory information on premarket and postmarket topics

   www.fda.gov/DeviceAdvice

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: www.fda.gov/DICE

Your Call to Action

- Stay current on MDR policies and regulations
- Establish your firm's MDR procedures
- Be proactive and meet your reporting deadlines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