Postmarket Activities: Mandatory Reporting Requirements and Recalls, Corrections and Removals

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Agenda

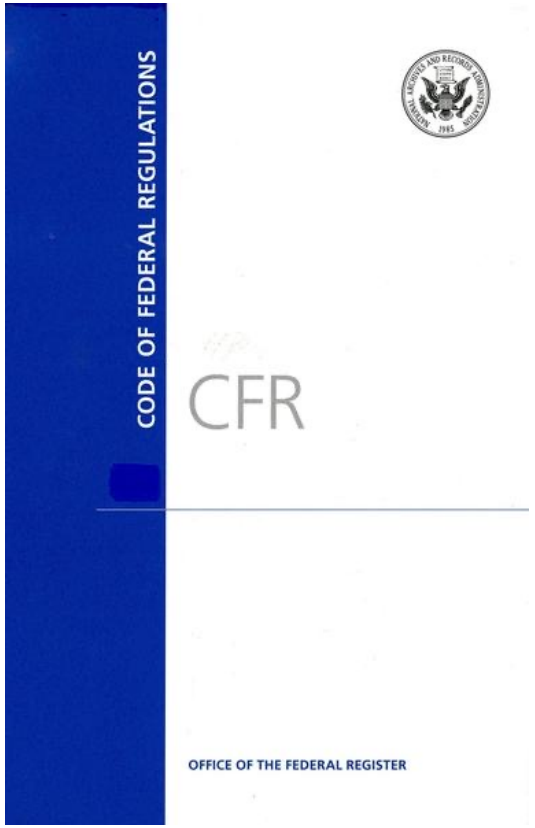
- Postmarket requirements
  - 21 CFR 820 – Quality System Regulation/Medical Device Good Manufacturing Practices
  - Medical Device Tracking
  - 522 Postmarket Surveillance Studies Program
  - Post-Approval Studies Program
  - **Mandatory Reporting Requirements**
  - **Recalls, Corrections and Removals**

Postmarket Requirements

- Medical device manufacturers, and others involved in the distribution of devices, must follow certain requirements and regulations once devices are on the market
  - tracking systems
  - reporting of device malfunctions, serious injuries or deaths
  - registering the establishments where devices are produced or distributed

Mandatory Reporting Requirements

- Section 519 of the Federal Food, Drug and Cosmetic Act describes the requirements for "Records and Reports on Devices"
  - *Every person who is a manufacturer or importer of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness.*
- 21 CFR Part 803, establishes the requirements for medical device reporting for mandatory reporting entities



Who Must Report Adverse Events?

- The regulation provides a mechanism for FDA and manufacturers to identify and monitor significant adverse events involving marketed medical devices
- Those who must report are:
  - Manufacturers
  - User Facilities
  - Importers
  - Distributors

Manufacturer

- Any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. This includes:
  - Domestic Manufacturers
  - Repackagers
  - Relabelers
  - Contract Manufacturers
  - Specification Developers
  - Foreign Manufacturers

Importer

- Any person who imports a device into the United States and who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper or labeling of the device or device package.

Distributor

- Any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. If you repackage or otherwise change the container, wrapper, or labeling, you are considered a manufacturer as defined in this section.

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Device User Facility

- A hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility which is not a physician's office. School nurse offices and employee health units are not user facilities.

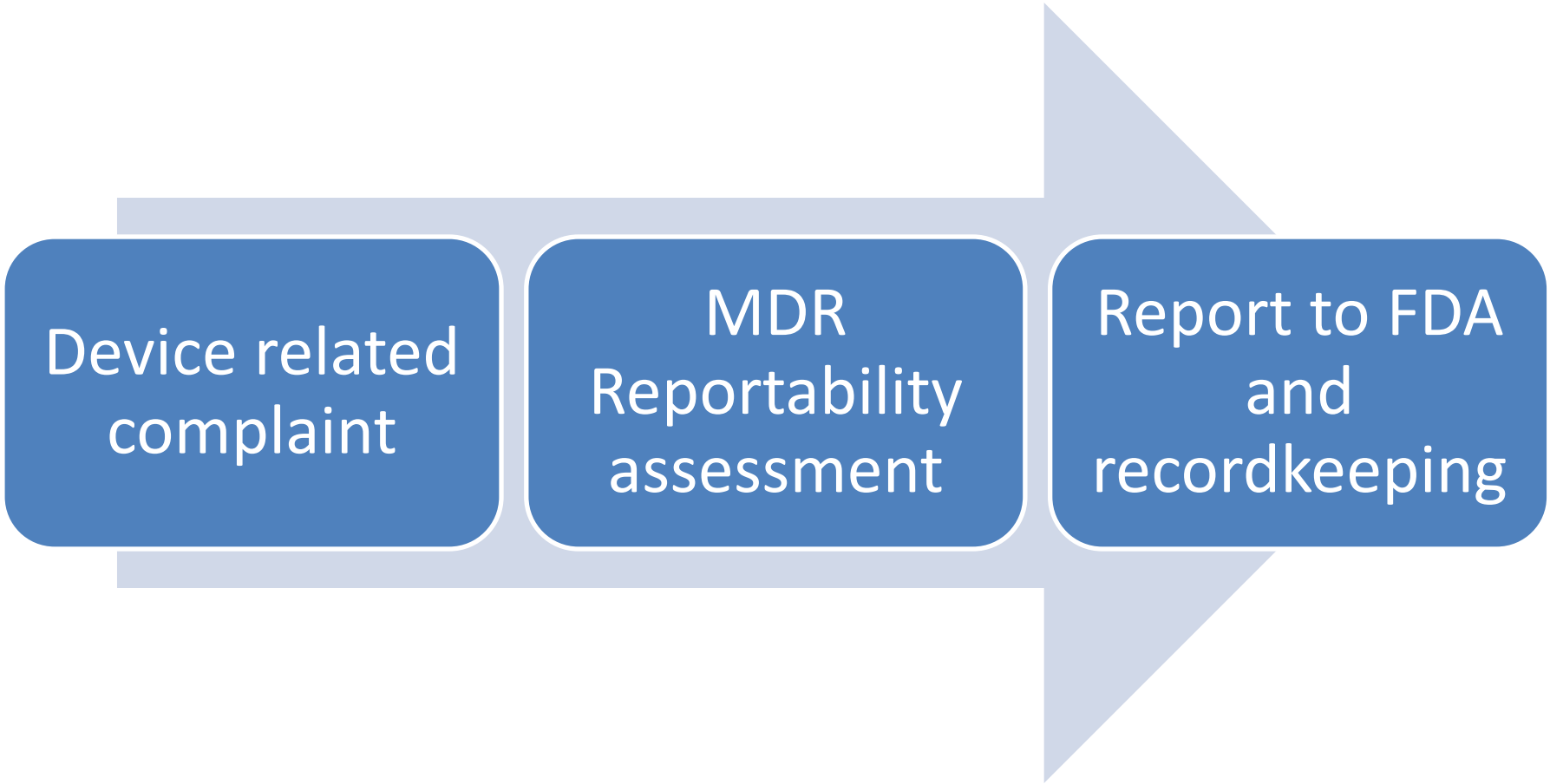
Reporting Requirements

REPORTER	WHAT TO REPORT	WHERE	WHEN
Manufacturer (Mfr.)	Deaths, Serious Injuries, Malfunction	FDA	Within 30 calendar days
	Events that require remedial action to prevent an unreasonable risk of substantial harm	FDA	Within 5 working days
	Supplements (Follow-up Reports)	FDA	Within 30 calendar days
Importer	Deaths and Serious Injuries	FDA and Mfg	Within 30 calendar days
	Malfunctions	Mfg	Within 30 calendar days
User Facility	Deaths	FDA and Mfg	Within 10 calendar days
	Serious Injuries	Mfg	Within 10 calendar days
	Annual summary of death and serious injury reports	FDA	January 1 for the preceding year

5-day reports and Remedial Action

- A “remedial action” is any action, other than routine maintenance or servicing of a device, necessary to prevent recurrence of an MDR reportable event. FDA does not consider an action taken to correct only a single device involved in an MDR reportable event to be a remedial action.
- Not all MDR reportable events requiring remedial action need to be submitted as 5-day reports. Only events that require remedial actions to:
  - Prevent an unreasonable risk of substantial harm to the public health or
  - Events for which FDA requests such report must be submitted

Reportability Determination

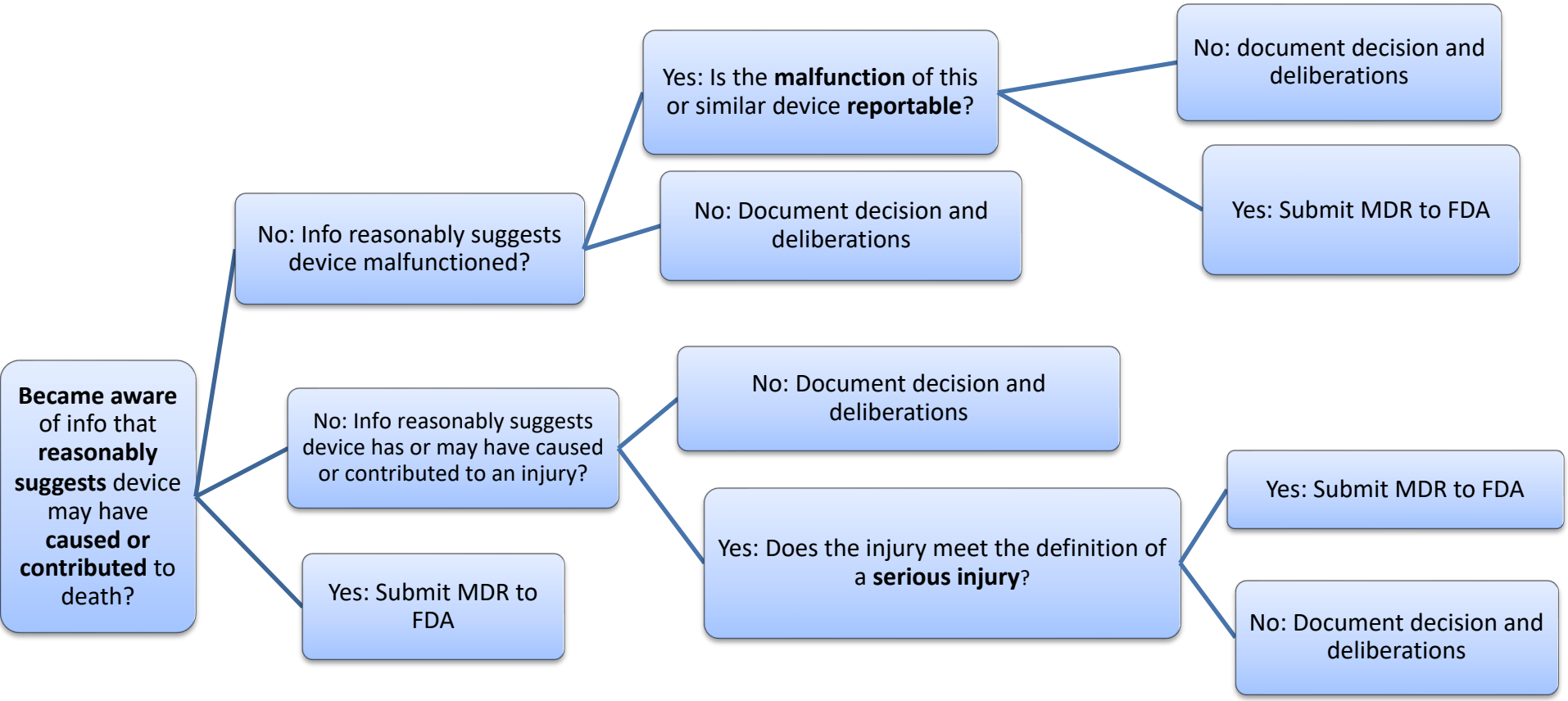


Complaints

- What is a complaint?
  - Any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution
- Sources for potential complaints:
  - Service reports
  - Social media, publicly available articles, news
  - Scientific journals
  - Returned devices
  - Clinical investigations

- Review and evaluate all device-related complaints to determine whether the complaint represents an MDR reportable event

Reportability Determination



Start with a device-related complaint

Becoming Aware

- A firm becomes aware of an event whenever
  - Any of its employees become aware of information that reasonably suggests that an event is required to be reported in a 30-day report or in a 5-day report that we have requested from you; or
  - Any of its employees with management or supervisory responsibilities over persons with regulatory, scientific or technical responsibilities (including consultants and contractors) or whose duties relate to the collection and reporting of adverse events, become aware from any source that an MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.

Reasonably Suggests

- Information that reasonably suggests can include:
  - Professional, scientific or medical facts and observations, trend analysis and opinions
- What if the information in the initial report does not reasonably suggest?
  - Then you have not yet become aware of a reportable event

Caused or Contributed

- A death or serious injury was or may have been attributed to a medical device, or
- A medical device was or may have been a factor in a death or serious injury, including events resulting from:
  - Failure
  - Malfunction
  - Improper or inadequate design
  - Manufacture
  - Labeling
  - User error

Serious Injury

- An injury or illness that is:
  - Life-threatening
  - Results in permanent impairment of a body function or permanent damage to a body structure
  - Necessitates medical or surgical intervention to preclude permanent impairment or damage to a body function or structure

Reportable Malfunctions

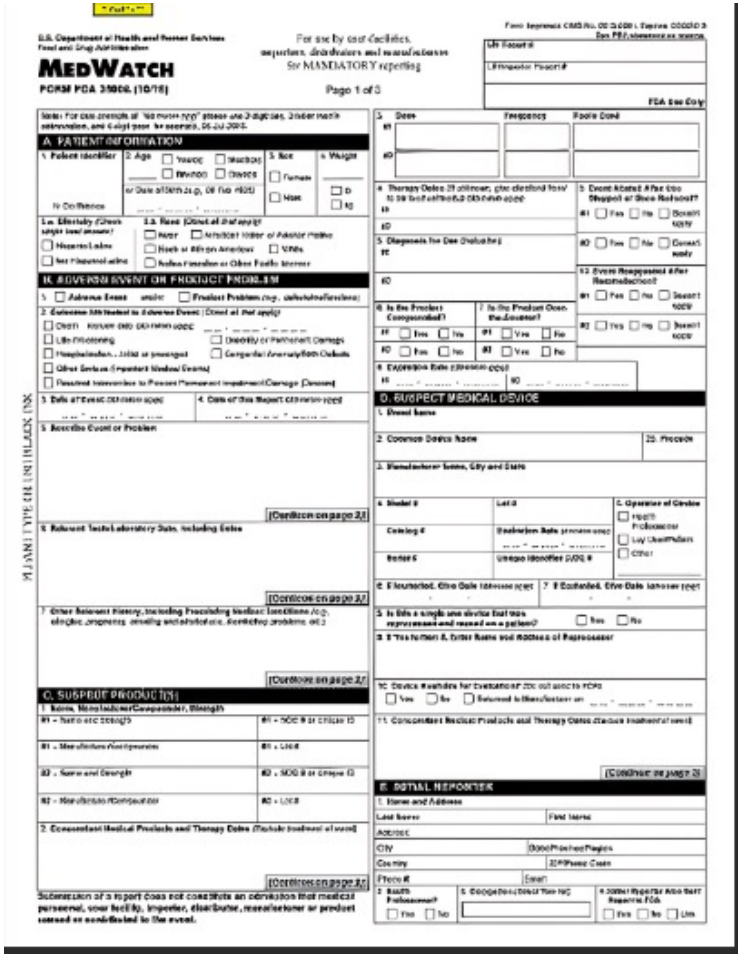
- The malfunction would be likely to cause or contribute to a death or serious injury, if the malfunction of the same or similar device were to recur
- The malfunction results in the failure of the device to perform its essential function and compromises the device's therapeutic, monitoring, or diagnostic effectiveness, which could cause or contribute to a death or serious injury or other significant adverse device experience required by the regulation

MDR Reportable Event

- An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices:
  - May have caused or contributed to a death or serious injury, or
  - Has malfunctioned and that device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if it were to recur

eMDR

- Since August 14, 2015, MDR reports must be submitted electronically by manufacturers and importers. User facilities are still allowed to submit paper MDRs using the FDA's Medwatch Form 3500A.
- Recordkeeping should include copies of all submitted reports and acknowledgements


MEDWATCH

FORM FDA 3500A (10/15)

For use by user facilities, importers, distributors and manufacturers for MANDATORY reporting

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A. PATIENT INFORMATION

B. ADVERSE EVENT OR PRODUCT PROBLEM

C. SUSPECT PRODUCT(S)

D. SUSPECT MEDICAL DEVICE

E. INITIAL REPORTER

Reporting Foreign Events

- U.S. based companies marketing devices OUS must report:
  - If a similar version is sold in the U.S.
  - If it is a 510(k) exempt device listed in the U.S. for a U.S. registered manufacturer.
- Foreign Manufacturers marketing a device solely OUS:
  - Not required to report if not FDA-cleared/approved and no similar version sold in U.S.

Not Reportable

- Manufacturers are not required to submit an MDR report if:
  - They determine that the information received is erroneous in that a device-related adverse event did not occur. Retain documentation.
  - They did not manufacture or import the device about which you have adverse event information
  - They are a contract manufacturer who does not distribute or market the devices it manufactures for a specification developer
  - They are a foreign manufacturer:
    - Who markets solely OUS, and
    - Has not received premarket clearance/ approval for OUS device, and
    - There is no similar version of the OUS device in the US

Additional Requirements

- Develop, maintain, and implement written MDR procedures
- Establish and maintain MDR event files
- Have a system in place that ensures access to information that facilitates timely follow up/ inspection by FDA

MDR Adverse Event Codes

- A system of codes, terms, and definitions used to describe and categorize medical device adverse events.
- Primarily used to complete MDRs

MDR Code Types

Code Type	Purpose: These Terms/Codes Describe
Medical Device Problem	Problems (malfunction, deterioration of function, failure) of medical devices
Medical Device Component	The parts and components which were involved in, or affected by, the medical device adverse event/incident.
Cause Investigation - Type of Investigation	What was investigated and what kind of investigation was conducted to specify the root cause of the adverse event.
Cause Investigation - Investigation Findings	The findings in the specific investigation that are the keys to identify the root cause of the event.
Cause Investigation - Investigation Conclusion	The conclusion regarding the root cause of the reported event.
Health Effects - Clinical Signs and Symptoms or Conditions	The clinical signs and symptoms or conditions of the affected person appearing as a result of the medical device adverse event/incident.
Health Effects - Health Impact	The consequences of the medical device adverse event/incident on the person affected.

MDR Codes and IMDRF

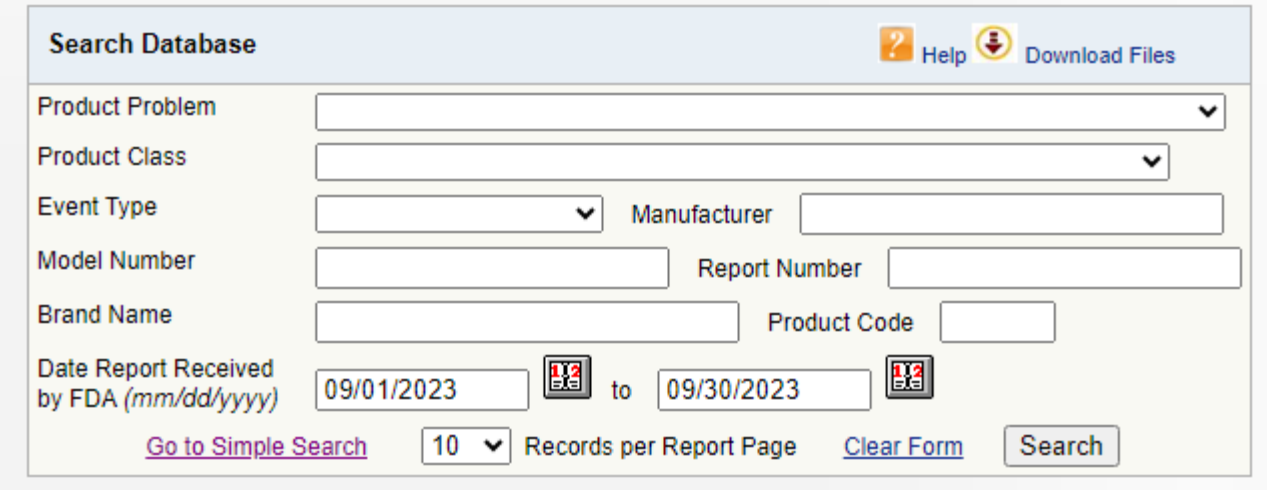
- FDA is a participant in the IMDRF Adverse Event Terminology working group
- Aim of the WG is to improve and harmonize medical device adverse event coding among participating regulatory authorities
- Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes was published 20 April 2020
- FDA codes are mapped to a single corresponding IMDRF code

Manufacturer and User Facility Device Experience (MAUDE)

- MAUDE is a searchable database containing 10 years worth of data on medical device adverse events
- Passive surveillance system that is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices
- FDA reviews all MDRs received

MAUDE

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm



Medical Device Recalls

- A recall is a method of removing or correcting products that are in violation of laws administered by the Food and Drug Administration (FDA).
- A recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.
- 21 CFR 7 provides guidance so that responsible firms may conduct an effective recall.
- FDA does have the authority to issue a recall order to the manufacturer per 21 CFR 810, but this is very rare.

Classification of Recalls

- A health hazard evaluation (HHE) must be conducted to determine the cause of an adverse event involving a medical device
- FDA will assign the recall a classification (Class I, II, or III) to indicate the relative degree of health hazard of the product being recalled or considered for recall

Classification of Recalls

- Class I - a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
- Class II - a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III - a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Recall Strategy

- The recalling firm should develop a recall strategy that takes into account the following factors as they apply to the individual circumstances of the particular recall:
  - Results of health hazard evaluation.
  - Ease in identifying the product.
  - Degree to which the product's deficiency is obvious to the consumer or user.
  - Degree to which the product remains unused in the market-place.
  - Continued availability of essential products.
- The FDA will review the adequacy of a proposed recall strategy and recommend changes as appropriate. A recalling firm should conduct the recall in accordance with an approved recall strategy but need not delay initiation of a recall pending review of its recall strategy.

Recall Strategy

- A recall strategy will address the following elements:
  - Depth of the recall – strategy will specify the level in the distribution chain to which the recall is to extend
  - Public warning – recalling firm is requested to submit proposed public warning. If FDA feels this is inadequate and firm doesn't revise, FDA can issue its own press
  - Effectiveness checks – recalling firm is responsible for determining how effective the recall has been and if consignees have received notification about the recall and have taken appropriate action. FDA will assist in this task where necessary and appropriate.

Corrections and Removals

- Under 21 CFR 806, Medical Devices; Reports of Corrections and Removals, manufacturers and importers are required to make a report to FDA of any correction or removal of a medical device(s) if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health.
- A report must be made even if the event was caused by user error.

Corrections and Removals

- The definition of "risk to health"' under 21 CFR 806 tracks the definitions of Class I and Class II recalls in 21 CFR 7.3(m). Therefore, reports of corrections and removals are required for Class I and Class II recalls.
- Under 21 CFR 806, manufacturers and importers need not report events categorized as Class III recalls under 21 CFR §7; only record keeping requirements would apply.
- The following actions are exempt from the reporting requirements:
  - Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device,
    - Market withdrawals,
    - Routine servicing, and
    - Stock recoveries.

Corrections and Removals – When to Report?

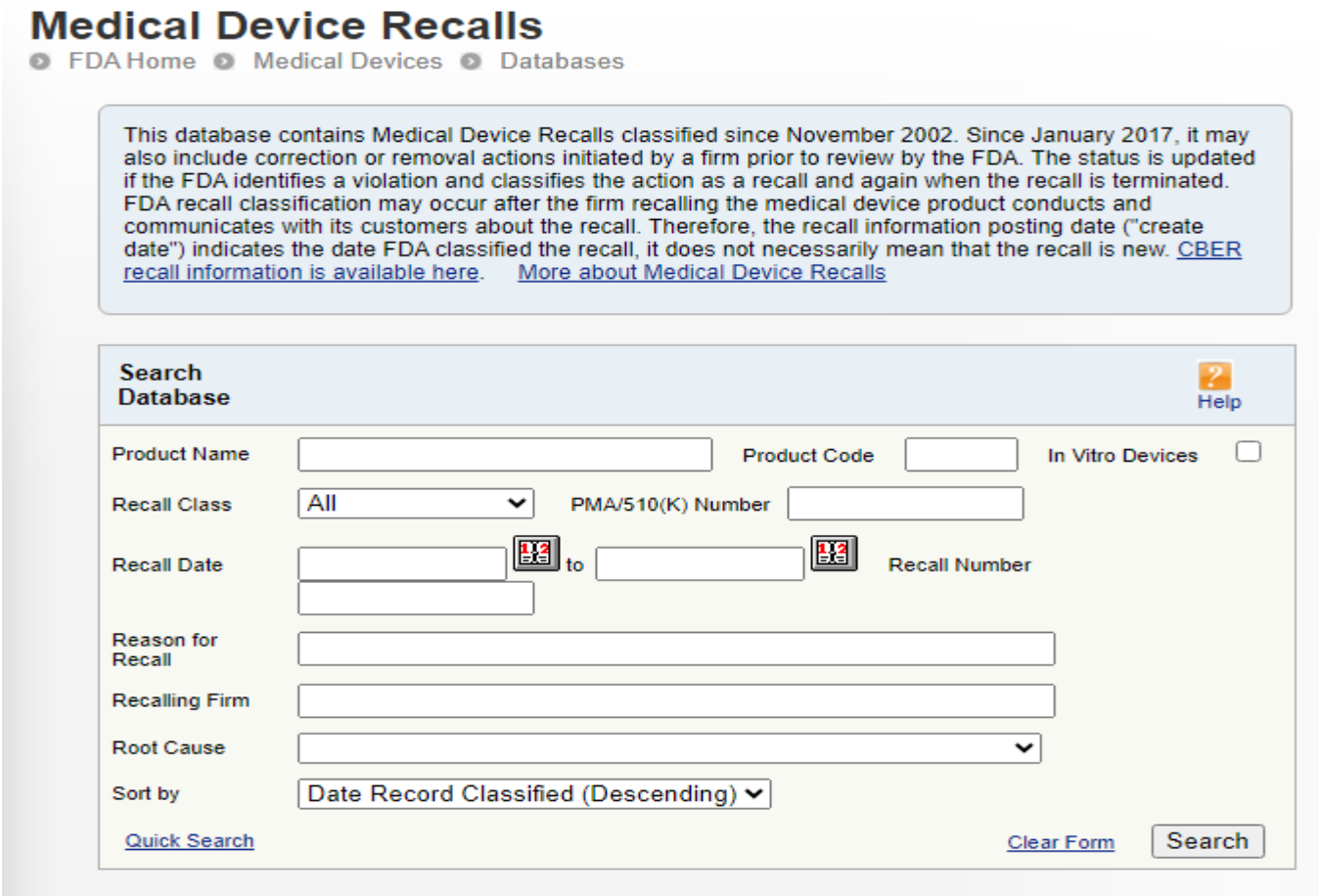
- The report must be submitted to FDA within 10 working days from the time the firm initiates the correction or removal . If there is not a "risk to health" involved, a report to FDA is not required, but the manufacturer or importer must keep a record of the correction or removal.

Corrections and Removals – Recordkeeping Requirements

- The device manufacturer or importer who initiates a correction or removal of a device that is not required to be reported to FDA must maintain records of the correction or removal.
- Records must be retained for a period of two years beyond the expected life of the device, even if the manufacturer or importer has ceased to manufacture or import the device. Records required to be maintained must be transferred to the new manufacturer or importer of the device and maintained for the required period of time.

Recalls Database

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm



Resources

Resource	URL
Medical Device Tracking 21 CFR Part 21	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=821
Medical Device Tracking – Guidance for Industry and FDA Staff	https://www.fda.gov/media/71205/download
Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act	https://www.fda.gov/media/81015/download
Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order	https://www.fda.gov/media/71327/download
Medical Device Reporting 21 CFR Part 803	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=803
Medical Device Reporting for Manufacturers	https://www.fda.gov/media/86420/download
Medical Device Reporting for User Facilities	https://www.fda.gov/media/73972/download
Questions and Answers about eMDR	https://www.fda.gov/media/76993/download
Enforcement Policy 21 CFR Part 7	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=7
Medical Device Recall Authority 21 CFR Part 810	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=810
Medical Devices; Reports of Corrections and Removals 21 CFR Part 806	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=806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