Medical Device Reporting (MDR) for Manufacturers & Importers

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Session Overview

- Purpose: To provide information about the Medical Device Reporting (MDR) regulation requirements for Manufacturers & Importers
- Goal: To help you better understand your obligations under the MDR regulation

Authority for Mandatory Reporting: Federal Food, Drug and Cosmetic Act

- Sec 519 - Records and Reports on Devices - grants the FDA authority to require mandatory medical device reports from:
  - (a) Manufacturers and Importers
  - (b) Device User Facilities
- Requirements for MDR are located in 21 CFR Part 803

What is a Medical Device?

An item either used for diagnosis, treatment or prevention of disease, or intended to affect the body, that does not achieve its primary purpose through chemical action or metabolism within the body

*** The FDA definition is in Code 301 Section 201 (h) of FD&C Act.**

Who Must Submit MDRs to the FDA?

Manufacturer

Importer

Device User Facility

- Hospital
- Ambulatory Surgical Facility
- Outpatient Diagnostic Facility
- Outpatient Treatment Facility
- Nursing Home

Mandatory Requirements for Manufacturers

Manufacturers are required to:

- Submit **initial reports** of death, serious injury and malfunction within 30 calendar days (21 CFR Part 803.50)
- Submit **5-day reports** within 5 work days (21 CFR Part 803.53)

  Work Day = Monday-Friday, excluding Federal holidays
- Submit **supplemental reports** within 30 calendar days of receipt of new/changed information (21 CFR Part 803.56)
- Have **MDR procedures** (21 CFR Part 803.17)
- Establish and maintain **MDR event files** (21 CFR Part 803.18)

Mandatory Requirements for Manufacturers

Manufacturers are required to:

- **Investigate each event** to determine the cause of the event (21 CFR Part 803.50(b);
- Provide all **information reasonably known** about the event to FDA, including (21 CFR Part 803.52):
  - Any information that can be obtained by contacting the reporter
  - Any information in your possession - or-
  - Any information that can be obtained by analysis, testing or other evaluation

Mandatory Requirements for Importers/Distributors

Importers are required to:

- Report **deaths** and **serious injuries** to the FDA and manufacturer
- Report **malfunctions** to the manufacturer
- Submit events within 30 calendar days (21 CFR Part 803.40)
- Have **MDR procedures** (21 CFR 803.17)
- Importers and distributors are required to:
- Establish and maintain **MDR event files** (21 CFR Part 803.18)

Mandatory Requirements for User Facilities

User Facilities are required to:

- Report **deaths** to the FDA and manufacturer
- Report **serious injuries** to manufacturer (or the FDA if manufacturer unknown)
- Submit events within 10 workdays (21 CFR Part 803.30)
- Submit **Annual Reports** to the FDA (21 CFR Part 803.33)
- Have **MDR procedures** (21 CFR Part 803.17)
- Establish and maintain **MDR event files** (21 CFR Part 803.18)

Who is a Manufacturer?

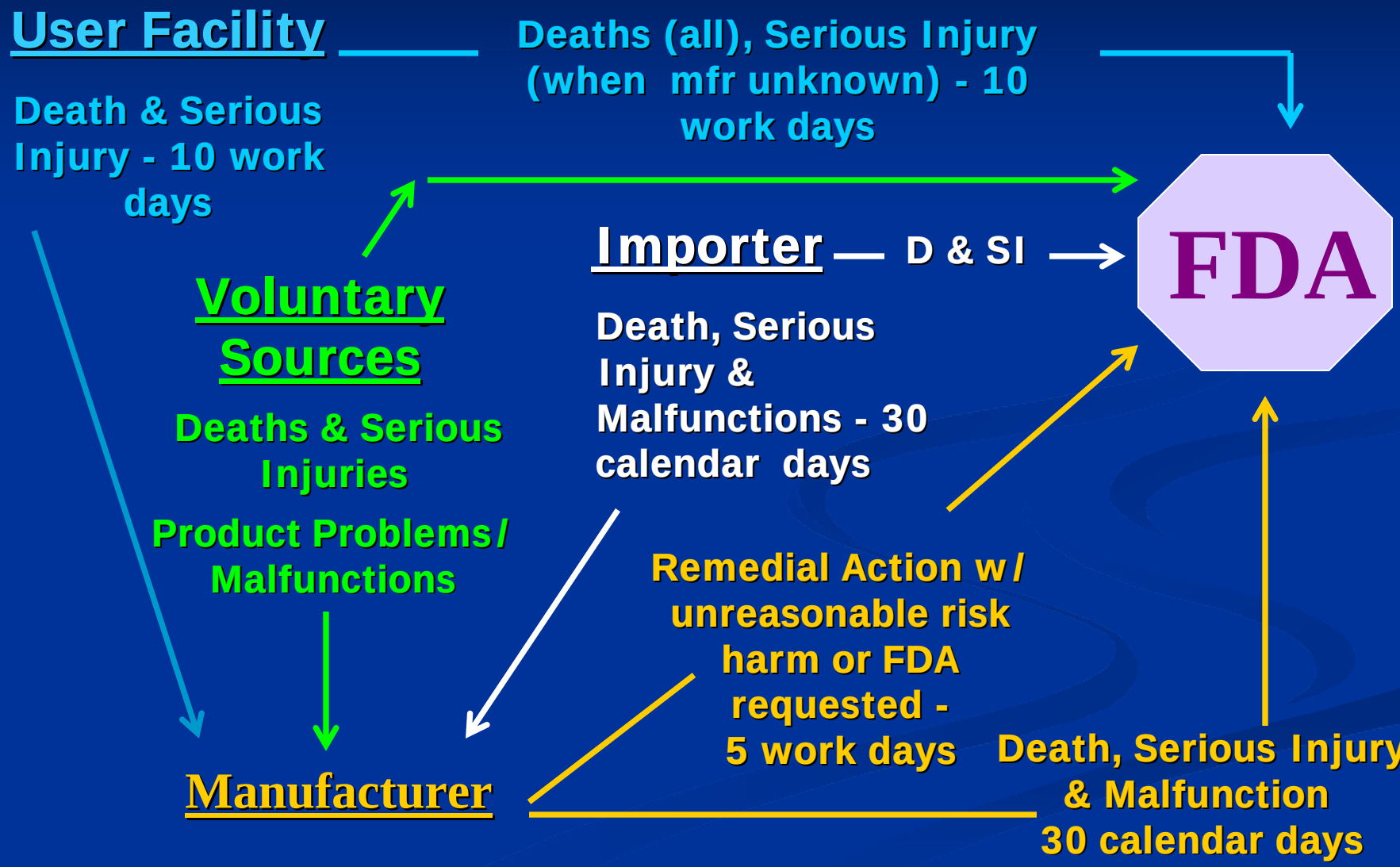
- Any person who manufacturers, prepares, assembles, or processes a device by chemical, physical, biological, or other procedure. This includes:
  - Domestic Manufacturers
  - Repackagers
  - Relabelers
  - Contract manufacturers
  - Specification Developers
  - **Foreign Manufacturers (ref. Part 803.58)**

Who is an Importer?

- Any person who imports a device into the United States and sells this imported device to an end-user or a re-seller without repackaging the device

NOTE: Repackagers are considered manufacturers

Data Flow and Reporting Timeframes



How Does the FDA Use Medical Device Reports?

- Event reports are analyzed by FDA staff including health care clinicians, engineers and scientists.
- Follow-up actions that the FDA may be take:
  - Request additional information
  - Conduct an investigation of event
  - Conduct an inspection at the manufacturer, importer or user facility
  - Contact the manufacturer about a recall
  - Issue a public health advisory/safety alert

When do the Reporting Requirements Apply to Manufacturers?

- When **any employee** becomes aware of information from any source that reasonably suggests that a device it markets:
  - Has or may have caused or contributed to a death or serious injury or experienced a reportable malfunction
- When FDA requests 5-day reports
- When an employee with **management or supervisory responsibilities** or with duties to collect and report adverse events becomes aware that a reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health (5 day report)

When do the Reporting Requirements Apply to Importers?

- When **any employee** becomes aware of information from any source that reasonably suggests that a device it markets may have caused or contributed to a reportable death or serious injury, or experienced a reportable malfunction

- Sources of information may include user facilities and individuals and additionally:
  - For reportable death and serious injury events, medical or scientific literature, whether published or unpublished;
  - For reportable malfunction events, research, testing, evaluation, servicing, or maintenance of one of its devices

Reasonably Suggests

Information that reasonably suggests that a reportable event has occurred includes:

- Professional, scientific or medical facts and observations or opinions that would reasonably suggest that a device has caused or may have caused or contributed to a reportable event

Do not report events where:

- A person qualified to make a medical judgment (i.e. physicians, nurses, risk managers, and biomedical engineers) has information to reasonably conclude that the device did not cause or contribute to a death or serious injury
- Information used to make this decision must be kept in your MDR event file

What Is “Caused or Contributed”?

MDR defines caused or contributed as:

- a medical device was or may have been a factor in a reportable death or serious injury, or
- a death or serious injury was or may have been attributed to a medical device including events resulting from:
  - Failure
  - Malfunction
  - improper / inadequate design
  - manufacturing (problems)
  - labeling (problems) or
  - user error

What are Five-Day Reports?

A manufacturer must submit a report within 5 work days of becoming aware of:

- a reportable event that necessitates remedial action to prevent unreasonable risk of substantial harm to the public health or
- a reportable event for which the FDA has made a written request for 5-day reports

What is a Serious Injury?

A reportable serious injury is defined as an **injury** or **illness** 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 to preclude permanent impairment of a body function or permanent damage to a body structure

**Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage

What is a Malfunction?

- The failure of a device to meet its performance specifications or otherwise perform as intended
  - Performance specifications include all claims made in the labeling for the device
  - Intended performance refers to intended use for which the device is labeled or marketed
- If the malfunction of a device or a similar device is likely to cause or contribute to a reportable death or serious injury if it were to recur, the event is reportable to the FDA

Reporting Events to FDA - Manufacturers

- Manufacturers are required to report information listed in 21 CFR Part 803.52
- Information requested corresponds to the FDA Form 3500A Sections:
  - A-E and G-H
  - H.10 - Additional narrative
  - H.11 - Corrections – Fill in to correct or add information to the original 3500A, including missing/incorrect codes from F.10

Information Reasonably Known - Manufacturers

- Manufacturers must provide **all information** reasonably known to them and are responsible for:
  - conducting an investigation of each event
  - evaluating the cause of each event
  - obtaining and providing missing information and
  - explaining why information is incomplete

- Required information obtained after the initial filing must be provided in a supplemental report

Supplemental Reports

- Supplemental reports must be submitted:
  - whenever a manufacturer becomes aware of information that was not provided in the initial MDR
  - within 30 calendar days from receipt of the additional information
- Indicate on 3500A that report is supplement
- Provide the Manufacturer Report Number from the initial MDR
- Only fill in the Blocks on the 3500A that are changing

Reporting Events to FDA - Importers

- Importers are required to the report information, if reasonably known, listed in 21 CFR Part 803.42
- Information requested corresponds to the FDA Form 3500A Sections:
  - A: Patient information
  - B: Adverse event or product problem
  - D: Suspect medical device
  - E: Initial reporter
  - F: For use by User Facility/Importer – devices only

Address for Mandatory Reporting

FDA/CDRH
Medical Device Reporting
P.O. Box 3002
Rockville, MD 20847-3002

Please note the topic on the envelope:
Manufacturer or Importer Initial Report
5-day or Supplemental Report

When Not to Report

An MDR is not required when:

- Importer or manufacturer receives erroneous information and a device-related event did not occur
- Manufacturer or importer determines that the device was manufactured or imported by another firm
  - When a manufacturer or importer receives this type of report, it must forward the report to FDA with a cover letter

Exemptions

Part 803.19 – Manufacturers or Importers can ask for:

- **Alternative Summary Reporting (ASR)** – a subset of the information required for FDA Form 3500A
- **Total exemption** for specific device and/or patient related events
- **Remedial Action Exemption (RAE)** for recalled products covered by 21 CFR Part 806 (Corrections and Removals)
- **Exemption** to submit a single MDR for one event where both the Manufacturer and Importer have reporting responsibility and requirements

Written MDR Procedures

Importers and Manufacturers must have **Internal systems** that provide for:

- Timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements
- Standardized review process/procedure for determining when event meets criteria for reporting
- Timely transmission of complete device reports

Written MDR Procedures…

Documentation and Recordkeeping for:

- any information evaluated to determine if the event is reportable
- all medical device reports and information submitted
- systems that ensure access to information that facilitates timely follow-up and inspection by FDA

File Requirements for Manufacturers and Importers

- Manufacturers and importers must establish and maintain MDR event files
- Files may be written or electronic and may refer to other information/files (i.e. medical records, patient files, engineering reports)
- Files must contain:
  - Information in your possession or references to information related to the event
  - Documentation of decision making processes used to determine if a death, serious injury or malfunction was/was not reportable
  - Copies of MDR forms and other information reported to FDA
  - An explanation of why information was not/could not be submitted to the FDA
  - Results of your evaluation of each event

MDR Event Files…

- You must permit FDA access to the files, to copy and verify the MDR records
- You must retain MDR event files for:
  - 2 years from the date of an adverse event; or
  - a period of time equivalent to the expected life of the device (whichever is greater)
  - If the device is no longer distributed, you still must maintain MDR event files for the time periods described
- If you are a manufacturer, you may maintain MDR event files as part of your complaint file, (21 CFR Part 820), if you prominently identify these records as MDR reportable events

New Patient and Device Codes for 3500A

The FDA worked with National Cancer Institute (NCI) terminology experts to:

- Reduce duplication and redundancy in current coding
- Create a hierarchy that allows grouping
- Store and maintain the new coding system in the NCI Thesaurus. (Available on the public website/can be downloaded into applications)
- Improve the detection of device safety problems

****Users can request new codes at:**
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/EventProblemCodes/default.htm

Electronic Medical Device Reporting (eMDR)

- Notice of Proposed Rule Making
  Published August 21, 2009
  Docket Number FDA-2008-N-0393

- Notice of Availability - eMDR Draft Guidance
  Published August 21, 2009
  Docket Number FDA-2008-D-0395

- **eMDR website:**

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR–ElectronicMedicalDeviceReporting/default.htm

Current Regulation

§ 803.12 Where and how do I submit reports and additional information?

(a) You must submit any **written report** or **additional information** required under this part to FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847–3002

(Proposed) Final Regulation

§ 803.12 How do I submit reports and supplements?

(a) Manufacturers, user facilities, and importers must submit initial and supplemental reports to FDA in an **electronic format that FDA can process, review, and archive**. FDA will provide and update information on how to provide the electronic submission (e.g., preparation and organization of files, file formats, media and method of transmission)

Final Regulation – Highlights

- Effective one year after publication of final rule
- Keep copies of all submitted reports and acknowledgments
- Reporters may request an exemption from electronic reporting under certain select circumstances
- Housekeeping changes
  - Incorporate § 303 of Medical Device User Fee and Modernization Act of 2002 (Reused Single Use Devices)
  - Change “Date of Report by the Initial Reporter” to “Date of Report”

eSubmitter - Single Reports

- The FDA developed and maintained
- Software free at: **http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm**
- Handles one report at a time
- Captures the data elements required by the FDA Form 3500A
- Validates all data
- Packages the report for the user to send to the FDA Electronic Submissions Gateway

Batch Reporting

- Based on Health Level 7 **(HL7)** Standards Committee Individual Case Safety Report message **(ICSR)**
- Reporter develops software to extract data from reporter's database and prepare the electronic submission
- Capable of handling multiple report submissions at a time
- Minimal human interaction compared to eSubmitter
- Validation of your process is required

Digital Certificates

- You will need a digital certificate to communicate with the FDA gateway
- Minimal cost per certificate renewable each year
- The certificate will cover any electronic submission that uses the FDA gateway such as Registration & Listing
- Information and instructions on setting up an account and communicating with the FDA gateway are available at:

http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm

Questions about eMDR?

- For technical questions about the HL7 or eSubmitter process, testing phases or for information on how to sign up for eMDR please contact the Information and Analysis Branch at: **emdr@fda.hhs.gov**

MDR Regulation Interpretation and Policy Questions:

Contact the Reporting Systems Monitoring Branch:

Phone: 301-796-6670
Email: **rsmb@fda.hhs.gov**

Mailing address:

Reporting Systems Monitoring Branch
FDA/CDRH/OSB/DPS
WO66, Room 3217
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Websites

- Code of Federal Regulations 21 CFR Part 803:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=803&showFR=1

- Medical Device Reporting for Manufacturers:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094529.htm

- Alternative Summary Reporting:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072029.htm

- Remedial Action Exemption:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071354.htm

Websites

- FDA Form 3500A and instructions:

www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm

- Event Problem Code Website:

www.fda.gov/MedicalDevices/Safety/ReportaProblem/EventProblemCodes/ucm134751.htm

- Reports (redacted copies) are publically available at:

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM