Medical Device Reporting (MDR)
21 CFR Part 803
Objectives

• Review applicable sections of 21 CFR 803 and 21 CFR 820
• Review and explain MDR reporting requirements
• Review FDA-483 observation examples
Medical Device Reporting 21 CFR 803

• §803.3 MDR Reportable Event means

• An event that user facilities become aware of that reasonably suggests that a device has or may have caused or contributed to a death or serious injury; or
Medical Device Reporting 21 CFR 803

• §803.3 MDR Reportable Event means

2. An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices;
   (i) May have caused or contributed to a death or serious injury
   (ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur
Medical Device Reporting 21 CFR 803

• §803.3  Becomes Aware

An employee of the entity required to report has acquired information that reasonably suggests a reportable event has occurred
Medical Device Reporting 21 CFR 803

• §803.3 Caused or Contributed

A death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of: (1) Failure; (2) Malfunction; (3) Improper or inadequate design; (4) Manufacture; (5) Labeling; or (6) User error
Medical Device Reporting 21 CFR 803

- §803.3 Serious Injury

An injury or illness that:

1. Is life-threatening
2. Results in permanent impairment of a body function or permanent damage to a body structure
3. Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure
Medical Device Reporting 21 CFR 803

• §803.3 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. The intended performance of a device refers to the intended use for which the device is labeled or marketed…
More on Malfunctions

Guidance

– Reporters do not need to assess the likelihood that a malfunction will recur. The regulation presumes that the malfunction will recur. Furthermore, FDA believes that once a malfunction has caused or contributed to a death or serious injury, a presumption that the malfunction is likely to cause or contribute to a death or serious injury has been established. This presumption will continue until the malfunction has caused or contributed to no further deaths or serious injuries for two years, or the manufacturer can show, through valid data, that the likelihood of another death or serious injury as a result of the malfunction is remote.

Who Has to Report an Event?

• User facilities
• Importers
• Manufacturers
• Distributors (maintain records only)
Manufacturer Reporting Requirements

• Individual adverse event reports no later than 30 calendar days after the day you become aware of a reportable death, serious injury, or malfunction

• Individual adverse event reports no later than 5 work days after the day that you become aware of
  (i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health, or
  (ii) A reportable event for which we made a written request
Manufacturer Reporting Requirements

• Supplemental reports are required if the manufacturer obtains information that was not submitted in the initial report. Must be submitted within 1 month of the day that the information was received.

• Generally submitted because the information was unknown at the time of the initial report or to correct information previously submitted.
Manufacturer Reporting Requirements

• Submit required information on FDA Medwatch Form 3500A or in an electronic equivalent as approved

• Medwatch Form 3500A and instructions can be found on the internet at

http://www.fda.gov/medwatch/getforms.htm
**Medwatch Form 3500A**

**Medwatch Form 3500A (109)**

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**SUBJECT PRODUCT**

- **Device, Frequency & Risk Level**
  - **Device**
  - **Frequency**
  - **Risk Level**

**SUBJECT MEDICAL DEVICE**

- **Brand Name**
- **Generic Name**

**ALL MANUFACTURERS**

- **Name of Person responsible for the report**
- **Phone Number**
- **Relationship to Manufacturer**

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**INITIAL REPORTER**

- **Name and Address**
- **Phone #**

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**VISION MANUFACTURERS ONLY**

- **Intended Use of Product**
- **Type of Reimbursement**
- **Type of Product**
- **Device Evaluation**
- **Supplier Name**

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**MEDWATCH**

**FORM FDA 3500A (109) (continued)**

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**PLEASE TYPE OR USE BLOCK LETTER**

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**SUBJECTIVE ANONYMIZED**

- **Device, Frequency & Risk Level**
  - **Device**
  - **Frequency**
  - **Risk Level**
  - **Type of Reimbursement**
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**INITIAL REPORTER**

- **Name and Address**
- **Phone #**
Manufacturer Requirements

• 820.198(a)(3) – Complaint procedure shall ensure that:

  – Complaints are evaluated to determine whether the complaint represents an event which is required to be reported under part 803
Manufacturer Requirements

• 820.198(d)
  – Any complaint which must be reported shall be promptly reviewed, evaluated, and investigated
  – Maintained in separate portion of complaint files or otherwise identified
Manufacturer Requirements

• 820.198(d)
• When a complaint is reportable the complaint file shall contain:
  – Information required under 820.198(e)
  – Whether device failed to meet specifications
  – Whether the device was being used for treatment or diagnosis
  – The relationship of the device to the event
Manufacturer MDR Requirements

• §803.17 Must develop, maintain, and implement written MDR procedures
  – Ensure timely and effective identification and evaluation
  – A standardized review process for reportability
  – Timely transmission of reports (5 or 30 days)

• §803.18 Must establish and maintain MDR event files

• Investigate to obtain required information and evaluate cause

• Document investigation, information and decisions in MDR event files
FDA-483 Observations

• Numerous citations in related to MDR’s
  These include complaint cites, specific MDR cites, and servicing records cites

• Most used cite is 803.17
  “Written MDR procedures have not been [developed] [maintained] [implemented.”
FDA-483 Observation Examples

• 21 CFR 803.50(a)(2) Report of Malfunction

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction were to recur.

Specifically, the firm received a report of a side rail latch failing to perform as intended leading to an injury of a patient on 3/9/07. All 142 complaints of malfunctions of the side rail latch which occurred after that incident should have been reported as MDRs.
FDA-483 Observation Examples

• 21 CFR 803.50(b)(1) Providing Incomplete or Missing Information

An MDR report submitted to FDA did not include all information that was reasonably known to the manufacturer.

Specifically, your firm did not provide complete information from reports submitted by user facilities, distributors, and initial reports. The reports are: 1) Facility Report 0533000000-1993-0001 dated 1/23/94 2) Facility Report 0034030-1995-0001 dated 8/03/95
FDA-483 Observation Examples

• 820.200(c) Servicing

Service reports that represent MDR reportable events were not automatically considered complaints and processed in accordance with the requirements of 21 CFR 820.198.

Specifically, the firm performed service on a hospital bed rail which collapsed and caused a patient to fall and hit his head, resulting in a concussion and laceration requiring 15 stitches. The firm did not file a complaint or an MDR
Compliance Program Guidance Manual

• The district **should consider a Warning Letter** when the following MDR **violation**s was/were disclosed during the inspection. This list only provides examples and is not all-inclusive.

  – Firm fails to report, within five workdays, after becoming aware that a reportable MDR event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.
  – Firm fails to submit **an** MDR death report.
  – Firm fails to submit **an** MDR serious injury report.
  – Firm fails to develop, maintain and implement written MDR procedures.

• When the firm has already received a Warning Letter for MDR violations and still fails to comply with the MDR regulation, then the district should consider recommending a seizure, injunction, civil money penalty or prosecution.

• **All failures** to comply with MDR should be listed on the FDA-483.
Warning Letter Examples

Failure to submit an MDR within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury, as required by 21 CFR 803.50(a)(1).

For example, your firm received information through its Service Report *****, dated October 5, 2010, of a patient that fell over the side rails of your firm's bed and sustained a broken hip. Your firm reported this event in its complaint file as ****, dated October 8, 2010. Your firm's MDR evaluation determined, "Serious injury not caused/contributed by product," and no report was submitted to FDA.
Warning Letter Examples

• Failure to submit a report to FDA no later than 30 calendar days of receiving information that reasonably suggests that your marketed devices may have caused or contributed to a death or serious injury, as required by 21 C.F.R. 803.50(a)(1). For example:

Complaint **** contains documentation that the bone fractured after insertion of the Trial, and that the surgeon was required to use a suture on the bone, which is information your firm became aware of on May 21, 2008. This information reasonably suggests that your device may have caused or contributed to a reportable serious injury. After the inspection, you submitted a Serious Injury MedWatch report for Complaint **** on March 8, 2010. This MDR was submitted approximately 620 days late.
Warning Letter Examples

• 1. Failure to submit a report to FDA after receiving information that reasonably suggested that a marketed device may have caused or contributed to a death or serious injury, as required by 21 CFR 803.50(a)(2).

For example, you were notified of an occurrence, which you recorded as Complaint ****, on August 12, 2009, which involved the service loop disconnecting from the tissue mold at the distal end of the device allowing the metal helical retractor to dangle. Subsequently, your complaint report states the side of the helical retractor "caught the esophageal 1/3 of the way out" during attempted removal of the device requiring a biopsy forceps to loosen the helical retractor enough for removal of the device.
The information in the complaint files indicates that your firm was in possession of information that reasonably suggested that your marketed device malfunctioned and this device would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur. Your firm failed to submit this report to FDA within the required 30 day timeframe as required by 21 CFR 803.50(a)(2).
Warning Letter Examples

Failure to ensure that all complaints are evaluated to determine whether the complaint should be filed as a Medical Device Report (MDR). [21 CFR 820.198(a)(3)]

Specifically, 4 of the 25 complaints reviewed by the investigator had not been evaluated to determine if they were medical device reportable events. For example, Complaint **** states that a patient claimed [redacted] was shocked and burned on the top of her head while being scanned in the **** system. The complaint was not evaluated to determine if it was a medical device reportable event.
Useful Links

• MDR Preamble

• Compliance Program Guidance Manual
  – http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072753.htm

• CDRH Learn
  – http://www.fda.gov/Training/CDRHLearn/default.htm

• eMDR Guidance
Useful Links

- MDR Guidance
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Questions?