MDR: Failures, Successes and Solutions

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Agenda

- Brief Overview of the Requirements
- Highlight MDR Failures
  - Discuss some common pitfalls and misinterpretations
- Discuss Successes and Solutions and Resources
Medical Device Reporting Regulation

Medical Device Reporting (MDR, 21 CFR Part 803)

- Establishes the reporting requirements for device user facilities, manufacturers and importers.

- A mechanism for FDA and manufacturers to identify and monitor significant adverse events involving marketed medical devices.
What Types of Events Must Be Reported to FDA?

- If device may have caused or contributed to a death or serious injury.
- Certain malfunctions must also be reported.
  - Malfunction is reportable when it is likely to cause or contribute to a death of serious injury if it were to recur.
Malfunctions

A malfunction is considered reportable if any one of the following is true:

- the chance of a death or serious injury occurring as a result of a recurrence of the malfunction is not remote;
- the consequences of the malfunction affect the device in a catastrophic manner that may lead to a death or serious injury;
- it causes the device to fail 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 experiences. The essential function of a device refers not only to the device’s labeled use, but for any use widely prescribed within the practice of medicine;
- it involves an implant malfunction that would be likely to cause or contribute to death or serious injury, regardless of how the device is used;
- the device is considered life-supporting or life-sustaining, and thus essential to maintaining human life; or
- the manufacturer takes or would be required to take action under section 518 or 519(f) of the FD&C Act as a result of the malfunction of the device or other similar devices.
# MDR Reporting Requirement

<table>
<thead>
<tr>
<th>Reporter</th>
<th>What to Report</th>
<th>Where</th>
<th>When</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer (Mfr)</td>
<td>Deaths, Serious Injuries, Malfunction</td>
<td>FDA</td>
<td>Within 30 calendar days of becoming aware</td>
</tr>
<tr>
<td>(Domestic and Foreign)</td>
<td>Events that require remedial action to prevent an unreasonable risk of substantial harm</td>
<td>FDA</td>
<td>Within 5 working days of becoming aware</td>
</tr>
<tr>
<td>User Facility</td>
<td>Deaths</td>
<td>FDA and Mfr</td>
<td>Within 10 working days</td>
</tr>
<tr>
<td></td>
<td>Serious injury</td>
<td>MFG (FDA if unknown)</td>
<td>Within 10 working days</td>
</tr>
<tr>
<td>Importer</td>
<td>Deaths and Serious Injuries</td>
<td>FDA and Mfr</td>
<td>Within 30 calendar days</td>
</tr>
<tr>
<td></td>
<td>Malfunctions</td>
<td>Mfr</td>
<td>Within 30 calendar days</td>
</tr>
<tr>
<td>Voluntary</td>
<td>Any type of event</td>
<td>FDA</td>
<td>Any time</td>
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Additional requirements

- Device manufacturer must conduct a complete investigation of each event (as per 21 CFR Part 820.198)
- All information required in 21 CFR Part 803.52
- Develop and implement written MDR Procedures (21 CFR Part 803.17)
- Establish and maintain MDR event files
- Have a system in place that ensures access to information that facilitates timely follow-up/inspection by FDA.
Caused Or Contributed

- 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
    - Manufacturing (problems)
    - Labeling (problems)
    - Use error
Why can we not get it Right?

- Complaint Handling and MDR Reporting continues to be a Top 483 Citation for Medical Device Firms
- Inadequate MDR procedures - 21 CFR 803.17;
  - For example:
    - Failure to develop, maintain, and implement written MDR procedures.
**MDR Pitfalls - Timelines**

- Firm continue to report MDRs later than the required 5, 30 Days.
  - Calendar Days not Working days
  - 30 Days is not 31, 32, 33...

- Supplemental reports are also required to be submitted within 30 days from the time you receive new information.
MDR Pitfalls - 5 Day Reports

- Report a 5 Day reportable MDR if you conduct any remedial action to prevent an unreasonable risk of substantial harm to the public health and other types of events designated by FDA. A remedial action is any action other than routine maintenance or servicing of a device where such action is necessary to prevent recurrence of a reportable event.
  - Recall
  - Field Corrections
  - Notifications

- Don’t Say Remedial Action Was Initiated if It Wasn’t. Another common pitfall is incorrectly completing Section H7, which asks whether remedial action was initiated.
MDR Pitfalls - Process & Procedures

- Firms continue to fail to have MDR Procedures (& Complaint Procedures)
  - Top issue in 483s and Warning Letters
- Understand your requirements
- If a consultant writes the procedure, understand the requirements.
- It’s not enough to have a good MDR procedure, you have to know, execute and follow your procedures.
MDR Pitfalls “Becomes Aware” Date

- Common Compliance Issue: Employees Don’t Know the Becomes Aware Date

- ANY EMPLOYEE ... All employees should know the Become Aware Date for MDRs
  - All employees should be trained on MDR reporting requirements
  - Field Employees greatest offenders
  - Consultants
  - Not just Quality, Regulatory and the Complaint Handling Unit.
  - Not Just US Employees, Multi National
MDR Pitfalls - Service MDR Requirement

- 820.200(c) Each manufacturer who receives a service report that represents an event which must be reported to FDA under part 803 (MDR Regulation)... shall automatically consider the report a complaint...

- Firms all too often forget about the service requirements as it relates to MDR requirements.

- Unscheduled Services calls (not Preventive Maintenance Reports) could be an MDR reportable event.
  - Evaluated Service Records for Serious Injury and Reportable Malfunctions.
  - Timely review of Service Reports is imperative to meet the 30 Day pitfall.
MDR Pitfalls - It’s just Cosmetic...

- A Defect that appears at first glance to be cosmetic may not be. Not always as simple as it sounds.
  - Examples:
    - Broken LCD screens
    - Casters/ Wheels Broke
    - Scratches on articulating surfaces of orthopedic implants
MDR Pitfalls - Foreign AE’s

- A common misconception is adverse event happened outside of the United States are not reportable to US FDA.
  - Incorrect, Adverse Events that occur outside the United States are reportable if the same or similar product or product family is marketed in the US.
MDR Pitfalls - Literature

- Literature such as Peer Review Articles that implicate your device as causing a Death, Serious Injury or Reportable Malfunction are required to be reported.
  - If you have read it, you have “become aware”
MDR Pitfalls - Not Knowing Industry Product Trends

- Know the adverse events and Recalls of “like” devices and/or predicate devices
  - Your competitor of a similar device may have experienced an adverse event or reported a malfunction that you may not have previously considered in your risk management file.
  - If an event happened to a like competitor device, it could be likely that the same event could happen to your device.
- Search Maude Database, Enforcement Report, Recall Database
**MDR Pitfalls - Contract Manufacturer**

- **Contract Manufacturer**: Unless you have an exemption, Contract Manufacturers have a responsibility to follow MDR procedures.
- Ensure the Contract Manufacturer and the Product Specification Designer knows Reporting Requirements.
- Make it clear to the agency who is responsible for reporting MDRs.
MDR Pitfalls - Attempts for Information

- Ensure you make a “Good Faith Effort” to obtain as much information about the event as possible
  - Three good faith efforts at a minimum
  - At least 1 in writing (or different than the past)
- Obtaining information in Legal cases can be difficult
  - Partner with and Educate your Legal Council on FDA MDR reporting requirements
- Document, Document, Document!
MDR Pitfalls - Inadequate Trending

- Inadequate trending of MDRs could lead to your firm not knowing the safety and effectiveness of your device

- Trending can identify issues
  - Know how your device is performing.
  - Know your severity and occurrence of post market devices.
    - Update Risk Management File

- Management Review should include MDR Reporting and MDR reporting Trends.
MDR Pitfalls - “Likely”.

- Malfunctions once reported - Always report.
- In the past there was a “Two Year Rule”, this rule is Dead.
- If you want to stop reporting MDRs for a product complaint failure mode, contact CDRH.
  - Be prepared with data to support your position.
The MDR regulation published in the Federal Register on December 11, 1995 did not define "likely", but a discussion of the term was included in the preamble to the MDR regulation published in the Federal Register on September 14, 1984.

" Likely" means more probable than not.

The regulation presumes that the malfunction will recur. Furthermore, 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.
MDR Pitfalls - Necessary Education, Background, Training and Experience

- Executive Management must ensure that employees responsible for Medical Device Reporting (MDR) have the sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed.

- Product Investigation and MDR reporting is not simply an administrative position.

- Knowing FDA expectations and ongoing industry education is critical to the success of RA/QA/MA Personnel.
MDR Pitfalls - Intraoperative Failures Causing a Delay in Surgery

- Interruptions in therapy or surgery while patient is under anesthesia (exposure)
  - Consider potential for delay as a reportable event (each situation is different).
  - Know how long the delay lasted
MDR Pitfalls - 803.20(c)(2)

- 803.20(c)(2) manufacturer does not have to report an event “if [it has] information that would lead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a . . . serious injury

- Be conservative and cautious when citing 803.20(c)(2) as a reason not to report an MDR.
  - Many examples of where this was inappropriately used as a justification not to report an MDR
Part 806(f) “No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 or 1004 of this chapter.”

It is not recommended that you report Recall exclusively via MDR reporting 806.10 - Sometimes tied to MDR events

Contact your Recall Coordinator.
Warning Letter Examples

- Failure to report to the FDA no later than 30 calendar days after the day that your firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that it markets has malfunctioned and this device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur; as required by 21 CFR 803.50(a)(2).

- Lesson Learned:
  - Ensure your Complaint Handling Unit is staffed with trained personnel that knows when the MDR clock starts.
  - Have a well defined process to ensure MDRs are reported on time.
Example from a Warning Letter

- The event was received by FDA as a 30-day initial report on December 17, 2009. Your firm received the device for analysis on or about January 21, 2010; however, follow-up report 001 was not received by FDA until April 29, 2010.

- Lessons Learned:
  - Ensure your Complaint Handling Unit is staffed appropriately and Complaint Investigations are given priority
  - Triage Complaints, highest risk complaints (MDRs) to be evaluated and investigated first.
  - Your responsibility for reporting does not end with the initial report.
Example from a Warning Letter

- Procedure, requires all Company employees who receive any complaint or adverse event information to "immediately communicate" such information to the Complaint Handling Unit. However, a review of complaints showed that the Complaint Handling Unit did not always immediately receive the complaint or adverse event information ...

- Lesson: Make sure all employees are made aware of their requirements to report complaints timely. Ensure complaint handling is enforced by Executive Management.
Example of a Warning Letter

- Failure to submit all information that is reasonably known to you, as required by 21 CFR 803.50(b)(1). For example:
  - This information was reported to FDA almost two years after your firm became aware of the information.

- Potential Lessons Learned:
  - Industry must understand that a commitment to quality starts at the highest level of management.
    - Executive Management should be made aware of such failures in the quality system.
    - Robust Internal Audits should identify quality system deficiencies.
    - Culture of Quality imperative for success
Do I have to report MDR’s if an adverse event was reported on social media?
  - Yes, you are obligated to report
  - Two Questions
    - Are you Aware?
    - Is it a reportable event?

The medium has changed, the requirement has not.

You have a responsibility to follow up.
Most Successful MDR Programs have an MDR Decision Tree

An MDR Decision Tree can help to consistently determine if an event is reportable.

Does Information Reasonably Suggest that a Device Caused or Contributed to a Death or Serious Injury?

- YES
- NO
Approximately 70% of MDR’s are sent in electronically.
e-Submit Via Electronic Submissions Gateway (ESG)
  - B2B (High Volume/Batch Reporting)
  - WebTrader (Low Volume/Single Reports)
Most Commercial Complaint Handling Systems (off the shelf) have e-MDR build in as a feature
Work Smarter vs. Harder - benefit in reduction in work load and human error
Communication with FDA and Coordination with your IT department critical to success.
FDA Website will guide you through process.
Final Rule Due Date? Unknown, but don’t wait.
Need Help? MDR POLICY BRANCH

- **Interprets Medical Device Reporting (MDR) regulation (21 CFR PART 803)**
  - Determines reportability of events for Center offices
  - Works closely with Center and Agency offices during inspections and regulatory actions

- **Educates industry and FDA staff on MDR policy issues**
  - Offers guidance, (independently or through venues such as the FDA’s CDRH Learn Modules
    - Provides publically available email and phone number to answer MDR questions:
      - E-MAIL: MDRPolicy@FDA.HHS.GOV
      - PHONE: 301-796-6670
Resources

- FDA’s CDRH Learn
  http://www.fda.gov/Training/CDRHLearn/ucm162015.htm#mdr

- Medical Device Reporting for Manufacturers
Quality of MDRs

- Ensure MDR reporters are educated on requirements
- Important to uncover what happened.
- Investigate as much as possible
  - Not receiving the product back is not a good excuse for not evaluating and investigating
  - DHR Reviews, Literature Review, Failure Simulation, Request Picture, Medical Review, Review Labeling, etc.
# MDR Success Story Example

<table>
<thead>
<tr>
<th>A little known Austin Device Company 2010</th>
<th>A little known Austin Device Company 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Complaint Handling Unit</td>
<td>Designated CHU - 800#, Email address</td>
</tr>
<tr>
<td>Inadequate Complaint Procedure No MDR Procedure</td>
<td>Procedures written, known, executed and followed.</td>
</tr>
<tr>
<td>No Complaint/ MDR Training</td>
<td>Company wide training, validated electronic system, employees compliant</td>
</tr>
<tr>
<td>Late MDRs</td>
<td>No Late MDRs</td>
</tr>
<tr>
<td>483s for MDR</td>
<td>No 483s for MDR</td>
</tr>
<tr>
<td>No Metrics</td>
<td>Metrics Established for AE’s and 30 Day Monitoring and Investigation Aging</td>
</tr>
<tr>
<td>Paper based System</td>
<td>Electronic System Purchased</td>
</tr>
<tr>
<td>Faxing / Mailing MDRs</td>
<td>eMDR</td>
</tr>
<tr>
<td>Management Unaware of Requirements</td>
<td>Management Educated and Engaged</td>
</tr>
</tbody>
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Conclusion

- It is imperative that device manufacturers have an effective system for identifying reportable MDR events, analyzing in a consistent manner whether events are reportable, and submitting accurate and timely MDR reports to FDA.

- Management commitment, properly trained and industry informed employees, well written (and followed) procedures and patient focused culture are keys to success.

- Lack of controls will certainly lead to FDA enforcement.
Questions?