Five MDR Traps That Doom Devicemaker Inspections

Patrick Caines, Ph.D., MBA
Director, Product Surveillance
GE Healthcare
June 25, 2014

Five MDR Reporting Challenges

1. **Inadequate Post market Surveillance system**

    ‣ Timely reporting
    ‣ Evaluating Information from all sources
    ‣ Servicing
    ‣ Events outside the US
    ‣ Events from clinical trials

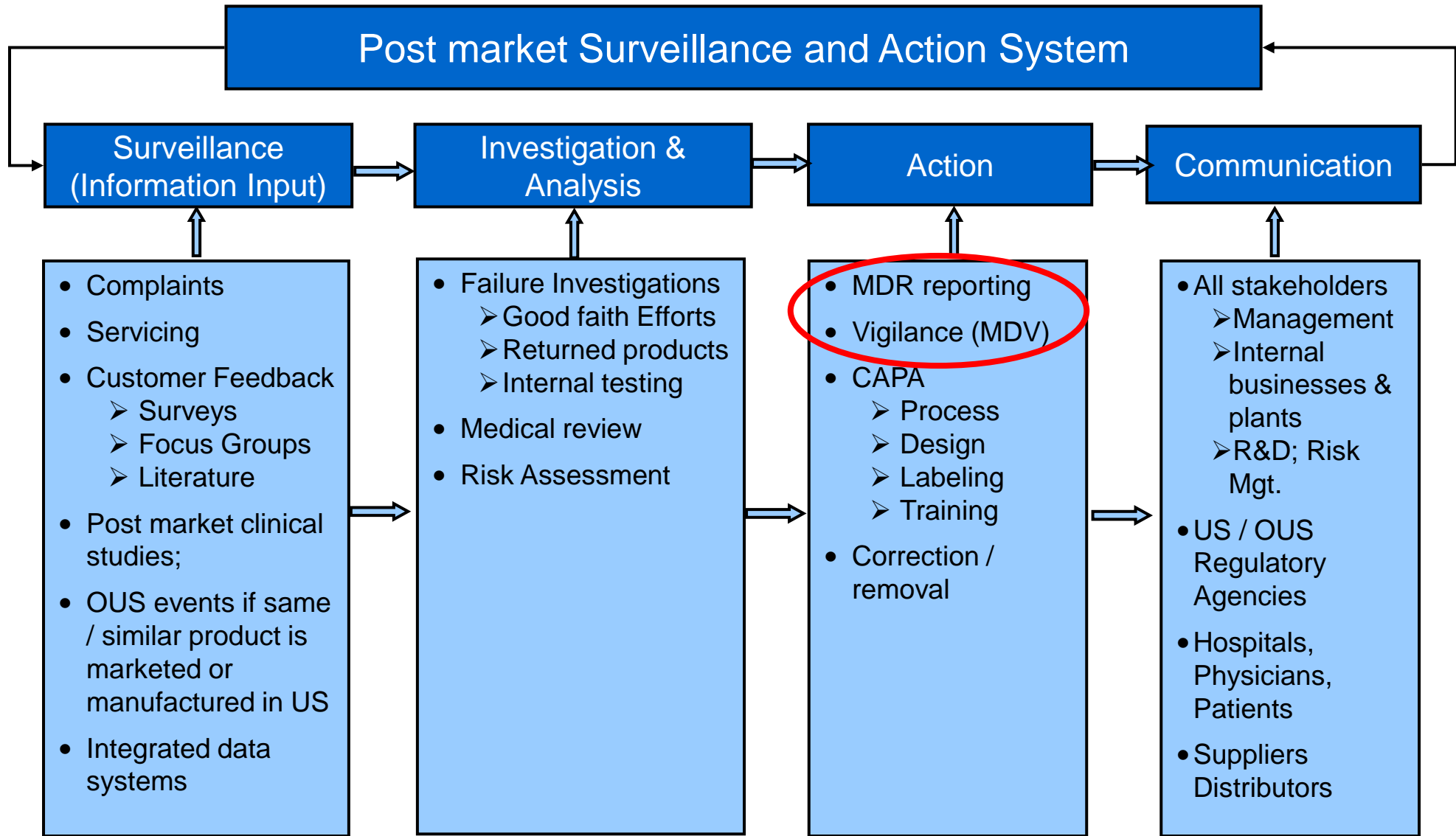2. **Conducting robust and timely investigations**

3. **MDR Reporting Decisions**

    ‣ Evaluating malfunctions
    ‣ Events that are the result of user error; off-label use; abnormal use
    ‣ Providing accurate information to FDA in the way FDA wants to receive that information
    ‣ Clear, consistent documentation

4. **Escalation and linkage to other quality systems**

5. **Evaluating Health of the MDR system**

Post market Surveillance System

Post market Surveillance and Action System

Surveillance (Information Input)	Investigation & Analysis	Action	Communication

Surveillance (Information Input)
- Complaints
- Servicing
- Customer Feedback
  - Surveys
  - Focus Groups
  - Literature
- Post market clinical studies;
- OUS events if same / similar product is marketed or manufactured in US
- Integrated data systems

Investigation & Analysis
- Failure Investigations
  - Good faith Efforts
  - Returned products
  - Internal testing
- Medical review
- Risk Assessment

Action
- MDR reporting
- Vigilance (MDV)
- CAPA
  - Process
  - Design
  - Labeling
  - Training
- Correction / removal

Communication
- All stakeholders
  - Management
  - Internal businesses & plants
  - R&D; Risk Mgt.
- US / OUS Regulatory Agencies
- Hospitals, Physicians, Patients
- Suppliers Distributors

Goal of PMS system is to take appropriate action to protect public safety and improve product performance

MDR Requirements

Requirements for MDR are defined in 21 CFR Part 803

21 C.F.R. §803.50(a) Subpart E Manufacturer Reporting Requirements

"... You must report to us no later than 30 calendar days after the day you receive or otherwise **become aware** of information, **from any source**, that **reasonably suggests** that a device that you market:

(1) May have **caused or contributed** to a **death**
      or **serious injury**; or

(2) Has **malfunctioned** and this device or a similar device that
      you market would be **likely to cause or contribute**
      to a death or serious injury, if the malfunction were to recur."

MDR Requirements

- Have written **MDR procedures** (21 CFR Part 803.17)

- Create a **standardized review process** for determining whether an event is MDR reportable.

- Establish and maintain **MDR event files** (21 CFR Part 803.18)
  - Ensure a system in place that allows for timely record review and follow-up/inspection by FDA.

- Provide all information reasonably known about the event on FDA **Form 3500A** (or eMDR) to FDA
  - Required information is listed in 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
    - Explain why information is missing or incomplete

- Ensure that MDR reports are submitted to FDA in a **timely fashion**.
  - FDA frequently cites manufacturers for failure to have in place adequate written MDR procedures.

- **Investigate each event** to determine the cause of the event (21 CFR Part 803.50(b)

MDR Procedures

Describe the following:

- Conduct timely, effective identification, communication and evaluation of events that may be subject to MDR requirements

- Determine when events meet the criteria for reporting
  - Each event must be considered on its own merits
  - Decision trees, examples can promote consistent reporting

- Submit timely and complete MDRs
  - Provide all information reasonably known about the event on FDA **Form 3500A** to FDA **(or EMDR)**
  - Send that information to FDA in a **timely fashion**.

- Document the information evaluated to determine if the event should be reported.

- Keep copies of the records submitted to FDA

Be certain your procedure mirrors the MDR Regulation!
  - Do not mingle International reporting with MDR reporting

MDR Files

- **MDR Complaint Files Must Include:**
  - All information required for a Complaint file **AND**
  - Whether Device Was Being Used for Treatment or Diagnosis
  - Whether Device Failed to Meet Specifications
    - ‣ Evaluate if device malfunction even when MDR determination to file as a death or serious injury
    - ‣ Important for field action decisions and compliance with (21 C.F.R. § 806)
  - Relationship of Device to Incident
  - All deliberations regarding reporting decisions
  - Copies of all submitted reports
  - Must Be Reasonably Accessible to Manufacturing Establishment

MDR Reports

- **Complete event descriptions and narratives**
  - Stick to the Facts and Use factual, non-speculative language.
  - MDRs may include:
    - Trending information
    - Non-return of device does not mean you don't need to investigate
    - Information may vary for different devices or device families
    - Human factors/use error follow up

- **Accurate event type (malfunction, injury, death)**
  - Event type "other" should not be used for device mandatory reports

- **Include Patient information and outcome**

- **Codes must mirror text**

Manufacturers – Reporting Timeframes

- **Within 30 calendar days** of receiving or otherwise becoming aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer
  - May have caused or contributed to a death or serious injury; or
  - Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.
  - This is called a 30-Day Report (21 CFR Part 803.50)
  - Submit **supplemental** reports within 30 calendar days of receipt of new/changed information (21 CFR Part 803.56)

- **Within 5 work days of:**
  - Becoming aware that a reportable MDR event, from any information, including any trend analysis, necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health; or
  - Becoming aware of an MDR reportable event for which FDA has made a written request for the submission of a 5-day report.
  - This is called a 5-Day Report (21 CFR Part 803.53)
    ‣ Work Day = Monday-Friday, excluding Federal holidays
    ‣ Not all MDR reportable events requiring remedial actions need to be submitted as 5-day reports

MDR Definitions

"Become Aware"

- When any employee of the manufacturer **becomes aware of information from any source** that reasonably suggests that a reportable event (death, serious injury, or malfunction)
  - That is required to be reported within 30 days, or
  - That is **required to be reported within 5 days pursuant to a written request from FDA**; and
- When an employee, who is a person with management or supervisory responsibilities (over persons with regulatory, scientific, or technical responsibilities), or a person whose duties relate to the collection and reporting of adverse events, becomes aware that an MDR event or events, **from any information, including any trend analysis, necessities remedial action to prevent an unreasonable risk of substantial harm to the public health.**

"Aware Date"

- The date on which any employee (**first**) Becomes Aware of information from any source, that reasonably suggests that an MDR reportable event has occurred.

MDR Definitions

"From Any Source"

- User and Employee Complaints
- Servicing
- OEMs & Suppliers
- Other sources of customer feedback
  - Trade Shows, Focus groups, Demonstrations and training sessions
  - Post market clinical studies, Registries (condition of approval)
  - Medical and Popular Literature
  - Internal Product Testing
  - Lawsuits
- Consider Same **and Similar** Devices

"Information That Reasonably Suggests"

- Information such as 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 an MDR Reportable Event.

Evaluate All Complaints for Reportability

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. 21 C.F.R. § 820.3(b)

- Evaluate all complaints to determine whether the complaint represents an event which is required to be reported to FDA under part 803 or 804 of the chapter, Medical Device Reporting 21 C.F.R. § 820.198(a)(3)

- **MDR Events**
  - Maintained in Separate Portion of Complaint Files or Clearly Identified
  - Promptly Reviewed, Evaluated and Investigated by Designated Individuals
  - Trended and appropriate actions taken
  - Escalation as required
    - ➢ Field action
    - ➢ CAPA / NCE

Surveillance Information Sources

- Customers, Sales Force, Field Service, Affiliates, Distributors; 3rd parties

  - Are roles, responsibilities, accountabilities for reporting complaints in a timely fashion, undertaking the necessary follow-up; when req'd; parts returns etc. clearly understood and documented by all parties?

  - Training

    - Do all employees know where and how to report complaints?

    - Complaint handlings staff trained on the products, use, and the regulation.

    - Document complaints so that they are easy to follow and understand – internal and external uses.

    - Training records for company employees service; sales force; documenting they have been appropriately trained in complaint handling.

  - Quality agreements between Manufacturing sites and Complaint handling unit; Quality agreements with Affiliates and Distributors.

Organizational Alignment

- Consider how is the company structured?
  - Multiple manufacturing sites, businesses, divisions
  - Call centers
  - Complaint processing site vs. Investigation site
  - Distributors, affiliates, 3'rd parties
    ‣ Clear definition roles & responsibilities
- Who are the designated complaint handling units
- Reporting – Central team; Regulatory Affairs; Local Units
- Electronic systems and flow of information
  - Service Systems
  - Complaint Handling Systems; Electronic vs. paper
  - Time zones; Local language and provisions for translation
  - Record availability

Service Reports

- **Field Service reports must be reviewed for complaint information and MDR reportability**

> *Each manufacturer who receives a service report that represents an event which must be reported to FDA under part 803 of this chapter shall automatically consider the report a complaint and shall process in accordance with the requirements of § 820.198. (21 C.F.R. § 820.200(c))*

- Complaint handling and MDR process should be able to identify service events for unusual conditions that may include complaint information vs. Routine Service
  - A request for routine service is not always a complaint
  - Process for capturing and reviewing service records
  - Review of addition of incremental information to service records
  - Training of field service staff to recognize and report complaints
    - Distributors and 3'rd parties providing service
  - Trending of service reports - malfunctions
  - Out of Box vs. post-installation failures

Events Outside the US

- **Events that occur outside of the U.S. ("OUS"). Such events are reportable to FDA if:**

  - The same product involved in the event is approved or cleared in the U.S.

  - The product was manufactured in the U.S.

  - A *malfunction* involves a "*similar*" product that is approved or cleared in the U.S.

    ‣ "Similar" Devices that would be assigned the same FDA product code (procode) are considered by FDA to be similar for the purposes of the MDR requirements of 21 CFR §803.

Events from Clinical Trials

Events that occur during Clinical Trials e.g. new indication may be reportable under 21 CFR § 803

- -Typically, events on investigational devices being studied fall under § **812 IDE** regulations

- -§ 812 IDE regulations cover the **unapproved** device.

- -Once the device is **approved**, reporting falls under **§ 803** regulations.

- -Events with a marketed (approved or cleared) device (either control or ancillary) on patients enrolled in an IDE study must be evaluated for reporting as MDRs under § 803 regulations.

Events from Clinical Trials

‣ **Reporting is required under MDR regulations even if IDE study is still on-going (in addition to any IDE annual report requirements e.g. if the IDE is kept open for long-term follow-up).**

- Can satisfy the IDE reporting requirements by just referencing the MDRs in the IDE annual report.

- If study involves blinding, the company "becomes aware" when the data is un-blinded for any reason (e.g., early un-blinding for safety reasons), in accordance with the protocol for data analysis, or inadvertently for any other reason.

- If the device is on the market in the US and is being studied under an IDE e.g. for a new indication, and the device is used outside of the IDE (either US or OUS) for the investigational indication (i.e., "off-label" use), and a complaint associated with this off-label use becomes known, then this complaint must be evaluated for reporting under § 803.

‣ **Clinical Complaint Reporting Management Plans may be helpful to define and document reporting rationale**

Five MDR Reporting Challenges

1. **Inadequate Post market Surveillance system**

   ‣ Timely reporting

   ‣ Evaluating Information from all sources

   ‣ Servicing

   ‣ Events outside the US

   ‣ Events from clinical trials

2. **Conducting robust and timely investigations**

3. **MDR Reporting Decisions**

   ‣ Evaluating malfunctions

   ‣ Events that are the result of user error; off-label use; abnormal use

   ‣ Providing accurate information to FDA in the way FDA wants to receive that information

   ‣ Clear, consistent documentation

4. **Escalation and linkage to other quality systems**

5. **Evaluating Health of the MDR system**

Investigation & Analysis

Must be both Patient- and Product-Centric

- **Patient–Related Questions**
  - ➢ What was the patient's condition prior, during, and after the use of the device?
  - ➢ Did or would the patient require medical or surgical intervention related to an issue associated with the use of the device?
  - ➢ What medication did the patient require prior to and subsequent to the adverse event?
  - ➢ Did the patient require return visits to a physician or health care provider to monitor healing after the adverse event?

- **Product-Related Questions**
  - ➢ How and why was Company made aware of this event?
  - ➢ What other experience has Company learned about the use of this device in the same or similar circumstances?
  - ➢ What have past Company investigations revealed about the use of this device?
  - ➢ What is the severity and frequency of reported complaints associated with this device?
  - ➢ Has there been any change to the manufacturing of, or materials used in the manufacturing of, the device, even ones meant to improve quality?

Investigation & Analysis

- **Accurate, complete, and timely information exchange**
  ‣ Between complaint handling unit, investigating site, and local site
  ‣ Request for follow-up information; Privacy issues
  ‣ End users, customers, regulatory authorities

- **Make it easy for auditors to read and understand complaint files, investigations, and reporting decisions**
  ‣ Record structure – goal is complaint file should be stand-alone;
  ‣ Complaint summary and record closure
  ‣ Periodic audits of complaint files
  ‣ Reviews of source documentation e.g. service records, and outputs e.g. associated CAPAs, field actions etc.
  ‣ Actions taken consistent and aligned with the objective data

- **Make it easy for customers and field service to return device**
  ‣ Consistent policy on when to request device for investigation

Risk Assessments

- **Risk assessments can be helpful in making MDR reporting decisions**
  - Formal evaluation of issues that may pose risk to patient safety
    - Evaluation of "potential to cause or contribute"
    - Combination of the probability of occurrence of harm and the severity of harm

  - May provide rationale on why reporting is or is not needed (Caution)
    - Medical / Clinical input required

  - Input to Escalation
    - May provide a basis for making determination of Field action
    - DFU changes
    - Manufacturing or Design changes
    - Update of product risk management file

Health Hazard Assessments

- **Health Hazard Assessments (Evaluations) key component of Risk Assessments**
  - Clear description of the issue
  - Comprehensive complaint review; include historical trends
  - Directions for Use (DFU) review; Literature
  - Review of FMEA and design risk assessments
  - Include all available qualitative and quantitative information e.g. complaint frequency; frequency of harm, severity of harm
  - Details of the non-conformance and results of failure analysis and performance testing

- **Health Risk assessments should be consistent with those used in Design or evaluation of product performance**

Five MDR Reporting Challenges

1. **Inadequate Post market Surveillance system**
   ‣ Timely reporting
   ‣ Evaluating Information from all sources
   ‣ Servicing
   ‣ Events outside the US
   ‣ Events from clinical trials

2. **Conducting robust and timely investigations**

3. **MDR Reporting Decisions**
   ‣ Evaluating malfunctions
   ‣ Events that are the result of user error; off-label use; abnormal use
   ‣ Providing accurate information to FDA in the way FDA wants to receive that information
   ‣ Clear, consistent documentation

4. **Escalation and linkage to other quality systems**

5. **Evaluating Health of the MDR system**

MDR Requirements

21 C.F.R. §803.50(a) Subpart E Manufacturer Reporting Requirements

"... You must report to us no later than 30 calendar days after the day you receive or otherwise **become aware** of information, **from any source**, that **reasonably suggests** that a device that you market:

(1) May have **caused or contributed** to a **death** or **serious injury**; or

(2) Has **malfunctioned** and this device or a similar device that you market would be **likely to cause or contribute** to a death or serious injury, if the malfunction were to recur."

MDR Reportable Events

"Serious Injury"

An injury or illness that

- is life threatening (even if temporary); or
- 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 Impairment

– Irreversible impairment or damage to a body structure or function, excluding trivial damage

Medical Intervention

– If a device caused or contributed to an injury, and surgical / medical intervention was necessary to prevent the patient from suffering permanent impairment of body function or permanent damage to the body structure then the event is MDR reportable.

– What is considered Medical Intervention?

➢ "Anything beyond basic first aid or diagnostic testing administered by health professional"

26

MDR Definitions

"Caused or Contributed"

- Means that 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 occurring as a result of:
  - Failure
  - Malfunction
  - Improper or inadequate design
  - Manufacture
  - Labeling or
  - User error

- Evaluate the 'c**ontributed**' portion of 'caused or contributed.'
  - Event may be reportable even if the device did not directly cause the patient's injury (if the information reasonably suggests that the device may have been a contributing factor in the death or deterioration of the condition of the patient.) e.g. procedural delay. Consider the patient condition before and after the event.

MDR Malfunctions

No Death or Serious Injury? You must then consider:

21 C.F.R. §803.50(a) Subpart E Manufacturer Reporting Requirements

" . . . You must report to us no later than 30 calendar days after the day you receive or otherwise **become aware** of information, **from any source**, that **reasonably suggests** that a device that you market:

(1) May have **caused or contributed** to a **death** or **serious injury**; or

(2) Has **malfunctioned** and this device or a similar device that you market would be **likely to cause or contribute** to a death or serious injury, if the malfunction were to recur."

Reportable Malfunctions

- A **malfunction is 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;

    - The malfunction involves:

        ‣ a long-term implant or

        ‣ a device that is considered to be life-supporting or life-sustaining and thus is essential to maintaining human life;

Malfunctions – How To Assess?

- Does the malfunction result in the failure of the device to perform its essential function and compromise the device's therapeutic, monitoring, or diagnostic effectiveness, which could cause or contribute to a death or serious injury?

- Has there been a previous device-related death or serious injury associated with the malfunction? (presumption rule)

- Has the device malfunction led to a recall?

- Did the device fail to meet its performance specifications or otherwise perform as intended?

  - Performance specs include all claims in the labeling

  - Intended performance refers to intended use for which the device is labeled or marketed

  - Consider:
    ‣ What did the reporter tell you?
    ‣ Did you get the device back?
    ‣ What are the results of your tests on the suspect device?
    ‣ Can you rule out a device malfunction?

MDR Definitions

Has malfunctioned and this device or a similar device that you market would be **likely to** cause or contribute to a death or serious injury, if the malfunction were to recur."

"Likely To"

- If there was a malfunction that did not cause or contribute to a death or serious injury, but would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, then the event should be reported as a malfunction.

- Consider the following:
  - Has there been a previous device-related death or serious injury?
  - Has there been a previous "Near miss" event?
  - Is the device used on critical patients who would face life-threatening consequences if the device malfunctioned?
  - Is the device used in a setting that includes alarms and close monitoring?
  - Have previous malfunctions of this type investigated to verify that they have not lead to death or serious injury. Are the investigations documented?

When NOT to Report

- Information would cause a person qualified to make a medical judgment to reach a conclusion that a device **did not cause or contribute** to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur.

  ‣ A person qualified to make a medical judgment: Includes physicians, nurses, risk managers, and biomedical engineers

  ‣ A device-related event did not occur.

  ‣ You receive information from multiple sources regarding same patient and same event (report only once).

  ‣ Information received in erroneous in that a device-related incident did not occur.

  ‣ You determine that the device was manufactured by another company (send reportable info to FDA with cover letter).

  - Be sure to document the information used to make this decision in your MDR event / complaint file

Five MDR Reporting Challenges

1. **Inadequate Post market Surveillance system**
   - ‣ Timely reporting
   - ‣ Evaluating Information from all sources
   - ‣ Servicing
   - ‣ Events outside the US
   - ‣ Events from clinical trials

2. **Conducting robust and timely investigations**

3. **MDR Reporting Decisions**
   - ‣ Evaluating malfunctions
   - ‣ Events that are the result of user error; off-label use; abnormal use
   - ‣ Providing accurate information to FDA in the way FDA wants to receive that information
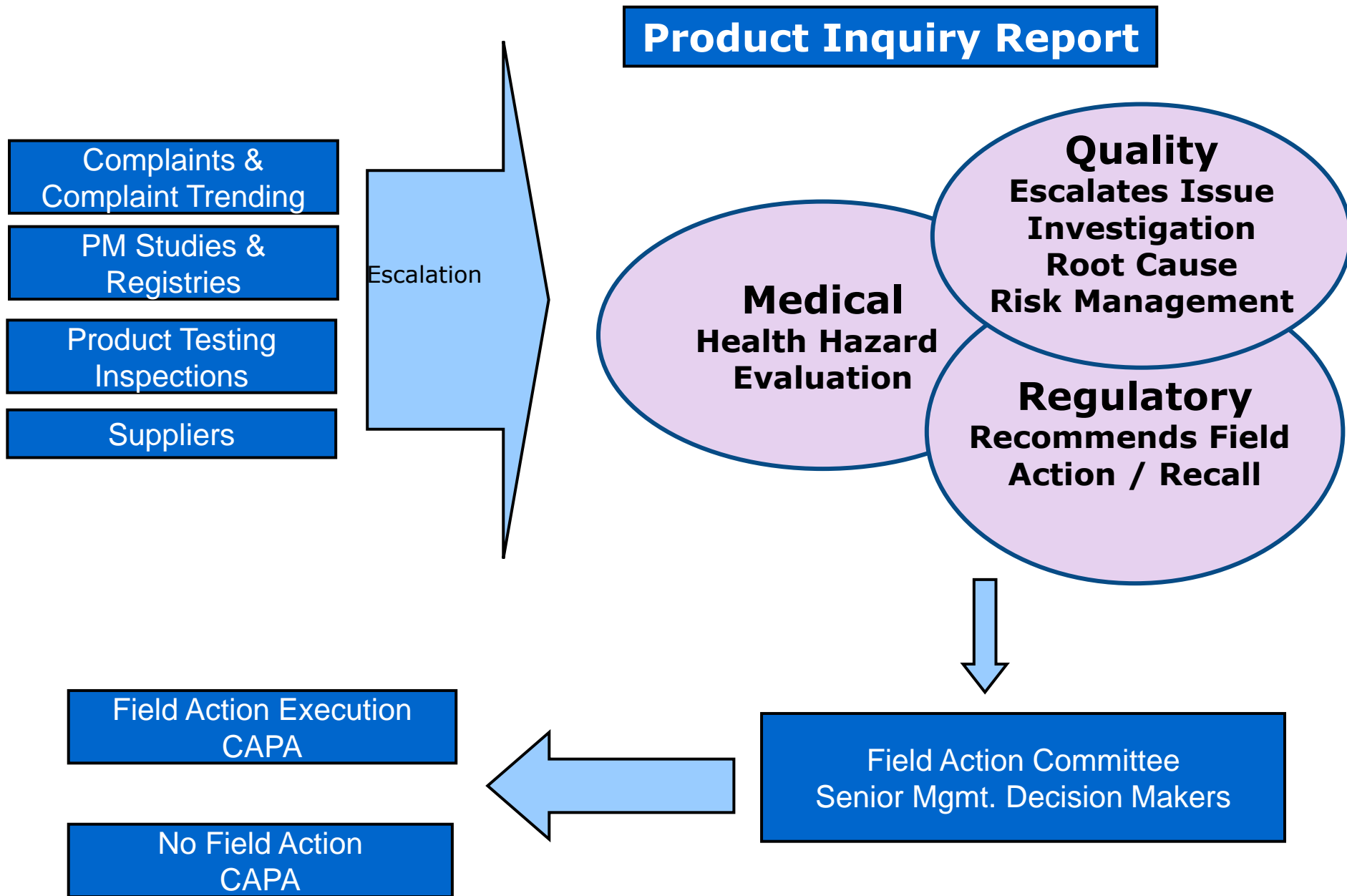   - ‣ Clear, consistent documentation

4. **Escalation and linkage to other quality systems**

5. **Evaluating Health of the MDR system**

Action System & Outputs

- CAPA
  - ‣ Process
  - ‣ Design
  - ‣ Labeling
  - ‣ Training

- Escalation
  - Correction / removal
    - ‣ Field action
    - ‣ Safety notice

- Risk Management

Action System & Outputs

Product Inquiry Report

Complaints & Complaint Trending

PM Studies & Registries

Product Testing Inspections

Suppliers

Escalation

Medical
Health Hazard Evaluation

Quality
Escalates Issue
Investigation
Root Cause
Risk Management

Regulatory
Recommends Field Action / Recall

Field Action Committee
Senior Mgmt. Decision Makers

Field Action Execution
CAPA

No Field Action
CAPA

Dissemination & Management Reviews

Timely & Accurate information Exchange

Internal & External stakeholders
- Site, Business Unit, Regional and Exec Management Reviews
- Local, Regional & Corporate quality boards
- Businesses; Manufacturing plants; R&D; Risk Mgt.
- Hospitals, Physicians, Patients
- US & Outside US Regulatory Agencies
- Suppliers, Distributors, other 3rd parties

Typical information disseminated/discussed
- Serious AE; Reportable events; Trends
- System performance efficiency and effectiveness metrics
- Relevant CAPAs; Projects/initiatives
- Complaint investigations Status & Aging
- Industry trends and new/changing regulations
- User feedback
- Procedural changes/improvements

Five MDR Reporting Challenges

1. **Inadequate Post market Surveillance system**
   - ‣ Timely reporting
   - ‣ Evaluating Information from all sources
   - ‣ Servicing
   - ‣ Events outside the US
   - ‣ Events from clinical trials

2. **Conducting robust and timely investigations**

3. **MDR Reporting Decisions**
   - ‣ Evaluating malfunctions
   - ‣ Events that are the result of user error; off-label use; abnormal use
   - ‣ Providing accurate information to FDA in the way FDA wants to receive that information
   - ‣ Clear, consistent documentation

4. **Escalation and linkage to other quality systems**

5. **Evaluating Health of the MDR system**

Post market Surveillance System Monitoring

Institute a systematic process for reviewing post market surveillance system and provide timely feedback

- **System Efficiency Metrics**
  - Late Regulatory Reports & Late Entered Complaints
    ‣ Feeder to CAPA / NCE process
  - Complaint and Investigation Cycle Times vs. Targets
  - Complaint and Investigation Aging
  - Total Complaints & Investigations Entered and Closed

- **System Effectiveness Metrics**
  - Independent Review of Complaint Files and Documentation
    ‣ Review MDR / MDV reportable and non-reportable decisions
    ‣ Use queries and filters to identify files with high risk of incorrect decision e.g. patient harm codes with non-reportable decisions; MDV with no MDR;
    ‣ Monitor results to identify if need for systemic fixes or additional training required

- **Product Performance Metrics**
  - Top 10 As Reported and As Analyzed Codes
  - Top Complaint Products
  - Unfavorable Trends

Tips for MDR Reporting

1. **MDR procedures must demonstrate they meet all of the applicable elements of 21 C.F.R Part 803**
   - Procedures should use FDA's terminology and align with the regulations.
   - If company has multiple procedures, e.g. corporate and local SOP, the procedures should be consistent in content, process, and terminology.

2. **Ensure that Supplemental MDRs are filed within 30 days of becoming aware of new or additional information**
   - Exercise caution when "resetting the clock"
   - Did you really receive new information?
   - Did the investigation result in only the original complaint "confirmed"?

3. **Ensure Medical Safety / Clinician input to aid in understanding of clinical outcomes**
   - Show that the healthcare professional rendering the opinion was provided with and understood the MDR reporting criteria.
     - Clinical impact of Adverse Events
     - Treatment/Therapy not achieved
     - Significance of delay in treatment

Tips for MDR Reporting

4. **Ensure that events (regardless of the source) are handled consistently and appropriately.**
   - Events in which little information was provided or is not available.
     ‣ Conservative (aggressive) reporting – When in doubt file; Supplement with additional information when it becomes available

   - Events that are the result of user error or "off-label" use may be reportable
     ‣ Events resulting from user error or off-label use **may** be the result of problems with the device labeling or training
     ‣ Off-label use cannot automatically be considered user error – may reflect accepted standard of care or medical practice

   - Events involving sterility failures or breach of packaging integrity; Labeling mix-ups; Out-of-box failures may be reportable

   - Whether malfunction failure modes have ever caused or contributed to a death or serious injury (and triggered the reporting "presumption")

5. **Deaths and serious injuries that are within the labeled frequency may be reportable**
   ‣ Evaluate each event individually. FDA does not accept a non-reportable rationale that the event is within an expected or labeled frequency or severity.

Tips for MDR Reporting

6. Simplify complaint and MDR process where possible

- Show how procedures align with regulatory requirements.
- Use decision trees and examples to facilitate consistent decision-making
  ‣ What Objective Evidence supports the "non-reporting" decision?
- Leverage Risk Documents to aid in Malfunction reporting decisions

7. Consider the use of Reporting/Non-reporting Guidelines

‣ Guidelines / rationales have been reviewed by cross-functional representatives (RA, Legal, Clinical, etc.) and are updated routinely.
‣ CAUTION – Guidelines augment decision-making but do not replace need to evaluate each complaint in totality

8. Review FDA publically available MDR databases

‣ MAUDE – Manufacturer and User Facility Device Experience
‣ Web search and downloadable MDR reports; FOI required for patient codes
  - http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
‣ MDR – MDR reports prior to 1996; Web search only
  - http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMDR/Search.cfm

Tips for MDR Reporting

9. **Provide training on the regulation to facilitate better MDR decision-making**
   - Test MDR decision-making staff to show consistent understanding
     ‣ Watch for problems caused by staff turnover!
   - Provide examples from where others have gone wrong
     ‣ Analysis of 483 and warning letters are useful

10. **Institute Independent reviews of MDR files and decision making**
    - Use both internal and outside company experts
    - Review both reportable and non-reportable decisions; queries for complaint files with high risk of incorrect MDR decision
    - Disseminate learnings and guidance around contemporary FDA thinking

FDA Draft MDR Guidance

Draft Guidance for Industry and Food and Drug Administration Staff; Medical Device Reporting for Manufacturers – July 2013

- Describes and explains the FDA regulation for MDR reporting and recordkeeping

- Question and Answer Format

- Manufacturer Reporting Requirements

- Procedures, record keeping, Public Disclosure

- Enforcement

- Terms & Definitions

Summary

- **Device manufacturers need to have an effective system for: identifying potentially reportable MDR events**
  - Analyzing in a consistent manner whether events are reportable,
  - Submitting accurate and timely MDR reports to FDA.

- **An effective MDR system has a set of written procedures that incorporate the principles of FDA's MDR and complaint files regulations.**
  - A manufacturer that lacks such a system may expose itself to FDA enforcement action, as well as increased product liability risk.

- **Helpful Websites:**
  - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094529.htm
  - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm175805.htm

CASE STUDY

**Eleventh Annual
Medical Device Quality Congress
Bethesda, MD   June 24-26, 2014**

FDANEWS

Case Study – Sweet Dream Device Inc.

Sweet Dream Device, *Inc*., a U.S. manufacturer of anesthesia devices is a Division of their parent holding company *Sleep More Devices,* located in Vietnam.

The global sales offices of *Sleep More* warehouse, sell, distribute and service *Sweet Dream Device* products.

During a routine quarterly visit to a client outside of the US a *Sleep More* global sales representative learned of a patient injury associated with the U.S. manufactured product. The *Sleep More's* sales representative returned to her office after her two week client road trip and left immediately for a 1 week vacation.

Upon her return, she sent the injury information to *Sweet Dream Device*, *Inc* in the U.S. for their evaluation and review.

Case Study – Sweet Dream Device Inc.

The firm's investigation determined the following:

The clinician accidentally pressed the wrong button on the machine, putting the device into a maintenance cycle that prohibited ventilation of the patient. The clinician had to manually ventilate the patient and was able to successfully stabilize the patient. Once the anesthesia machine completed its maintenance cycle, the clinician was able to ventilate the patient normally using the machine.

Both the Hospital and the Firm's Biomedical Engineers tested the device and found the device operated normally and that there was no system malfunction.

As part of the firm's investigation, a complaint review identified two similar events. In one of these events, the patient expired. The firm's investigation of this previous event was unable to conclude whether the interruption of ventilation caused the patient death.

Case Study – Sweet Dream Device Inc.

- *Parent company sales rep waited 3 weeks before reporting incident to the firm.*

- *Clinician accidently pressed the wrong button and could not exit checkout cycle delaying patient ventilation.*

- *Required medical intervention to preclude serious injury*

- *Device operated normally; no system malfunction.*

- *Two previous complaints. One was a death event; firm unable to determine if interruption of ventilation caused the patient death.*

Questions

1. Should *Sleep More Devices* employees report such events to Sleep Dream Inc.?

   - *Yes; Sweet Dream Device Inc., needs to be clear who is the designated complaint unit - All employees, affiliates, distributors need to be trained on identifying a complaint, required information, where to send the information and timeframes for reporting the information.*

2. *Sweet Dream Device, Inc* first learned of the injury upon receipt of the *Sleep More Devices* Sales rep. report. Is that the "Become Aware Date"?

   - *No! The firm's become aware date is the date when the firm <u>first</u> became aware of the incident; this is the date the sales representative first received the report that an injury occurred.*

3. At what point was the Become Aware Date reached?

   - *The date the sales representatives had been present and observed the surgical procedure at which this injury occurred.*

Case Study – Sweet Dream Device Inc.

4. Will any subsequent MDR filing, if needed, be late?

- *There is a potential for a late MDR. The firm has 30 days after the day the firm first became aware to report the MDR. Given the sales rep took 3 weeks to report the complaint, the firm has only a short time left to complete the investigation and file the MDR if needed.*

Case Study – Sweet Dream Device Inc.

5. What steps can be taken to reduce this problem (potentially late MDR) from recurring?

- *The firm needs to ensure all company personnel – Sales reps, Service, all employees know how to identify a complaint, what information is minimally required, where to report the complaint.*

- *Roles, responsibilities need to be clearly documented between the parent company and its Divisions.*

- *The Firm needs to clarify and document:*
  - *Who holds the registration for the product?*
  - *Who manufactures the product?*
  - *Investigation site?*
  - *Designated Complaint Handling Unit?*
  - *Who is responsible for reporting MDRs and Vigilance reports?*

51

Case Study – Sweet Dream Device Inc.

6. Was there a serious injury?

   Yes, medical intervention to preclude a serious injury

7. If there was a serious injury, did the device cause or contribute to the patient injury?

   Device did not cause (e.g. system malfunction), however, it contributed to the serious injury.

8. Is the event reportable as an MDR?

   Yes, although the serious injury was attributable to User error, this event is reportable as a MDR.

2.5 What is meant by "caused or contributed" to a death or serious injury?

This means that 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 [21 CFR 803.3]:*Contains Nonbinding Recommendations Draft – Not for Implementation 7*

1. Failure;
2. Malfunction;
3. Improper or inadequate design;
4. Manufacture;
5. Labeling; or
6. User error.

2.6 What is device "user error" and why do you want to know about events involving user error?

We consider a device "user error" to mean a device-related error or mistake made by the person using the device. The error could be the sole cause of an MDR reportable event, or merely a contributing factor. Such errors often reflect problems with device labeling, the user interface, or other aspects of device design. Thus, FDA believes these events should be reported in the same way other adverse events a device causes or contributes to should be reported. This is especially important for devices used in non-health care facility settings.

9. What other actions should the firm take?

   Utilize risk assessments for determination of whether the hazardous situation has been reduced to As Low as Reasonably Practicable.

   – Labeling alone or relying on training may be inadequate for this device and intended use.

   – Investigate adequacy of the design to prevent user error.

10. Does the firm have a potential recall?

   Potentially - depends on whether the firm intends to take any field actions to address the complaint.

QUESTIONS & DISCUSSION