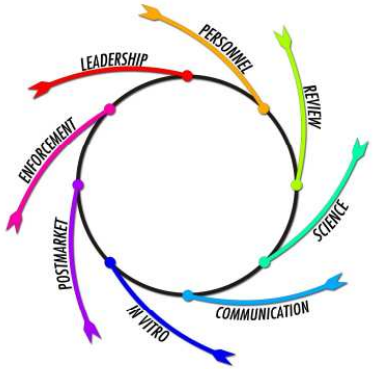

Medical Device Recall Communication

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Recall Challenges

- Understanding the Risk
- Adequate Notification
- Root Cause Analysis
- Corrective and Preventive Actions
- Closing a Recall
- Terminating a Recall

Understanding the Risk

A Health Hazard Evaluation (HHE) is a risk assessment to guide the Center in classifying the recall and determining what actions are needed by the firm and FDA to protect the public health.

21 CFR part 7

- Part 7
  - How to conduct a recall
  - FDA expectation of industry's actions
  - Provides guidance
    - For manufacturers and distributors
    - On voluntary recalls

- 21 CFR 7.46
  - You are requested to report corrections or removals to your FDA District Recall Coordinator as soon as possible.

21 CFR 7.42 Recall Strategy

- The recall strategy will include the following elements:
  - Depth – level in the distribution chain
  - Public Warning – purpose is to alert the public that the product being recalled presents a serious hazard to health
  - Effectiveness Checks – verifies that all consignees at the recall depth specified have received notification and have taken appropriate action
- The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted

Reporting Requirements

- 21 CFR 806
  - This is a reporting requirement
  - It is not instructions on how to conduct a recall
  - It is not a requirement to conduct a recall
- 21 CFR 806.10(b)
  - Remember, you are required to report within 10 business days after initiating such correction or removal.

Exemptions from Requirements

- 21 CFR 806.1b Exemptions
  1. Changes which improve quality but do not reduce a risk to health or remedy a violation
  2. Market Withdrawals
  3. Routine Servicing
  4. Stock Recoveries

Who Must Report to FDA?

- 21 CFR 806.10(a)
  - Each device manufacturer or importer shall submit a written report to your FDA district office of any **correction or removal** of a device initiated by such manufacturer or importer if the correction or removal was initiated:
    1. To **reduce a risk to health** posed by the device; or
    2. To **remedy a violation of the act** caused by the device which may present a risk to health

Required Information

- All information according to 21 CFR 806.10(c)(1-12).

- Business Rule: If any of the required information is unavailable at the time of submission, the reporter must indicate why it is not available and when it will be submitted (21 CFR 806.10(c)(13)).

Reporting Requirements

- 21 CFR 806.10(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 – Medical Device Reporting or 1004 – Repurchase, Repairs, or Replacement of Electronic Products.

Reporting Requirements

- 21 CFR 806.20
  - (a) Each device manufacturer or importer who initiates a correction or removal of a device that is not required to be reported to FDA under 806.10 shall keep a record of such correction or removal.
  - (b) Records of corrections and removals not required to be reported to FDA under 806.10 shall contain the information listed in this part.

    (4) Justification for not reporting the correction or removal action to FDA, which shall contain conclusions and any follow-ups, and be reviewed and evaluated by a designated person.

Reporting Requirements

- 21 CFR 806.20
- (5) A copy of all communications regarding the correction or removal.
  - c) The manufacturer or importer shall retain records required under this section for a period of 2 years beyond the expected life of the device, even if the manufacturer or importer has ceased to manufacture or import the device.

Tell the FDA

- Your local FDA District Office Recall Coordinator (DRC)
- Foreign manufacturers use the DRC local to their importer/agent
- It's not just a good idea; it's the LAW
  - If there is a risk to health, report
  - Within 10 days of initiation
- 21 CFR 806
  - This is reporting.
  - It is NOT instructions on how to conduct a recall.

What else will FDA ask for?

21 CFR Part 7.46 - Guidance

- Product identity
- Reason, date discovered
- Risk Evaluation
- Quantity manufactured
- Quantity distributed
- Distribution information
- Recall letter or script
- Recall strategy
- Firm official's contact information

Regulatory Procedures Manual Chapter 7 - Attachment B

- Labeling
- Code information
- Similar to 21 CFR Part 7

Mandatory Recalls

21 CFR 810

- Cease distribution and notification order

- There is a reasonable probability that the medical device will cause serious adverse health consequences or death.
  - 21 U.S.C. 360h(e)
  - FD&C § 518(e)

Recall Communications

- Communications with FDA
  - When to initiate discussions with FDA
  - Approaching the District or the Center
  - What are Agency expectations
  - Appropriate and productive interactions
  - Inappropriate and counter-productive interactions

Recall Communications

- Communications with other stakeholders
  - Communications with patients and providers
  - Updating procedures according to new health risk information
  - User notifications of new information – recall or not?
  - Press releases
  - Communications with the business community

Recall Communications

Sec. 7.49 Recall communications.

(a)*General.* A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall. In general terms, the purpose of a recall communication is to convey:

Recall Communications

- (1) That the product in question is subject to a recall.
- (2) That further distribution or use of any remaining product should cease immediately.
- (3) Where appropriate, that the direct account should in turn notify its customers who received the product about the recall.
- (4) Instructions regarding what to do with the product.

Recall Communications

- (b)*Implementation.* A recall communication can be accomplished by telegrams, mailgrams, or first class letters conspicuously marked, preferably in bold red type, on the letter and the envelope: "drug [or food, biologic, etc.] recall [or correction]". The letter and the envelope should be also marked: "urgent “ for class I and class II recalls and, when appropriate, for class III recalls. Telephone calls or other personal contacts should ordinarily be confirmed by one of the above methods and/or documented in an appropriate manner.

Recall Communications

- (c)*Contents.* (1) A recall communication should be written in accordance with the following guidelines:
- (i) Be brief and to the point;
- (ii) Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;
- (iii) Explain concisely the reason for the recall and the hazard involved, if any;

Recall Communications

- (iv) Provide specific instructions on what should be done with respect to the recalled products; and
- (v) Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product, e.g., by sending a postage-paid, self-addressed postcard or by allowing the recipient to place a collect call to the recalling firm.

Recall Communications

- The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where necessary, follow-up communications should be sent to those who fail to respond to the initial recall communication.

Recall Communications

- *Responsibility of recipient.* Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its consignees in accordance with paragraphs (b) and (c) of this section.

Important Factors to Consider

- Get it right the first time
- Work with the FDA
- Title – URGENT MEDICAL DEVICE RECALL
- Describe the risk to patients
- Post for visibility

Common Mistakes

- Engineering risk instead of public health risk
- Multiple revisions
- Inappropriate Information
  - Qualification data
  - Promotional materials
  - Other statements that may detract from the message

Thank You

Questions?

Additional information

- The additional slides are for your information and examples of what can be included in your template.

Adequate Notification

- Company Name
- Date (Month, Day, Year)
- URGENT: MEDICAL DEVICE RECALL
- **<PRODUCT NAME>**

- **(1) Attention to Customer**:

- Customer Name
- Device Name
- Street Address
- City, State, Zip Code

- Dear Device Customer/Distributor,

Adequate Notification

- **(2) Purpose of this letter**

- The purpose of this letter is to advise you that Company Name is voluntarily recalling Product X (include the name, intended use statement, and any additional identification detail not covered in the Product and Distribution Information section).

- Note: If any serious injuries and/or deaths have occurred or could occur as a result of the failure of the device, add this sentence in bold font: **"Serious injuries and/or deaths have occurred or could occur due to the failure mode associated with this recall. We have reports of** [number of] **deaths and/or**[number of] **of serious injuries."**

Adequate Notification

- **(3) Reason for the Voluntary Recall:**

- Identify the product concerns/problems, whether actual or potential, in detail (For example, what happens when the device fails). Include the following information, if available:

- **Frequency of failures and complaints (**for example, “We are aware of [number of] product failures and [number of] complaints associated with the problem.”)
- **Magnitude of the error, if applicable** (for example, the failure results in values 15% lower than true values)
- **Adverse events** (that is, injuries, deaths)

Adequate Notification

Notification Letter (Footnote)

- Recommended for Class I and II recalls. "Urgent" should be noted on both the letter and envelope as per 21 CFR 7.49(4)(b).
- For radiation-emitting electronic products, a recall action is governed by 21 CFR 1004 – Repurchase, Repairs, or Replacement of Electronic Products – under which manufacturers are required to bring such products into conformity with applicable performance standards or correct any reported device defect at no charge to the user. Medical device recalls are governed by 21 CFR 806 – Reports of Corrections and Removals – which does not contain an equivalent requirement.

Adequate Notification

- **(4) Risk to Health:**

- **4a)** Explain how the device failure or problem will affect patients, health care providers, or other persons who are exposed to the device. If the device failure can cause injuries, delays in surgical procedures, or other delays in treatment or therapy, provide an explanation of why that is so.

- **4b**) Add the statement **"How to recognize that the device may fail."** Describe the methods of recognition of the device failure by the customer/user. Give an explanation (in lay terms) of how the failure occurs and how to detect/recognize the issue.

Adequate Notification

- **(5) Actions to be taken by the Customer/User:**

- Describe actions for safe handling of the recalled product (for example: discontinue use, discard or correct the product, return the product, etc.) State whether these actions are temporary or long-term and, if applicable, when a long-term solution will be implemented. At a minimum, ensure that the following elements are included:

- Recommended treatment or actions for users to minimize risks of illness or injury
- Actions to be taken pending corrective or removal action
- Alternative products that can be used, if applicable, and/or whether removal of the product will cause a shortage
- Specific instructions for sub-recall and any associated recalls (for example, private labeling or associated kits, if applicable)
- Instructions for acknowledgement (FAX back, email, telephone, etc.).

Adequate Notification

(6) Product and Distribution Information: This table is not limited to the information listed below; please insert additional information as applicable. Photographs of the product are optional.

Product and Distribution Information Table					
Product Names, Unique Device Identifier (if applicable)	Manufacturer's Product Number/Catalog Number	Lot/Serial Number	Manufacturing/Distribution Dates	Expiration Date (MM/DD/YYYY)	Quantity

Adequate Notification

- **(7) Type of Action by the Company:**

- What is the firm doing to correct this issue? – (for example, system updates, removal, and change in labeling). When will these corrective actions be taken by the company (short and long-term)?

- Failure Investigation findings:

Adequate Notification

- **(8) OTHER INFORMATION:**
- Contact information for questions
- Attachments of Acknowledgement and Product Replacement Forms (separate sheets)
- Authorized by:
- Name: (Print)

  _____

- Signature:

  _____

- Title:

  _____

- Contact Information: Include Days/Hours Available (with Time Zone) for calls such as, Monday
- through Friday, 8:00 AM to 4:30 PM, Eastern Time. Add toll-free number if available. Add website information, if available.

- Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Adequate Notification

- **MEDICAL DEVICE RECALL RETURN RESPONSE**
  - **Acknowledgement and Receipt Form**
    - Response is Required

- **Customer Information:**
- Customer Name
- Street Address
- Town, State, Zip Code

- **PRODUCT NAME**

- **Lot/Serial numbers:**

- I have read and understand the recall instructions provided in the <date of> letter. Yes _ No_

- Any adverse events associated with recalled product? Yes _ No _

- If yes, please explain:
- _____
  _____
  _____

- Was this device implanted? (If yes, please s**pecify the implant dates, the quantities implanted, and provide available tracking information**).

Adequate Notification

Affected Product Information: Include information that is applicable for affected product.

Affected Product Information Table					
Product/Brand Names, UDI (if applicable)	Manufacturer's Product Number/Catalog Number	Lot/Serial Number shipped to Customer	Quantity in inventory	Quantity relabeled	Quantity destroyed/ returned

Adequate Notification

Return Response Box:

Please provide any additional information, if applicable.

Distributors:
I have checked my stock and have quarantined inventory consisting of _____ <units, cases, etc.>.

I have identified and notified my customers that were shipped or may have been shipped this product by (**specify date and method of notification**); <or>
Attached is a list of customers who received/may have received this product. Please notify my customers.

Adequate Notification

- **Questions: (when applicable)**
- ☐ Please have Customer Service contact me.
- Signature of Receipt _____

Name/Title	
Telephone	
Email address	

PLEASE FAX COMPLETED RESPONSE FORM TO: Tel. # < >,
ATTN: < >
OR MAIL TO: FIRM NAME AND ADDRESS

MAUDE - Manufacturer and User Facility Device Experience

- MAUDE data represents reports of adverse events involving medical devices. The data consists of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. MAUDE may not include reports made according to exemptions, variances, or alternative reporting requirements granted under 21 CFR 803.19.
- The on-line search allows you to search CDRH database information on medical devices which may have malfunctioned or caused a death or serious injury. MAUDE is scheduled to be updated monthly and the search page reflects the date of the most recent update. FDA seeks to include all reports received prior to the update. However, the inclusion of some reports may be delayed by technical or clerical difficulties.
- MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices. Please be aware that reports regarding device trade names may have been submitted under different manufacturer names. Searches only retrieve records that contain the search term(s) provided by the requester.

Search MAUDE Database Help | Download Files | More About MAUDE

Enter a search term below, choose a date range and select *Search*

Date Report Received by FDA
(press CTRL key for multiple years)

ALL YEARS
2013
2012
2011
2010

Enter a single word (e.g., electromechanical), an exact phrase (e.g., electromechanical pump) or multiple words. To Search by Brand Name, Manufacturer, Event Type, 510K Number, PMA Number, Product Code, or date, select *Go To Advanced Search* button.

Go to Advanced Search | 10 Records per Report Page | Search | Clear

- The Freedom of Information Act (FOIA) is found in Title 5 of the United States Code, Section 552. FOIA generally provides that any person has the right to request access to federal agency records or information except to the extent the records are protected from disclosure by any of nine exemptions

806 eSubmitter

- **Objective: To provide a voluntary automated process for the submission and processing of information related to medical device Corrections and Removals in accordance with 21 CFR 806.**

- **Goals: To improve the 806 submission process and enhance consistency of submission data.**

- **NOTE: The eSubmitter process will not alter the current procedures for handling 806 reports by the District Offices or the Center. eSubmitter provides a means to receive and share 806 documents; however, we are still working with the IT contractors to have the information directly entered into RES.**