Supplier-Related Medical Device Recalls and Other Compliance Initiatives

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AFDO
June 22, 2010
Topics to be Covered

– What is Considered a Recall
– Responsibilities of FDA in a Recall
– Responsibilities of Recalling Firm
– Recall Statistics
– Recall Root Causes
– Supply Chain Problems
– Purchasing Control Examples
– OCER Responsibilities
What is a Recall?

• An effective method to remove or correct FDA regulated products from the market place
• An alternative to FDA initiated court action for removing violative products from the market (seizure) or import detention
  – **Violative Product** – a product that is in violation of the applicable regulatory and statutory laws. Typically, medical device recalls occur because the device is either Adulterated, §501 or Misbranded, §502 of the Act.
How firms determine if they have a Medical Device Recall

• Does it meet the following criteria:
  – A Removal - the physical relocation of the device from where it is used or sold, to some other location for:
    ➢ Repair
    ➢ Modification
    ➢ Adjustment
    ➢ Relabeling
    ➢ Destruction
    ➢ Inspection
  – A Removal that is not part of regularly scheduled maintenance
How firms determine if they have a Medical Device Recall

• Does it meet the following criteria:
  – A Correction – On site
    ➢ Repair
    ➢ Modification
    ➢ Adjustment
    ➢ Relabeling
    ➢ Destruction
    ➢ Inspection
    ➢ Including patient monitoring
Actions That Are Not Recalls

• A Correction or Removal Action is NOT a Recall, if it is a:
  o Market Withdrawal – firm’s removal or correction of a distributed product which involves no violation or a minor violation that would not be subject to legal action by the FDA.
    o E.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.
  o Stock Recovery – firm’s removal or correction of a product that has not been marketed or that has not left the direct control of the firm.
  o Safety Alert – notification by responsible persons to device users that the use of a device may, in certain circumstances, pose a risk of substantial harm.
FDA Responsibility in Recalls

- Provide regulatory oversight of process
- Comment on proposed strategy
- Review communications
- Audit effectiveness of recall
- Witness product destruction or approve reconditioning plan
- Notify firm of termination
Most Medical Device Recalls are Voluntary and Firm Initiated
Firm Responsibility in Recalls

• 21 CFR 806 requires that Firms report, within 10 days, most medical device corrections and removals to the District Office Recall Coordinator.
• Customer notification letters should be written using 21 CFR 7.49 as a guide.
• Recall notifications should be posted on the Firms website, and should not be removed until an accounting of all units has taken place.
• Effectiveness checks verify that the customer has received the notice AND has taken the appropriate action.
## Reports

### 21 CFR 7
- Product identity
- Reason, date discovered
- Risk Evaluation
- Quantity manufactured
- Quantity distributed
- Distribution info
- Recall letter or script
- Recall strategy
- Firm official’s contact info

### 21 CFR 806
- C&R number
- Recalling firm contact info
- Brand name, intended use
- 510(k), PMA, exempt
- Model #, Lot #
- Manufacturer contact info
- Reason, actions taken
- Injuries, MDR#s
- Quantity
- Mfr dates, expected life
- Consignee information
- Recall letter or script
- Why any info missing
- Root Cause
A Firm’s Strategy

• A planned specific course of action to be taken in conducting a recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.
A Firm’s Strategy

• An effective recall strategy takes into account:
  – The results of the risk assessment
  – Ease of identifying the affected product(s)
  – Degree to which the product’s deficiency is obvious to the consumer or user
  – Degree to which the product remains unused in the marketplace
  – Continued availability of essential products
Quality System Requirements

- Firms are responsible for following the Quality System Requirements found in 21 CFR Part 820.100 thru 21 CFR 820.250
  - Establishing and maintaining procedures for implementing corrective and preventative action
- This will aid in ensuring that the necessary corrective fixes are made on all units
- Additional information can be viewed at: http://www.fda.gov/Training/CDRHLearn/ucm162015.htm
Recall Status Reports

• FDA requests that a recalling firm submit recall status reports to their FDA District Office.
  – This is so the agency may assess the progress of the recall

• The frequency of these reports will be determined by the relative urgency of the recall and will be specified by the District Office.
  – Generally between 2 and 4 weeks.
Recall Numbers FY05-09

### Chart: Action/Product Recalls 5-yr Period

- **FY 05**
  - Recalled Products: 1598
  - Actions: 571
- **FY 06**
  - Recalled Products: 1550
  - Actions: 651
- **FY 07**
  - Recalled Products: 1279
  - Actions: 661
- **FY 08**
  - Recalled Products: 2472
  - Actions: 832
- **FY 09**
  - Recalled Products: 2306
  - Actions: 776
Class II Recalls FY05-09

Class 2 Recall Actions for 5-year Period

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<th>Year</th>
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<tr>
<td>FY 05</td>
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<tr>
<td>FY 06</td>
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<td>FY 07</td>
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<td>FY 09</td>
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Class III Recalls FY05-09

Class 3 Recall Actions for 5-year Period

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<td>130</td>
<td>96</td>
<td>108</td>
<td>67</td>
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</tbody>
</table>
Recalls by Panel FY06-09
FY 09 Recall Root Cause Data

Class I Root Cause

- Design Control: 41%
- Change Control: 41%
- Process Control: 41%
- Nonconformance: 6%
- PMA: 6%
- Nonconformance: 6%

Class I by Panel

- Anesthesiology
- Cardiovascular
- Dental
- General Hospital
- Neurology
- Ophthalmology
- Orthopedics
- General/Plastic Surgery

Graph showing the distribution of Class I root causes and by panel.
FY09 Recall Root Cause Data

Class II Root Cause

- Process Control: 30%
- Design Control: 42%
- Nonconformance: 13%
- Other: Incorrect/no expiration date
- Other: Radiation control
- Other: Labeling false/misleading
- Other: Employee error
- Under investigation
- Change Control
- Process Control
- Design Control
- Nonconformance
Class III Root Cause

- Nonconformance: 22%
- Design Control: 15%
- Change Control: 7%
- Process Control: 47%
- Labeling false/misleading
- Employee error
- Incorrect/ no expiration date
OIVD 2009 Root Cause

- Noncompliance: 20%
- Software Design: 13%
- Device Design: 12%
- Change Control: 7%
- Other Design: 10%
- Other: 8%
- Process Control: 23%
- Other: 8%
Nonconformance Includes:

• Nonconforming material/component

• Material/Component Contamination
SUPPLY CHAIN PROBLEMS THAT COULD LEAD TO RECALLS
Commonly Cited Issues – 820.80 Incoming Acceptance

• Incoming acceptance activities not performed/documented
  – e.g., No procedures for incoming, required inspections not documented, not following sampling plans

820.80(b) Receiving acceptance activities. Each manufacturer shall establish and maintain procedures for acceptance of incoming product. Incoming product shall be inspected, tested, or otherwise verified as conforming to specified requirements. Acceptance or rejection shall be documented.
“…while finished device manufacturers are required to assess the capability of suppliers, contractors, and consultants ... inspections and tests, and other verification tools, are also an important part of ensuring that components and finished devices to approved specifications ...”

Preamble to the 1996 QS Regulation, Comment 106
Commonly Cited Issues – 820.50

Supplier Evaluations

- No documentation of supplier evaluations

820.50(a)(1) **Evaluate** and select potential suppliers, contractors, and consultants **on the basis of their ability to meet specified requirements**, including quality requirements. **The evaluation shall be documented.**
Commonly Cited Issues – 820.50

Quality Requirements

• Inadequate requirements for suppliers
  – e.g., control over validated processes, reliance on supplier self-assessments

820.50(a)(1) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.

820.50(a)(2) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.
Supplier Assessments/Evaluations

“... the initial assessment or evaluation, depending on the type and potential effect on device quality of the product or service, should be a combination of assessment methods ... the capability of the product or service suppliers should be reviewed at intervals consistent with the significance of the product or service provided ...”

Preamble to the 1996 QS Regulation, Comment 103
Third Party Certification

“… [FDA] cautions manufacturers against relying solely on certification by third parties ... third party certification should not be relied on exclusively in initially evaluating a supplier. If a device manufacturer has established confidence in the supplier's ability to provide acceptable products or services, certification with test data may be acceptable.”

Preamble to the 1996 QS Regulation, Comment 103
Commonly Cited Issues – 820.50

Approved Supplier List

• Supplier not on Approved Supplier List

820.50(a)(3) Establish and maintain records of acceptable suppliers, contractors, and consultants.
Commonly Cited Issues – 820.50 Purchasing Data

• No or inadequate purchasing data
  – e.g., No written supplier agreements, inconsistent revision levels on drawings, etc.

820.50(b) *Purchasing data*. Each manufacturer shall establish and maintain **data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services**. Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the quality of a finished device. Purchasing data shall be approved in accordance with 820.40.
Internal/External Suppliers

“... FDA emphasizes that the requirements apply to all product and service received from outside of the finished device manufacturer, whether payment occurs or not. Thus, a manufacturer must comply with these provisions when it receives product or services from its “sister facility” or some other corporate or financial affiliate.”

Preamble to the 1996 QS Regulation, Comment 100
Examples Related to Purchasing Controls
The inspection also revealed that your firm did not adequately establish and maintain the requirements, including quality requirements, that must be met by suppliers, as required by 21 CFR 820.50(a). More specifically,

- Your firm did not sufficiently evaluate your contract manufacturer to ensure that documentation was available to show the supplier could consistently produce device in accordance with the designated specification; and
Example #2 Warning Letter Citation

• Failure to sufficiently evaluate and select potential contractors, suppliers, and consultants on the basis of their ability to meet specified requirements, including quality requirements.
  – Specifically, your firm has not adequately evaluated the contract manufacturer for its ability to meet your quality requirements despite the fact that your firm experienced quality issues which resulted in many complaints and two product removals (recalls).
Example #3 Warning Letter Citation

• Failure to clearly define the type and extent of control to be exercised over suppliers.
  – For example, your Supplier Approval Procedure & Process Map states you will perform ongoing monitoring of Level 1 suppliers. The procedure does not define the frequency and type of monitoring required for these suppliers.

• Failure to evaluate potential contractors.
  – For example, you did not evaluate the company who conducted steam sterilization validation studies for the XYZ Screw System to ensure they could conduct the validation studies in accordance with the specified standard.
Injunction Example #1 – Shutdown Letter to Firm

• … failed to establish and maintain adequate procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR § 820.50.
  – … relies on its PCB supplier to perform a comparison (verification) between electronic design files … and the manufacturing files … the requirement that this verification be performed and appropriately documented was not specified in XXX purchasing documentation or supplier agreement.
  – … relied on the supplier to perform its own First Article Inspection, but failed to established any criteria for the supplier to conduct the verification …
  – … continues to have solder flux contamination issues from a supplier even after implementing previous corrective actions. … has not implemented procedures to adequately control the products from this supplier or to inspect incoming products to detect contamination.
Injunction Example #1, cont. – No-Resume Letter (Follow-up Insp.)

- Failure to establish and maintain adequate procedures that define the extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the supplier evaluation results, as required by 21 C.F.R. 820.50(a)(2). For example:
  - CAPA XXX actions relating to supplier controls are not effective …
  - CAPA XXX … actions failed to establish adequate controls to identify and prevent substitution of RoHS parts …
  - As outlined in section 7.5, "Escalation of Chronic Underperforming Suppliers," in Supplier Maintenance Work Instruction (XXX), a Development Plan may be used as a means for ensuring that corrective or preventive actions are implemented at suppliers. This revision is inadequate in that it does not establish criteria for determining when to place an underperforming supplier on a Development Plan.
Injunction Example #2 – CDRH GMP Review Memo

• Failure to establish and maintain adequate requirements, including quality requirements, that must be met by suppliers, contractors, and consultants, as required by 21 CFR 820.50(a). For example:
  – The firm has not specified a requirement that the sterility test used for the microbiological analysis of their products be validated by their contract laboratory...

Injunction Example #3 – CDRH GMP Review Memo

• Failure to establish and maintain adequate procedures that ensure the evaluation of suppliers, contractors and consultants to include establishing requirements, including quality requirements, that must be met, as required by 21 CFR 820.50(a).
  – For example, Purchasing/Supplier Control procedure (XXX) requires a Supplier Survey Form (XXX) and a Supplier History Log Form (XXX) to be completed for each approved supplier. There are no quality requirements identified in the purchasing control procedure or the forms (XXX) related to each supplier. Additionally, there were no Supplier Survey Forms or Supplier History Log Forms for the following list of suppliers of finished devices…
Recall Classification

• **Class I Recall** - *A Situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death*
  
  - The recalling firm notifies its customers and directs them to notify the intended recipients of the device.
  
  - The notification usually contains the name of the device being recalled, identifying lot or serial numbers; the reason for the recall; explains concisely the risk involved; and instructions about how to correct, avoid, or minimize the problem. It should also provide a telephone number for questions related to the recall.
  
  - The recalling firm issues a press release to notify the public, if appropriate to minimize health consequences.
Class I Recall Example, Ventricular Assist Device (VAD)

• 378 VAD devices recalled due to potential for excessive brush wear and/or broken brush wires causing intermittent power to the motor leading to a loss of VAD support for the circulatory system.

  – Root Cause was identified as a change to the brush material of the motor. New supplier changed the composition without informing the firm of the change.
Recall Classification

- **Class II Recall** - A situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote
  - The recalling firm notifies its customers and sometimes asks them to notify the intended recipients of the device.
  - A press release would be issued if there was a specific need to do so
    - E.g. if the device could affect the health of a large number of people, if patients need more information, or if the recalling firm could not reach every intended recipient
Class II Recall Example, Hip Implant

- Multiple U.S. firms recalled >25,000 hip implants due to a potential component problem.
  - The component, a zirconia ceramic femoral head, was recalled by the contract manufacturer because it was fracturing at a higher rate than expected in some patients 13 to 27 months after being implanted.
  - All potentially defective batches were manufactured after the beginning of 1998 when the contract manufacturer changed part of its manufacturing process.
Class II Recall Example, Cardiac Pacemaker

• 49,500 pacemaker devices recalled in which there is a possibility for a loss of output (36 confirmed failures).
  – Root cause was identified as foreign material within a crystal timing component obtained from a supplier.
Class II Recall Example, Ventilator

- Approximately 250 ventilators recalled because of a potential problem related to electrolytic capacitors leaking on a printed circuit board. If this occurs, the ventilator can malfunction resulting in potential failure to breathe for the patient and/or failure to properly alarm.
  - Root cause was identified as exposure to corrosive flux during wave soldering/cleaning process at a supplier.
Class II Recall Example, Automated External Defibrillator

• 20,525 AED devices recalled because a Printed Circuit Board Assembly (PCBA) could be contaminated with solder flux which could cause a short that may eventually render the device inoperative.
  
  – Root cause was identified as two issues at the PCBA supplier: (1) solder flux applied incorrectly, and, (2) cleaning process used to remove solder flux was not utilized correctly. The process had not been adequately validated.
Recall Classification

• **Class III Recall** - A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.
  – The recalling firm notifies its customers
  – Press release is not usually expected
Class III Recall Example

• A labeling defect where the expiration date does not appear on the product label.

• A mislabeled package that contains one size of a particular medical device but is labeled as another size and patient injury is unlikely.
References

• 21 CFR Part 820

• Preamble to the QS Regulation Final Rule

• Compliance Program (7382.845) – Inspection of Medical Device Manufacturers
  – http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072753.htm
References, cont.

• Quality System Inspection Technique (QSIT)
  – http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074883.htm

• “Quality System Information for Certain Premarket Application Reviews: Guidance for Industry and FDA Staff” 2003

• Global Harmonization Task Force (GHTF) Guidance Document on Supplied Products
Public Notification

• OCER prepares draft recall notices to be posted to the Agency web site
  – Reviewed by OC

• In conjunction with the CDRH webmaster, posts notices to the CDRH Recall Webpage
Outreach Communications

• In order to magnify the message in the recall notice:
  – OCER notifies others within CDRH and FDA via:
    • MedWatch
    • FDA Patient Safety News
    • Office of Enforcement Weekly Report
References and Websites

- Federal Register - June 16, 1978- Part 7
- FDA Regulatory Procedures Manual, Chapter 7 Guidance for firms (Voluntary)
- 21 CFR Part 7 21 CFR Parts 806, 810, 820 (Requirements)
  - [http://www.fda.gov/opacom/Enforce.html](http://www.fda.gov/opacom/Enforce.html) (ORA site)
- FDA Weekly Enforcement Report
  - [http://www.fda.gov/bbs/topics/ENFORCE/ENF00416.html](http://www.fda.gov/bbs/topics/ENFORCE/ENF00416.html)
- Questions – email “CDRH Recall Group” Box or any individual recall branch staff
Questions?

Thank you!