Corrective and Preventive Action

Jay Jariwala
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration

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Disclaimer

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.
Overview

• Background and Requirements
• Why Closed Loop System
• Review CY2012 and CY2013 Quality System (QS) Data
  – Inspection and Warning Letter Data
• Review CY2012 and CY2013 CAPA subsystem Data
  – Inspection and Warning Letter Data
• Recent CAPA Warning Letter Examples
Purpose of the CAPA Subsystem

• Collect and Analyze Information

• Identify and Investigate Existing and Potential Product and Quality Problems

• Take Appropriate, Effective, and Comprehensive Corrective and/or Preventive Actions
CAPA Subsystem in Context

Management Controls

Production & Process Controls

Design Controls

Material Controls

Corrective and Preventive Actions

Records, Documents, & Change Controls

Service Reports

Equipment & Facility Controls
# Definition

<table>
<thead>
<tr>
<th>Key Term</th>
<th>Correction</th>
<th>Corrective Action</th>
<th>Preventive Action</th>
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<tbody>
<tr>
<td>Existing</td>
<td></td>
<td>Reoccurrence</td>
<td>Occurrence</td>
</tr>
<tr>
<td>The Focus Is</td>
<td>Immediate solution</td>
<td>Eliminating the root cause(s)</td>
<td>What could potentially happen</td>
</tr>
</tbody>
</table>
Why is CAPA Important?

• Linked to many other requirements
  – 820.198 Complaint Files
  – 820.90 Nonconforming Product
  – 820.80 Acceptance Activities
  – 820.200 Servicing
  – 820.22 Audits
  – 803 Medical Device Reporting
  – 806 Reports of Corrections and Removals
  – ... and many more

• Ensures problems are detected AND resolved
Why is CAPA Important?

“... The objective of § 820.100 is to correct and prevent poor practices, not simply bad product ... Correction and prevention of unacceptable quality system practices should result in fewer nonconformities related to product. ... For example, it [CAPA] should identify and correct improper personnel training, the failure to follow procedures, and inadequate procedures, among other things”

61 Fed. Reg. at 52633-52634, Comment 162
The CAPA Process

- Analyze
- Investigate
- Identify
- V & V
- Implement
- Disseminate
- Management
- Review
- Document

Elements:
- 820.100(a)(1)
- 820.100(a)(2)
- 820.100(a)(3)
- 820.100(a)(4)
- 820.100(a)(5)
- 820.100(a)(6)
- 820.100(a)(7)
- 820.100(b)
Data Sources

INTERNAL SOURCES
- Inspection/Test Data
- Nonconforming Material Reports
- Equipment Data
- Scrap/Yield Data
- Rework Data
- Returned Product
- Internal Audits
- Process Control Data
- Acceptance Activities

EXTERNAL SOURCES
- Complaints
- Field Service Reports
- Legal Claims
- Warranty Claims
- External Audits
- Medical Device Reports (MDRs)
- Social Media
- Scientific Literature

CAPA
“BIG C” CAPA SYSTEM

Quality Data Sources Within the QMS

- 820.200 Service
- 820.198 Complaints
- 820.170 Installation
- 820.100 CAPA
- 820.90 Nonconforming Prod.
- 820.80 Acceptance Activities
- 820.75(c) Process Changes (PV)
- 820.72 Calibration
- 820.70(b) Production & Proc Chg
- 820.50 Purchasing
- 820.40(b) Document Changes
- 820.30(e) Design Review
- 820.30(i) Design Changes
- 820.22 Quality Audit
- 820.20(c) Management Review
- 803 MDRs
- 806 Corrections & Removals

“Little C” CAPA
100(a)(2) – (7)

Courtesy – Jan B. Welch, OC, CDRH, FDA
CAPA and Risk Management

“FDA agrees that the degree of corrective and preventive action taken to eliminate or minimize actual or potential nonconformities must be appropriate to the magnitude of the problem and commensurate with the risks encountered...FDA does expect the manufacturer to develop procedures for assessing the risk, the actions that need to be taken for different levels of risk, and how to correct or prevent the problem from recurring, depending on that risk assessment”

61 Fed. Reg. at 52633-52634, Comment 159
Closed Loop System

“The involvement of management with executive responsibility, the concept of a total quality system which is a closed feedback loop system, and the practice of using that closed loop system in taking appropriate corrective and preventive action is paramount in ensuring that safe and effective medical devices are available to the public”

61 Fed. Reg. at 52653
## CAPA System Options

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Option</th>
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<tbody>
<tr>
<td>A</td>
<td>No correction required, continue measurement and monitoring</td>
</tr>
<tr>
<td>B</td>
<td>Correction required, continue measurement and monitoring</td>
</tr>
<tr>
<td>C</td>
<td>Correction required, escalation to further investigation under the improvement phase</td>
</tr>
<tr>
<td>D</td>
<td>No correction required, escalation for further investigation under the improvement phase</td>
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Symptoms of a Less than Effective CAPA System

• Recurring issues
• Inability to “manage” sources of quality data to understand early trends and issues
• More reaction than prevention
• Resources are spent on “handling” failure rather than learning from it and preventing “more of the same”
• Field issues
When Does FDA Review CAPA?

- **Establishment Inspections**
  - Quality System Inspection Technique (QSIT) – CAPA Subsystem
  - Compliance Program (7382.845) – Inspection of Medical Device Manufacturers

- **Premarket Approval Applications (PMAs)**
  - Original PMAs
  - PMA supplements e.g. Site changes, 30-Day Notices

- **Recalls**

- **CAPA is NOT Reviewed in 510(k)s**
FDA CY2012 and CY2013 Quality System Data

483 Observations and Warning Letters
CY2012 and CY2013 Data

• Source of data:
  FDA’s Turbo EIR database

• Time frame:
  January 2012 – December 2012
  January 2013 – December 2013
## QS Regulation

### Cites by Subsystem

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Routine Quality System Surveillance Inspections

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<td>196</td>
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<td>2006</td>
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<td>2007</td>
<td>198</td>
<td>1276</td>
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<td>2008</td>
<td>201</td>
<td>1222</td>
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<td>2010</td>
<td>267</td>
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<td>2011</td>
<td>315</td>
<td>1806</td>
</tr>
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<td>2012</td>
<td>378</td>
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## Most Frequent QS 483 Observations

<table>
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<tr>
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<th>No. of Observations</th>
<th>2012</th>
<th>No. of Observations</th>
<th>2013</th>
<th>No. of Observations</th>
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<td>355</td>
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<td>207</td>
<td>820.22</td>
<td>234</td>
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<td>214</td>
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<td>190</td>
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<td>127</td>
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<td>145</td>
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<td>820.25(b)</td>
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<td>820.198(c)</td>
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### 483 Observations

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<th>QS Subsystem</th>
<th>483 Observations</th>
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<tr>
<td></td>
<td><strong>2012</strong></td>
<td><strong>2013</strong></td>
</tr>
<tr>
<td>CAPA</td>
<td>1258 (30%)</td>
<td>1085 (31%)</td>
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<tr>
<td>P&amp;PC</td>
<td>1303 (30%)</td>
<td>1151 (33%)</td>
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<tr>
<td>DES</td>
<td>630 (15%)</td>
<td>506 (14%)</td>
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<td>DOC</td>
<td>469 (11%)</td>
<td>367 (10%)</td>
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<td>MGMT</td>
<td>583 (14%)</td>
<td>425 (12%)</td>
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<tr>
<td>TOTAL</td>
<td>4243</td>
<td>3534</td>
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## CAPA Subsystem 483 Observations

<table>
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<tr>
<th>Citations</th>
<th>Number of 483 Observations</th>
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<tbody>
<tr>
<td></td>
<td>2012</td>
</tr>
<tr>
<td>Complaint Files (820.198)</td>
<td>534 (42%)</td>
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<tr>
<td>CAPA (820.100)</td>
<td>505 (40%)</td>
</tr>
<tr>
<td>Nonconforming Product (820.90)</td>
<td>219 (18%)</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>1258</strong></td>
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Warning Letters
CY2004-2013 Warning Letters (WLs) with QS Citations

<table>
<thead>
<tr>
<th>Year</th>
<th># of WLs</th>
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<tbody>
<tr>
<td>2004</td>
<td>113</td>
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<td>97</td>
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<td>2008</td>
<td>98</td>
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<td>2009</td>
<td>77</td>
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<td>2011</td>
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<td>2012</td>
<td>164</td>
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<tr>
<td>2013</td>
<td>144</td>
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## Numbers of WLs with QS Subsystem Citations

<table>
<thead>
<tr>
<th>QS Subsystem</th>
<th>2012 (164 WLs)</th>
<th>2013 (144 WLs)</th>
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</thead>
<tbody>
<tr>
<td>CAPA</td>
<td>143 (87%)</td>
<td>127 (88%)</td>
</tr>
<tr>
<td>P&amp;PC</td>
<td>134 (82%)</td>
<td>127 (88%)</td>
</tr>
<tr>
<td>DES</td>
<td>91 (55%)</td>
<td>91 (63%)</td>
</tr>
<tr>
<td>DOC</td>
<td>78 (48%)</td>
<td>77 (53%)</td>
</tr>
<tr>
<td>MGMT</td>
<td>70 (43%)</td>
<td>71 (49%)</td>
</tr>
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</table>
Numbers of QS Citations in WLs

2012

- DOC: 131 (12%)
- DES: 174 (16%)
- P&PC: 331 (30%)
- CAPA: 342 (32%)
- MGMT: 107 (10%)

2013

- DOC: 108 (12%)
- DES: 156 (17%)
- P&PC: 286 (30%)
- CAPA: 276 (29%)
- MGMT: 112 (12%)
## CAPA Subsystem Warning Letter Cites

<table>
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<tbody>
<tr>
<td></td>
<td>2012</td>
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<tr>
<td>Complaint Files (820.198)</td>
<td>154 (45%)</td>
</tr>
<tr>
<td>CAPA (820.100)</td>
<td>130 (38%)</td>
</tr>
<tr>
<td>Nonconforming Product (820.90)</td>
<td>54 (16%)</td>
</tr>
<tr>
<td>Acceptance Status (820.86)</td>
<td>4 (1%)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>342</td>
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CAPA
Warning Letter Examples
Warning Letter Example
CAPA Procedures

• Your firm failed to establish, maintain, and implement a corrective and preventive action procedure, as required by 820.100(a). For example,
  – Your firm has no CAPA procedures as defined in the QS regulation including: failure investigation, procedures to analyze quality data...procedures to verify/validate corrections, procedures that ensure that information related to quality problems is disseminated and for submitting relevant information on identified quality problems to management for review.
Warning Letter Example
CAPA Procedures

• Failure to establish and maintain adequate procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a).
  – For example, the firm's procedure XYZ, does not include requirements for analyzing sources of quality data (other than complaints) to identify existing and potential causes of nonconforming product, or other quality problems. Nor does the procedure require documentation of the verification/validation of corrective and preventive actions to ensure that such action is effective and does not adversely affect the finished devices.
Warning Letter Example

Verification/Validation of a CAPA

- Failure to establish and maintain adequate procedures for verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4).
  - For example, no protocol, including acceptance criteria, was established for the validation of Change Request XYZ. Additionally, there was no documentation showing that this change was validated. The change was implemented to fix cracked cooling pumps in the device.
Warning Letter Example

Verification/Validation of a CAPA

• Failure to establish and maintain adequate procedures to verify or validate corrective action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4).
  – For example, based upon the investigation of the cause of irradiation batches receiving doses below the specified minimum dose requirement (due to incorrect packaging and product density), the firm implemented new packaging procedures and retrained employees. Irradiation batches receiving doses below the specified minimum dose requirement have recurred after implementation of the cited corrective action. The firm’s management stated that the recurring nonconformities may be attributed to employees not following directions.
Warning Letter Example

Verification/Validation of a CAPA

• Failure to establish and maintain adequate procedures for verifying or validating corrective and preventive action to ensure that such action is effective, as required by 21 CFR 820.100(a)(4).

  – For example, CAPA XYZ involved the sticking of silicone tubing used in monitors when the devices remained out of use for 3-6 months. In reaction, you implemented a design change (the addition of a talcum coating to the tubing). Your procedure did not ensure that the corrective action was verified or validated as effective in preventing the sticking of silicone tubing in distributed products.
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

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

• Global Harmonization Task Force (GHTF) Guidance Document on Corrective and Preventive Action
Providing Industry Assistance

CDRH Resources

- **CDRH Learn**
  - Modules include various premarket and post-market information
  - Available 24/7
  - Certificate generated per topic upon passing post-tests

- **Device Advice**
  - Self-service website
  - Searchable by topic
  - [http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm)

- **Division of Industry and Consumer Education (DICE)**
  - Technical Assistance for the Medical Device Industry
  - 301-796-7100
  - DICE@fda.hhs.gov
Discussion

jay.jariwala@fda.hhs.gov  | (301) 796-5573