The Quality System Inspection Technique: “QSIT”

QSIT Workshops
Introduction

- What is QSIT?
- How we inspect with QSIT
- QSIT findings
- Implementing QSIT
What is QSIT?

- Moves FDA closer to Global Harmonization guideline for regulatory auditing of quality systems of medical device manufacturers
- Incorporates the seven subsystems concept
- Provides specific guidance on auditing each subsystem
Quality System’s Sub-systems

- Design Controls
- Corrective & Preventive Actions
- Production & Process Controls
- Equipment & Facility Controls
- Material Controls
- Records, Documents, & Change Controls
- Corrective & Preventive Actions
- Management
Major Themes of QSIT
Theme #1 = Management

- Management is responsible for Implementing Quality System
- Start & Finish with Management
- All product, process, design & CAPA problems can be tied to management
Inspection Conclusion

“Did management ensure that an adequate and effective Quality System has been established?” (Mgt. #7)
Theme #2 = CAPA

- We are checking the “system”
  - Non-conformances happen
  - What kind of system does the firm have?
  - Is the system effective?
Management

Controls

Design Controls
Material Controls
Records, Documents, & Change Controls
Corrective & Preventive Actions
Production & Process Controls
Equipment & Facility Controls
The Inspection Approach

- Top-down (versus Bottom-up)
- Sampling records (use tables)
- Pre-inspection activities (ask for and review documents)
- Start and end with Management
How Will Each Subsystem be Inspected?

- QSIT Guide
  - Purpose and Importance
  - Objectives
  - Flow charts
  - Narratives
  - Sampling Plans
Establish - [21CFR 820.3(k)]

- Define
- Document
- Implement
The “Establish” Test

- Proof of “Establish”
  - Is the firm doing what regulation says?
  - Is the firm doing what their procedure says?
The “Establish” Test

- Proof of “Establish”
  - Is the firm doing it adequately?
  - Bore down...using:
    » Vertical Probes
    » Sampling
Order of Systems

- Management
- Design
- CAPA
- Production & Process Controls
- Conclude with Management
QSIT Findings
In-Plant Time

Average Hours

- Mgmt.
- Design
- CAPA
- PAPC
- QSIT Total

- 4.2
- 5.2
- 10.7
- 8.1
- 28.2
QSIT FDA 483’s

200 Total (FDA 483) Items
QSIT Inspection Classifications

<table>
<thead>
<tr>
<th></th>
<th>OAI</th>
<th>VAI</th>
<th>NAI</th>
</tr>
</thead>
<tbody>
<tr>
<td>QSIT</td>
<td>21</td>
<td>45</td>
<td>34</td>
</tr>
<tr>
<td>non-QSIT</td>
<td>19</td>
<td>42</td>
<td>39</td>
</tr>
</tbody>
</table>
Implementing QSIT

- Training on-going
- Compliance Program
- Industry Workshops
- Monitoring and Improvements
Compliance Program

- Incorporates Several Program areas
- Utilizes QSIT
- Uses Three Levels of Inspection
- Establishes OAI

**SUBJECT:**
INSPECTION OF MEDICAL DEVICE MANUFACTURERS

**IMPLEMENTATION DATE:**
Upon Receipt of Final Document

**COMPLETION DATE:**

**DATA REPORTING**

<table>
<thead>
<tr>
<th>PRODUCT CODES</th>
<th>PRODUCT/ASSIGNMENT CODES</th>
</tr>
</thead>
<tbody>
<tr>
<td>73-91</td>
<td>82830L-42830L</td>
</tr>
<tr>
<td></td>
<td>82830C-42830C</td>
</tr>
<tr>
<td></td>
<td>82830F</td>
</tr>
<tr>
<td></td>
<td>82830A</td>
</tr>
<tr>
<td></td>
<td>82830B</td>
</tr>
<tr>
<td></td>
<td>81011</td>
</tr>
</tbody>
</table>

(To Be Assigned)
(To Be Assigned)

Field Reporting Requirements

**483s.** A copy of all FDA 483s issued as a result of inspections conducted under this program should be sent to HFZ-306 for entry into the national 483 database.

**EIRs.** All EIRs and administrative/regulatory action recommendations should be sent to HFZ-306. Send an EIR to CDRH, HFZ-306, only if the inspection resulted in an OAI classification.

**Warning Letters.** A copy of all Warning Letters should be sent to HFZ-306 and HFC-210.
One Last Item

- HACCP vs. QSIT
  - QSIT is NOW
  - HACCP is FUTURE
    » HACCP is being tested.
    » Possible role is........
For Further Information

Tim Wells or Chris Nelson
Quality System Inspections
Reengineering Team
2094 Gaither Road, HFZ-300
Rockville, Maryland, USA 20850
301-594-4611
For Further Information

- **QSIT Website:**
  - www.fda.gov/cdrh/gmp/gmp.html

- **QSIT Study:**

- **QSIT “Guide”:**
  - www.fda.gov/cdrh/gmp/qsitbook.html
    » Changed to........
Thank You