The Quality System Inspection Technique:

“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 Subsystems
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

Theme #2 = CAPA

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

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
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?
  - Is the firm doing it adequately?

Order of Systems

- Management
- Design
- CAPA
- Production & Process Controls
- Conclude with Management
Not in the Law

- Preannounced Inspections
  - Call prior to inspection to advise firm of inspection
  - Request copies of Quality Policy and high level Quality System Procedures
- FD-483 Annotation
- Post Inspection Notification

As required by law

- Credentials displayed
- Written Notice of Inspection
- List of Observations
  - FD-483

Preparation

- Assignment
  - Compliance Program
  - Inspectional Guidance
- Past history
  - District files
  - Previous investigator
Preparation

• MDR Database
• Complaints
  – Customer complaints to FDA
  – Trade complaints
• Headquarters
  – 510(k)/PMA reviewers

On-site

• Introductory discussion
  – Purpose of the inspection
  – Rough schedule - time estimate
  – Special needs
    • Firm
    • FDA

• Overall plant tour
  – Overview of operations
  – Location of key operations
  – Production flow
  – Include offices
On-site

- Complaint file review
  - Numbers of complaints
  - Types of complaints
  - Trends
  - MDR's

On-site

- Manufacturing operations
  - Start with incoming materials
  - Follow process to completion
  - Look at the details of each process
- Support procedures
  - Calibration
  - Training
  - Change procedures
  - Audit procedures

Record Review

- Device Master Record
- Device History Records
  - Chosen at random
  - Chosen from complaint files
- Incoming Inspection reports
  - may be separate from DHR's
Record Review

- In-process Inspection reports
  - may be separate from DHR's
- Service records
  - may be included in complaint file review
- Calibration records
- Maintenance records

Close out

- Issue FD-483
  - To most responsible person
  - Listing of problem areas
  - Includes examples

Close out

- Discuss FD-483
  - Has corrective action been initiated?
  - Are issues understood?
  - Is management serious about correction?
  - Will a written response be forthcoming?
Close out

- Discuss other findings
  - Minor problems
  - Areas without problems
    - Was anything being done right?

Post inspection

- Establishment Inspection report
  - Prepared
  - Reviewed
- Follow up assignments
  - Sample collections
  - Investigate complaints or service reports

Post inspection

- Initiate action
  - Warning letter
  - Injunction
  - Seizure
  - Prosecution
Any regulation establishing a requirement pursuant to clause (i) of the preceding subsection shall be authorized such device and distributors to elect, in lieu of immediately furnishing such information to the same extent to hold and present such information until required by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 332, and (ii) provides that the device or distributor shall, upon making such election, give prompt notice to such arsenic together with information identifying the maker and the product to the manufacturer and shall, when disdain to the manufacturer or Secretary, or the need thereof for the purposes of section 332, immediately furnish the manufacturer with the required information. If a maker or distributor distributes the device in a distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection continuing to purchase from the manufacturer other than would have done so if continued and may use it only if necessary to the purpose of notifying persons pursuant to section 332(a).

Sec. 386. (1) It shall be unlawful—
(2) ***
(3) ***
(4) "For any person to fail or to refuse to establish or maintain

Records required by this subsection or to submit copies by the Secretary or to any duly authorized representative or, or the copying of such records, or of any permit or inspection, as required or pursuant to section 332(a)."

Part 5 – Quarantine and inspection

Sec. 381. (a) "The Surgeon General, with the approval of the Secretary is authorized to refuse and order such requirements as in his judgment are necessary to prevent the introduction, transmission, or spread of quarantinable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possessions. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, identification, disinfection, destruction or withholding of articles found to be in infected or diseased as to be the source of quarantinable diseases or human beings, and other measures as in his judgment may be necessary."
<table>
<thead>
<tr>
<th>FIRM NAME</th>
<th>STREET ADDRESS</th>
<th>CITY, STATE AND ZIP CODE</th>
</tr>
</thead>
</table>

DURING AN INSPECTION OF YOUR FIRM IT WAS OBSERVED:

<table>
<thead>
<tr>
<th>EMPLOYEE'S SIGNATURE</th>
<th>EMPLOYEE'S NAME AND TITLE (Position)</th>
<th>DATE ISSUED</th>
</tr>
</thead>
</table>

FORM FDA 483 (8/06)  PREVIOUS EDITION OBSOLETE  INSPECTIONAL OBSERVATIONS  PAGE OF PAGES
The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment: (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."