Medical Devices
QSIT Then and Now
Tips and Tools for FDA
Compliance and Building Stronger Internal Quality Systems

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Learning Objectives

• What to expect during an FDA QSIT inspection
• Tips on preparing for the inspection.
  – Tips for preparing your SMEs to address risks with FDA investigators
• Best practices for understanding your Device Inspection risks and how they relate to current FDA Inspection trends

Format: Lecture, Group Discussions & Final Exam
TOPIC ONE
What to expect during an FDA QSIT * Inspection

• Expect the unexpected
• Little consistency between Investigators
• Little consistency between Districts

FDA still does QSIT - but it may not necessarily follow the traditional QSIT approach.

* QSIT = Quality System Inspection Technique
• Management is responsible for establishing a quality system.
“Quality management is the responsibility of all levels of management but must be led by top management. Its implementation involves all members of the organization.”

ISO 8402:1994
Management Controls
The Beginning and the End ...

1. Management Controls
2. Design Controls
3. Corrective and Preventive Actions
4. Production and Process Controls
5. Management Controls
QSIT Theme # 2

• CAPA Happens!
How QSIT Works: CAPA

Corrective and Preventive Actions (CAPA) …

QSIT auditors should look at the “system” as opposed to the “gotcha” approach.

How did you deal with problems once they were brought to your attention?
How QSIT Works: CAPA

• Nonconformities happen
  – Was the CAPA System “established”?  
  – Is the CAPA System “effective”?  

• Don’t expect to get “Credit” for doing the right thing if you never opened a CAPA!
(1999) Principle of QSIT
CAPA

• Focus on teaching firms to have systems, rather than looking at a product problem

Teach a man to fish!
Group Discussion

• Knowing FDA will look at your CAPAs do you avoid putting things (issues) in CAPA to keep them from being so visible?

• What are the pros and cons of putting things (issues) in CAPAs?
Is QSIT Alive or Dead?

• It is still used
• Don’t expect it to go away
• It may be changed
• Even CDER uses a QSIT type approach

The issue is not QSIT. The issue is using it or not!
More and more inspections are bottom-up.
What were the benefits of QSIT

• We all know the play book
  – The book is pretty easy to understand
    • 38 or 211?

• Inspection time decreased, focus increased.

• 38 Key areas in the Quality System

• Industry has been using the tool in reverse
  – Learn what FDA expects and be prepared
What is QSIT?
The Standard QSIT Inspection

- The four Main systems
  - Management Controls
  - Design Controls
  - CAPA
  - PPC
FDA’s Medical Device Quality System Inspection Types

Abbreviated QSIT – Two subsystems; Corrective and Preventive Actions (CAPA) plus Production and Process Controls (P&PC) or Design Controls

Comprehensive QSIT - The four major subsystems; Management Controls, Design Controls, CAPA and P&PC

Compliance Follow-up* - As directed by inspectional guidance and elements of QSIT

Special For Cause* - As directed by inspectional guidance and elements of QSIT

Special Risk Based Work Plan - As directed by CDRH inspection assignment and elements of QSIT

Source: FDA Compliance Program 7382.845

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Other Systems Often Inspected

– Supplier Controls
– Risk Management
– Control of Nonconforming Product
– Complaints and MDR
– Corrections and Removals
Downsides for Industry with Over-Reliance on QSIT

• You can’t ignore the non-QSIT areas
• FDA Still expects compliance to all 211 requirements
• It’s not FDA’s only Weapon
Non-QSIT areas FDA inspects

- Supplier Controls (820.50)
- Risk Management (beyond 830.30(g))
- Complaint Investigations & Trending (feeders to CAPA) (820.198 & 820.100)
- Nonconforming Product (820.90)
- Training (820.50)
Examples
Recent FDA-483s

- Procedures have not been adequately established to control product that does not conform to specified requirements. Specifically …..

- Requirements that must be met by suppliers have not been adequately established. Specifically, According to the your Supplier Evaluations Procedure XXXX "Critical and Major observations will be tracked for proper closure based on supplier CAPA plan." The following were not adequately tracked for closure: YYYYY
Examples

• Procedures for training and identifying training needs have not been adequately established. Specifically, your training procedures are inadequate in that:
  – Your training procedure allows for new procedures and work instructions to become effective prior to employees being trained.
Some Key Questions to Look Out for during FDA Inspections

- Did you ship that?
- Are you still shipping?

- Example is findings related to process validation.
- Shipping Records are an important signal.
- Remember: FDA is protecting the American Public from medical devices that may present a risk of harm and enforcing the “adulteration” laws.
Group Discussion

- Why are QSIT Inspections Inconsistent?
- How do we prepare for QSIT Inspections knowing that?
TOPIC TWO
Tips on preparing for the inspection.

• Have Subject Matter Experts (SMEs)
• Have Proof Books
• Have Objective Evidence
• Plan and Rehearse
You can play (some) Offense or You can play (only) Defense
You need to be prepared
For All Three of These

• Each Quality System Area
  – Especially the “QSIT” areas
  – In theory you should have 18 SMEs

• All FDA-483 items and all Warning Letter items
  – Have a SME and Proof Book for each

• All recalls and high MDR reported area
  – These are your “product issue” SMEs
Example list of QS SMEs Needed

- Management responsibility.
- Quality audit.
- Personnel.
- Design controls.
- Risk Management
- Document controls.
- Purchasing controls.
- Production and process controls.
- Inspection, measuring, and test equipment.
- Process validation.
- Receiving, in-process, and finished device acceptance.
- Nonconforming product.
- Corrective and preventive action.
- Device master record.
- Device history record.
- Complaint files.
- Servicing.
- Statistical Techniques.
Other SMEs Needed

- Each Recall
- High MDR issues
- HHE/HHA and those devices not recalled

- Each FDA- 483
- Each Warning Letter item
- Including those from your parent, sister or child sites
Roles during FDA Inspections

• Facilitators – One for each Investigator
• Scribes - One for each Investigator & back-ups
• Runners - One for each Investigator
Audit Room

Auditor

Facilitator

Runner

SME

Scribe(s)

Back-up SME or Instant Messenger
Break Out Exercise
Inspection Management

• List good practices for handling FDA inspections that you think may have worked.
• List examples where FDA complimented you during an inspection.
• List any examples where you felt you may have been able to drive the inspection, as opposed to being driven.
TOPIC THREE
Best Practices for Passing FDA Inspections

• Get top management involved
  – Robust Internal Audits
    • Use 3rd parties as needed
  – Robust Management Reviews
    • Metrics and Scorecards
  – Compliance Master Plans
    • PMO and Work Streams
Some Best Practices

• Link complaint system with design control risks
• Use aggressive risk management in PPC
• Risk applies in Complaints, Supplier Controls, CAPA, Training, Auditing, NCP, Etc., Etc.

Note: Both the Preamble and ISO 13485 mention “risk” management throughout the quality system and throughout product realization.
Some Best Practices

• **Apply Risk throughout the Quality System**
  – CAPAs
  – Complaint System
  – PPC
  – Design Controls
  – Supplier Controls
  – Management Controls
WELL DON'T SAY I DIDN'T WARN YOU

RISK ASSESSMENT

5 MPH
DANGER SIGN ON FLOOR
MAY BE HEAVY
NOT Eatable
MONKEYS

SPEECH BUBBLE UNSTABLE
TURBULENCE RISK
WILL RUIN EYESIGHT
PAPER CUTS!
INDUCES MADNESS

HOT
DANGER SMOKE INHÄNATION
MAY CAUSE DIZZINESS

DREW
Some Best Practices
Use the Quality System to Fix the Quality System

• Open CAPAs to address product issues
• Open CAPAs to address quality system issues
• Use Quality Plans
  – For changes to the Quality System
  – Changes such as Moves (location), PPC or Software changes
• No “Rogue” systems
• Document
Best Practices
Comprehensively Handle FDA Findings

• All FDA-483 items must be addressed
• All Warning Letter item must be addressed

How?
• Locally and Systemically
• Globally?
• What about Retroactively?
Best Practices
Repeats are “OAI”

• “Noncorrection or inadequate correction of major deficiencies from previous inspection(s).
• Repeat deficiencies of same or similar deficiencies from previous inspection(s).
• If any major deficiencies exist, the district is expected to classify the EIR as OAI”

Source: FDA Compliance Program 7382.845
Best Practices
Legacy Clean Up

• Develop Protocols for each area for Legacy clean up – Remediation Work

  Most Important are:

  – Complaints
  – MDR
  – CAPAs
  – Validations
  – CSVs
Hire Someone to Do the Legacy Work

• Internal or 3rd Party
  – Follow the Protocols
    • Do the Review
    • Do the Re-Work
  – Document each item reviewed
  – Write Reports
Break Out Exercise

• List good practices that FDA liked.
• List examples that you think as best practices.
• List any examples or “repeats” noted by FDA during inspections.
Break Out Exercise

• Share experiences with Legacy Reviews
• Share experiences with Legacy Clean-ups
What Puts You at Risk with FDA

• Warning Letters
  – At any of your sites

• Recalls
  – Good and Bad news with recalls

• MDRs
  – Under Reporting
  – Actual Reporting
What Puts You at Risk with FDA

• Your Reputation
  – FDA talks among themselves.

• Your “relationship” with local District
  – Is it strained or healthy?

• Any “honesty” issues with FDA
  – During a recent inspection did the investigator tell you he thought you were lying or misleading?
  – Does FDA think you have been “hiding” things?
What Puts You at Risk with FDA

• Your attitude towards FDA
  – How to you treat the Investigator?
  – Are your people arrogant or cocky?
  – Do you withhold information, or take days to fill a document request? Do you bring in the wrong information (on purpose)?
  – Has your company had an adversarial relationship with the local FDA?
  – Has the local FDA brought in “big guns” from HQ?
What Puts You at Risk with FDA

• Your Class of Devices matters
• Risk-Based inspections result in
  – Over Inspecting some
  – Under Inspecting others
• PMAs versus 510(k)s
  – Pre-Approval inspections
Break Out Exercise

• What are FDA’s Hot Buttons?
• What bad things happened during an inspection, and how did you handle those?
• Cite examples of FDA going bonkers during an inspection.
Two Types of Inspections
Top Down Device Inspection

- Management System
- Design Control System
- CAPA System
- Production & Process Control System

Final Determination Made

Systems are Adequate & Effective?

Etc.
Bottom-Up Inspection

Event

- Procedures
- Training records
- Product Testing
- PPC or Lab
- Validations

Investigation or CAPA

- Procedures
- Material acceptance
- Trends
- Effectiveness
- Validations
- Procedures
Sometimes you get both!
Classifying Findings
Practices in Industry & FDA

• Industry uses several models
  – Major, Minor
  – Critical, Major, Minor
  – Major, Minor, Concern

• FDA uses only one model
  – FDA-483 items are always Major

You should treat every FDA finding as Major
When to Worry
When to Worry During Inspections

• The investigator has asked for shipping records
  ─ They want to demonstrate Interstate Commerce
    • Why this is important.

• The investigator has an Affidavit for someone to sign
  ─ They want to demonstrate responsibilities and knowledge
    • Why this is important.
What should you do?

• Shipping Records
  – You must provide them!

• Affidavits
  – Do not sign them
  – Do not listen to them
  – Do not acknowledge them
  – Do not acknowledge listening to them
  – Do not initial any errors

• Notify Your Attorneys
Group Discussion

• Which is more effective bottom-up or top-down inspections in terms of finding issues?
• Which is more potentially damaging to us?
• Do your internal audits mirror top down or bottom up inspections?
Final Exam 1
Which are Hotter Findings?

- CAPA Effectiveness lacking
- Processes not validated
- Risk Analysis uses inappropriate settings
- Nonconforming product not quarantined
- Design Validations not done properly
- MDRs were not filed
- Supplier controls are not adequate
- FDA not notified of recalls
- Training metric is at 80% accomplished
Final Exam 2
True or False

- FDA Inspections are predictable.
- We should plan, prepare and practice for inspections.
- FDA will follow the QSIT manual.
- Previous 483 items probably won’t be re-inspected when FDA returns.
- We are confident that we can drive the FDA adequately during inspections.
- We prefer top-down versus bottom up inspections.
- FDA will warn us if they deviate from QSIT.
- If we handle the logistics well during inspections that should make up for gaps in our quality system.
Any Questions?