The Quality System Inspection Technique: "QSIT"

QSIT Workshops

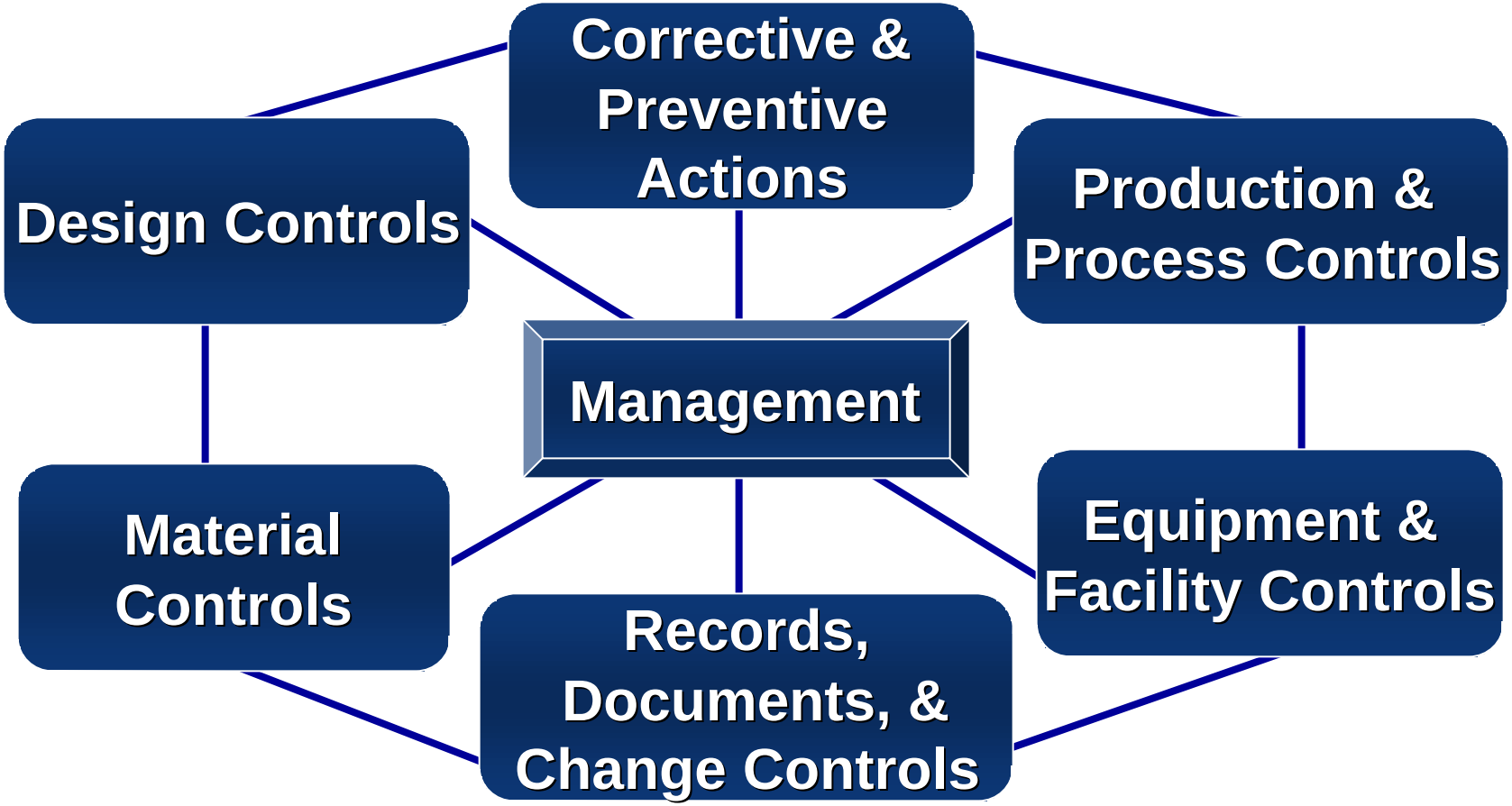
Introduction

- 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



Major Themes of QSIT

Theme #1 = Management

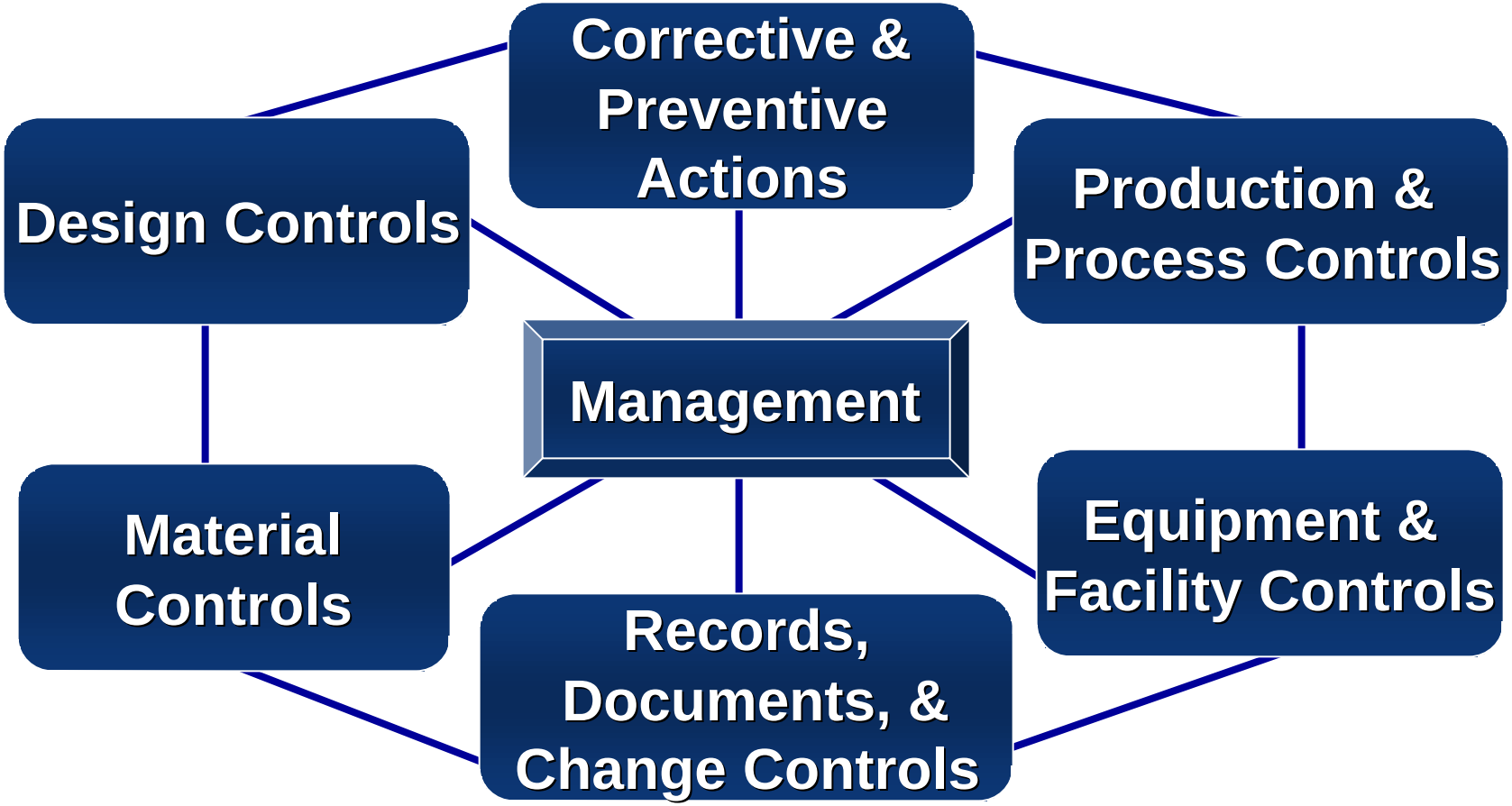
- **Management is responsible for Implementing Quality System**
- **Start & Finish with Management**
- **All product, process, design & CAPA problems can be tied to management**

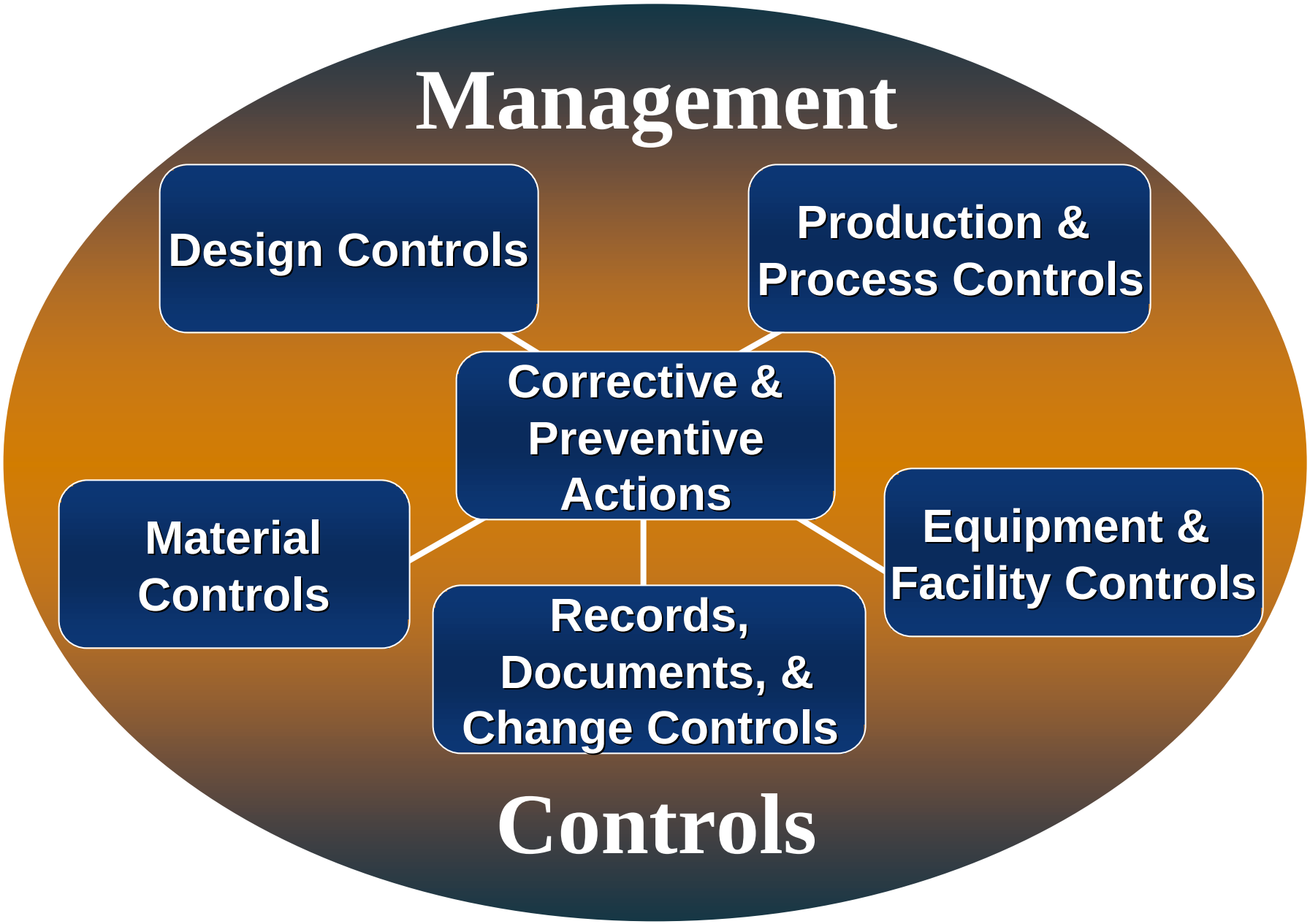
Inspection Conclusion

“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?**


Corrective & Preventive Actions
Design Controls
Production & Process Controls
Management
Material Controls
Equipment & Facility Controls
Records, Documents, & Change Controls


Management
Design Controls
Production & Process Controls
Corrective & Preventive Actions
Material Controls
Equipment & Facility Controls
Records, Documents, & Change Controls
Controls

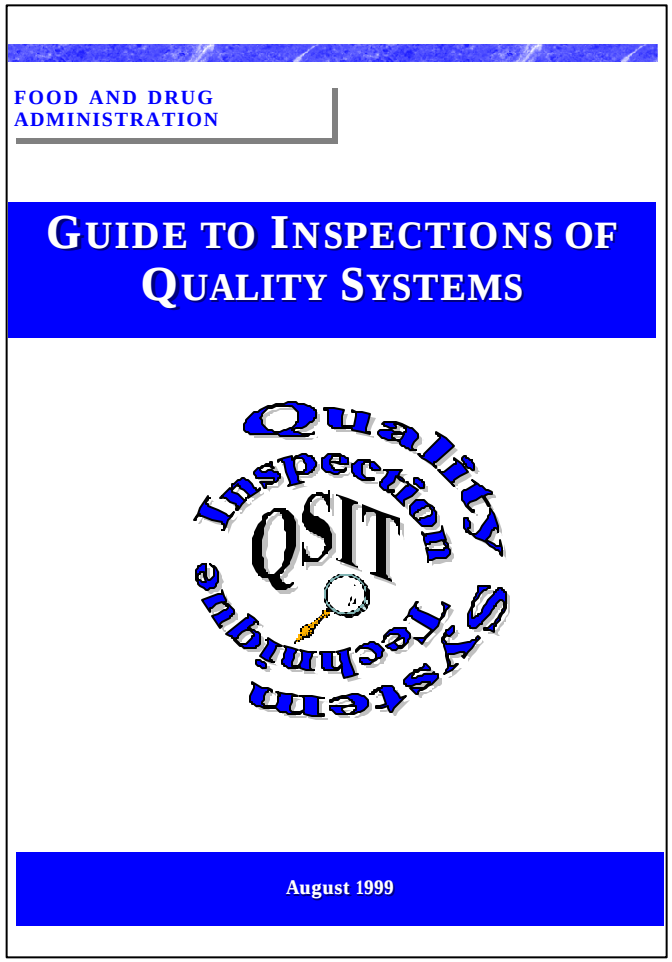
The Inspection Approach

- Top-down (versus Bottom-up)
- Sampling records (use tables)
- Pre-inspection activities (ask for and review documents)
- Start and end with Management


Reports of Corrections and Removals
Medical Device Reporting
Medical Device Tracking
Corrective & Preventive Actions
Facility & Equipment Controls
Design Controls
MANAGEMENT
Material Controls
Production & Process Controls
Records/ Documents/ Change Controls
Sterilization Process Controls

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?**

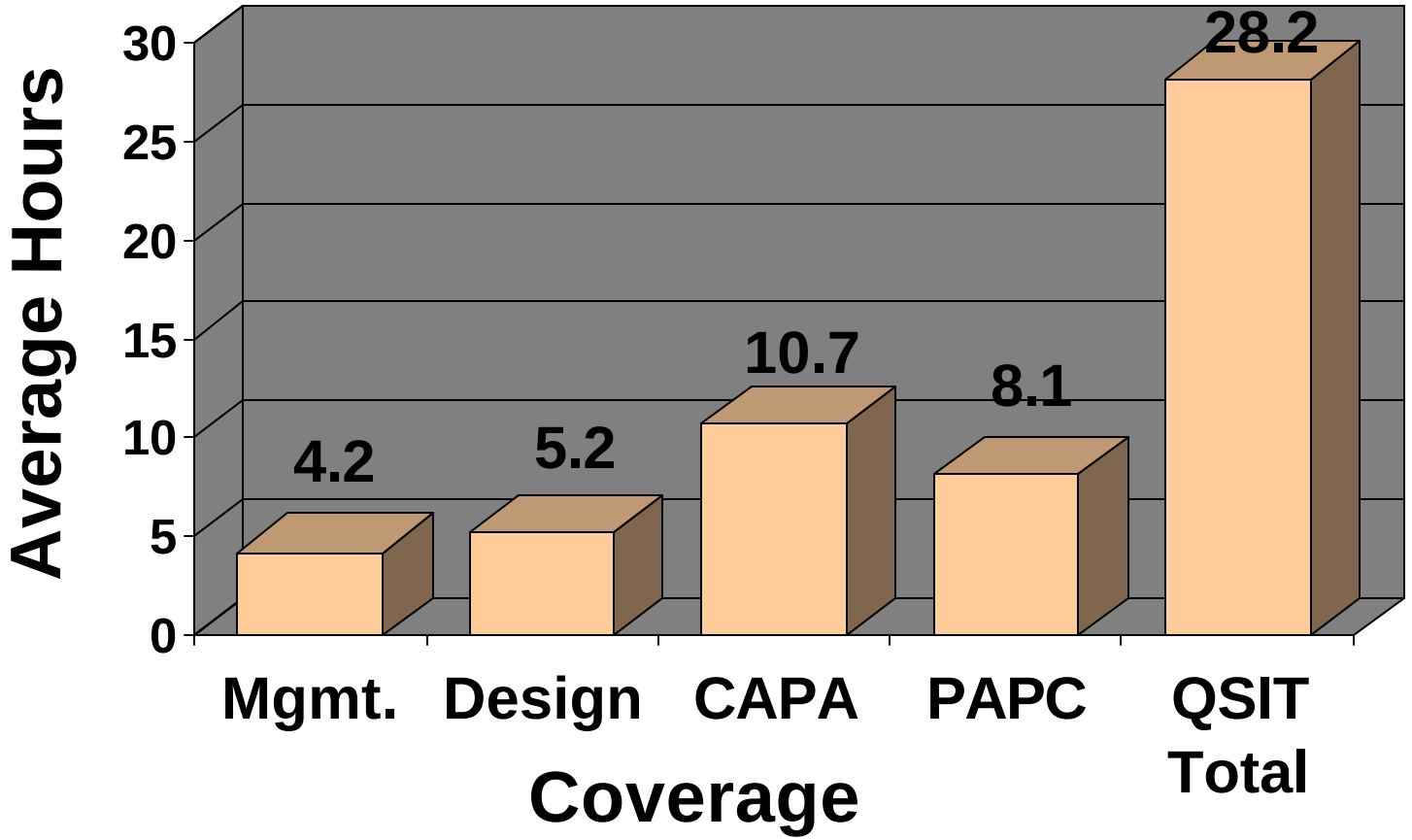
The “Establish” Test

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

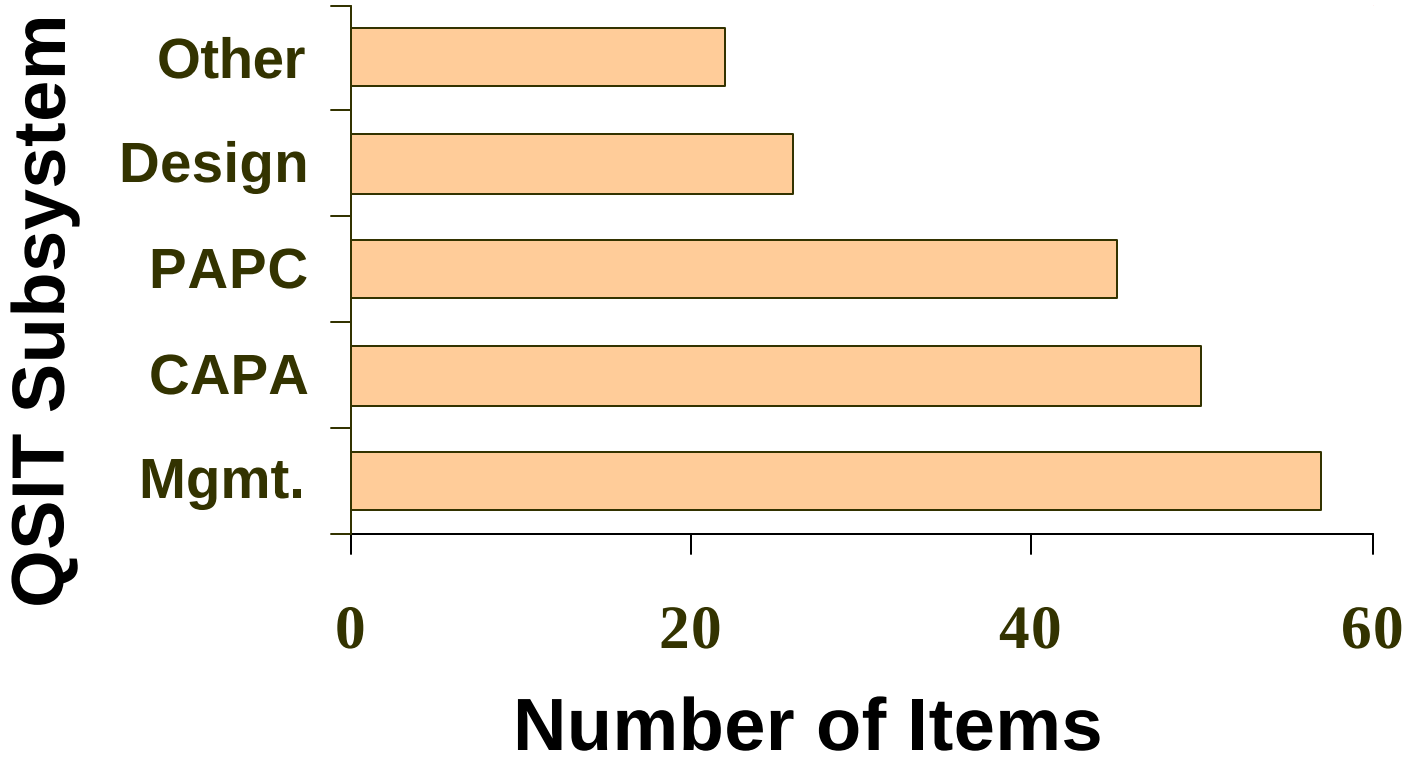
Order of Systems

- Management
- Design
- CAPA
- Production & Process Controls
- Conclude with Management

QSIT Findings
In-Plant Time

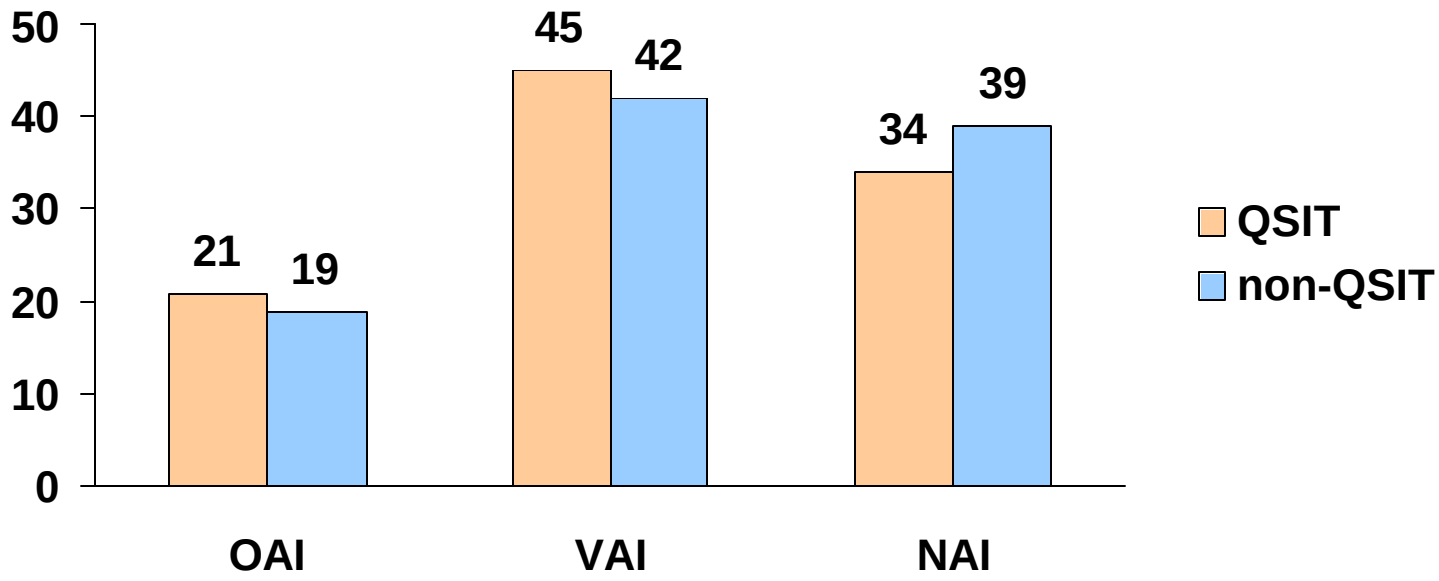


QSIT FDA 483's



200 Total (FDA 483) Items

QSIT Inspection Classifications



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:	IMPLEMENTATION DATE
INSPECTION OF MEDICAL DEVICE MANUFACTURERS	Upon Receipt of Final Document
	COMPLETION DATE

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
73-91	82830L 42830L -- All Level 1 (Routine) Inspections 82830C 42830C -- All Level 2 (Initial or Comprehensive) Inspections 82830F -- All Level 3 (Compliance Follow-up) Inspections 82830A -- Report Time spent on Assessment of Firm's Sterilization processes 82830B -- Contract Sterilizers Inspections 81011 -- Report Time spent on Assessment of Firm's MDR Practices (To Be Assigned) -- Report Time spent on Assessment of Firm's Tracking Practices (To Be Assigned) - - Report Time spent on Assessment of Firm's Corrections and Removals Practices

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

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For Further Information

- **QSIT Website:**
  - **www.fda.gov/cdrh/gmp/gmp.html**
- **QSIT Study:**
  - **www.fda.gov/cdrh/gmp/qsit-study.pdf**
- **QSIT "Guide":**
  - **www.fda.gov/cdrh/gmp/qsitbook.html**
    - **» Changed to…….**

Thank You