

# QSIT Management Controls

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**QSIT Workshops**



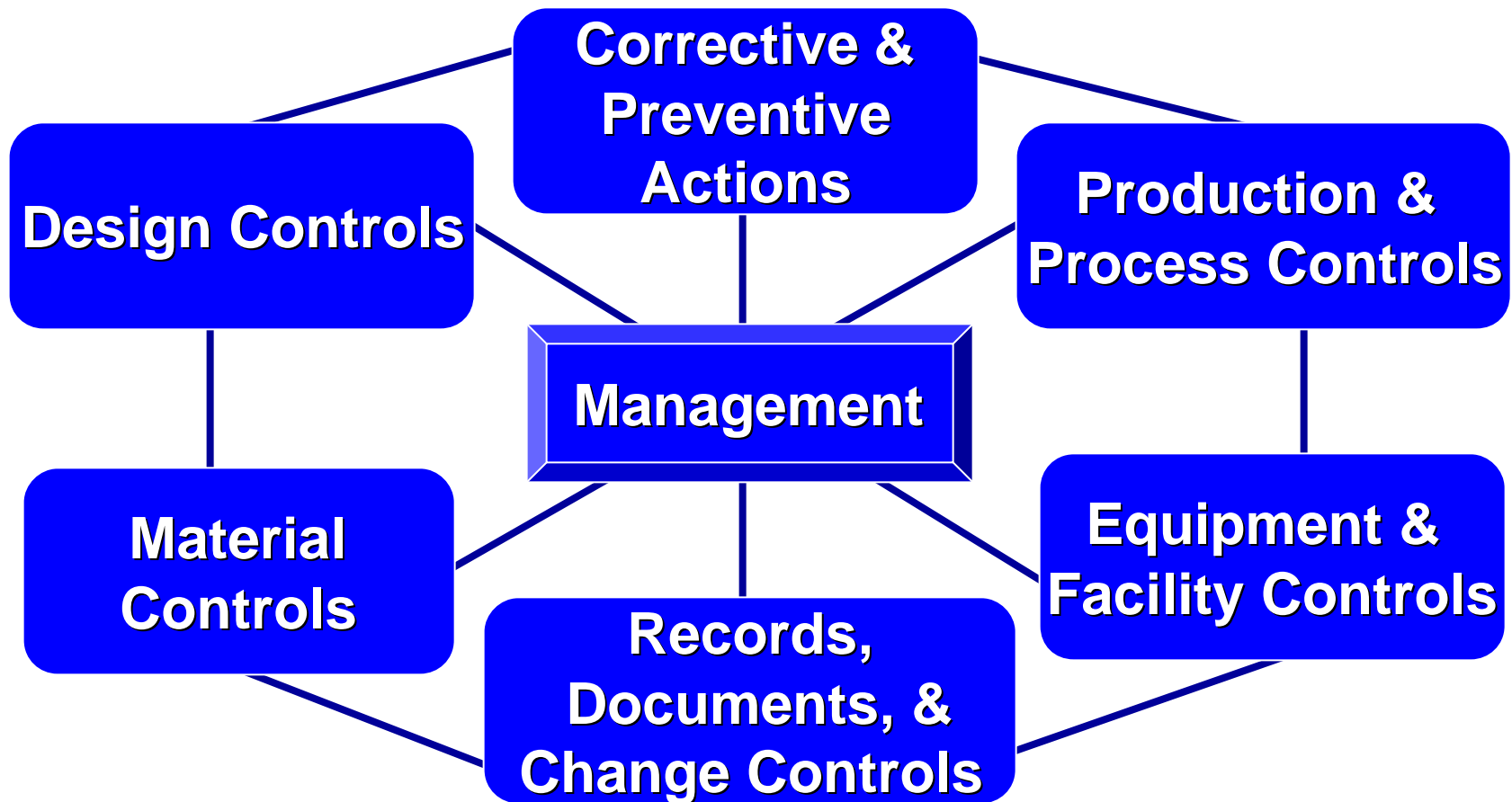
# Management Controls

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- ◆ **Importance**
- ◆ **Assessment**
- ◆ **Demonstration of Compliance**

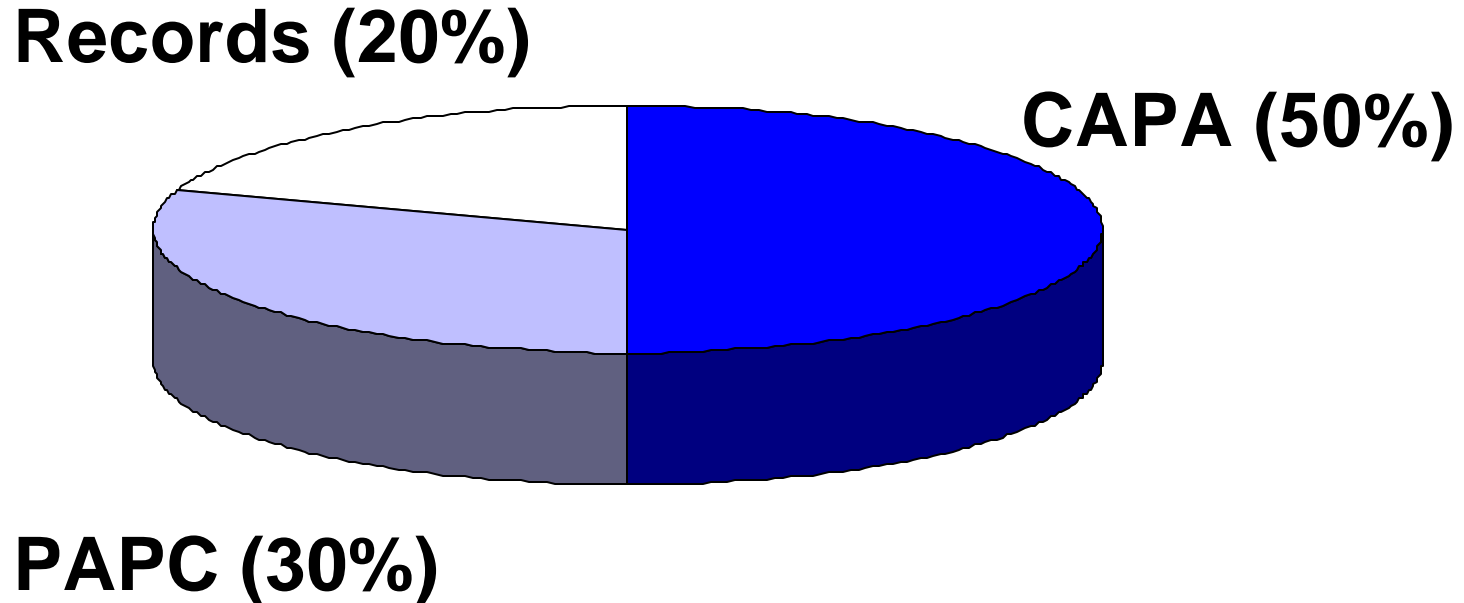
# Quality System

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# Top Ten FDA 483 Items

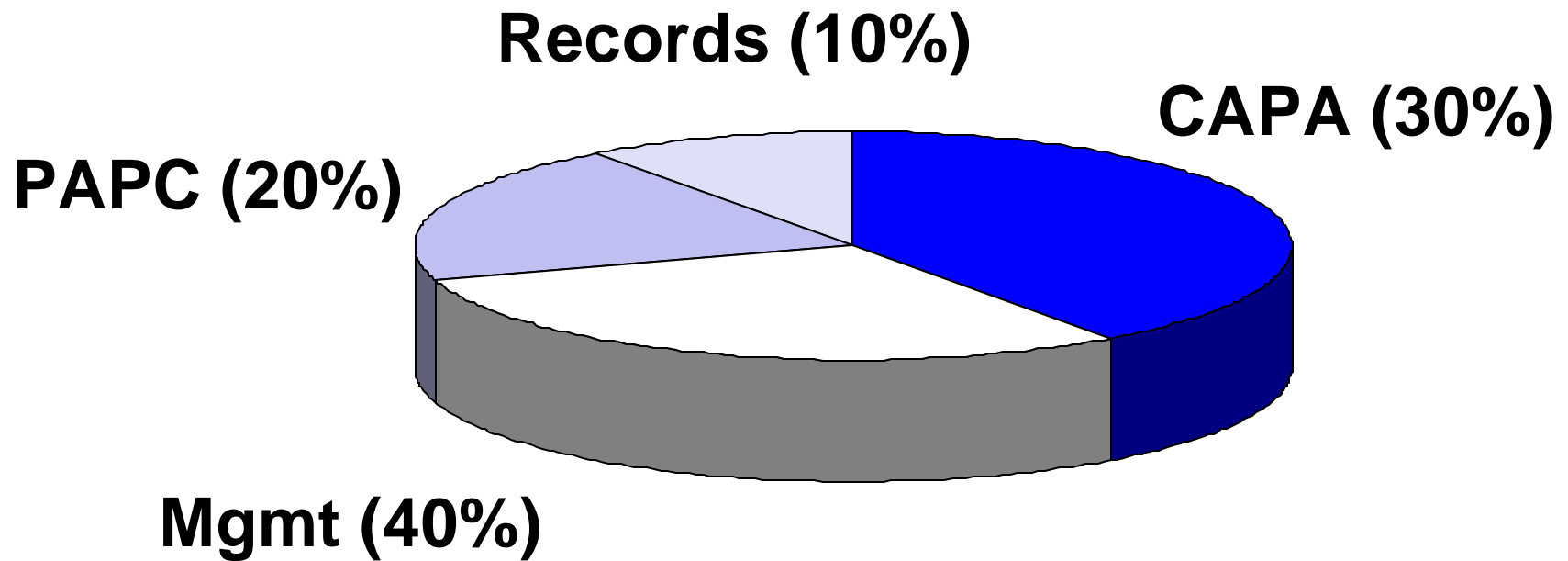
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**Non-QSIT Inspections**

# Top Ten FDA 483 Items

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**QSIT Inspections**

# QSIT Progression

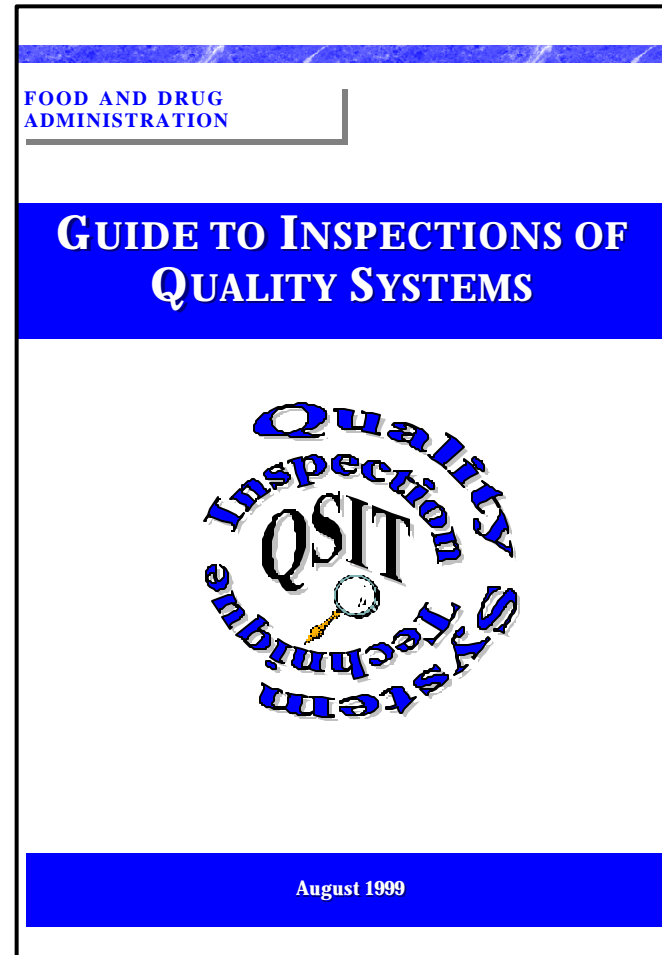
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- 1. Management Controls*
- 2. Design Controls**
- 3. Corrective and Preventive Actions**
- 4. Production and Process Controls**
- 5. Management Controls*

# How Will Management be Inspected?

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- ◆ **QSIT Guide**
  - Purpose and Importance
  - Objectives
  - Flow chart
  - Narratives



# Assessment

**“Top Down” - *Defined and Documented***

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## **1. Quality Policy**

**Management Review Procedures**

**Quality Audit Procedures**

**Quality Plan**

**QS Procedures and Instructions**



# Assessment

## “Top Down” - *Implemented*

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- 2. Quality Policy and Objectives**
- 3. Organizational Structure**
- 4. Management Representative**
- 5. Management Reviews**
- 6. Quality Audits**

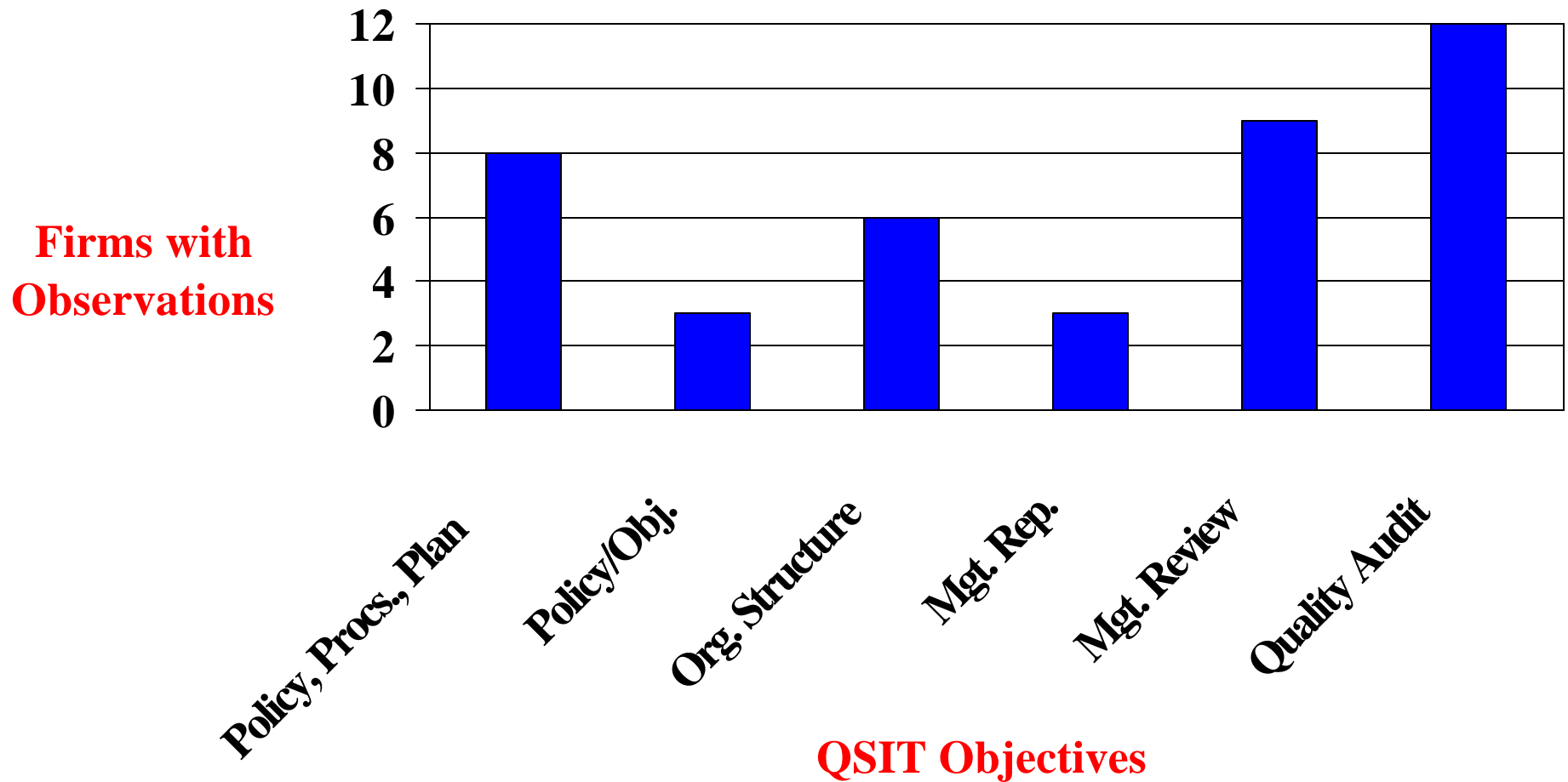
# Assessment

## “Top Down” (At Inspection Conclusion)

### **7. Quality System Established and Maintained**

# QSIT Study Findings

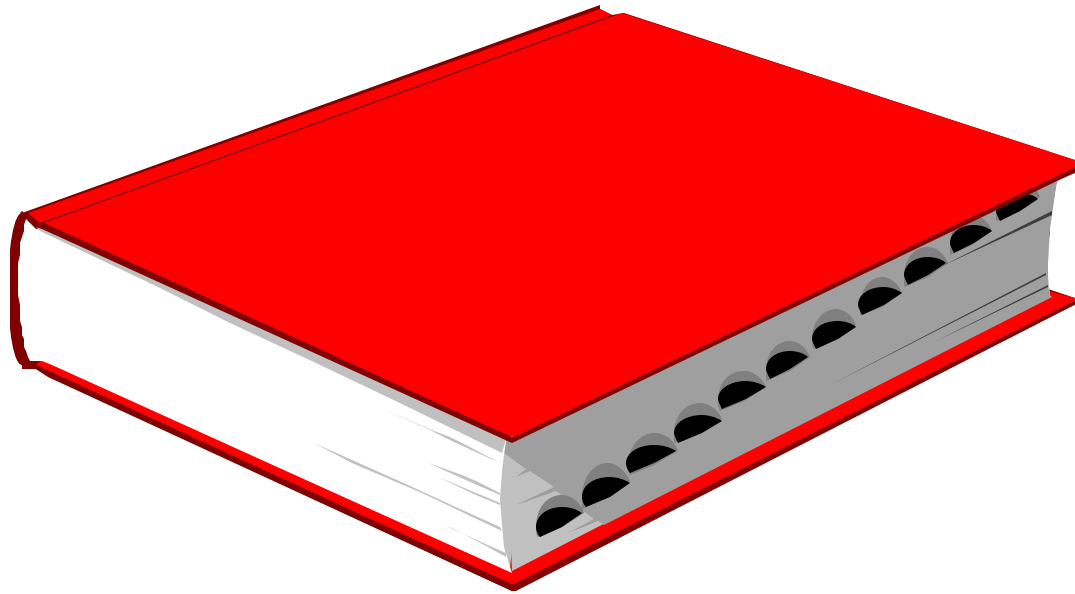
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(Population = 42 Firms)

# Terms and Definitions

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# **Management with Executive Responsibility - 820.3(n)**

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- ◆ **Those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy and quality system**
- ◆ **Possess responsibility, authority and power**

# Management Representative

## 820.20(b)(3)

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- ◆ **Has established authority over and responsibility for:**
  - **Ensuring the quality system requirements are effectively established and maintained**
  - **Reporting on the performance of the quality system to management with executive responsibility to review**

# **Quality Policy - 820.3(u)**

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- ◆ **The overall intentions and direction of an organization with respect to quality**
- ◆ **As established by management with executive responsibility**

# **Quality System - 820.3(v)**

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- ◆ **The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management**



# **FDA's Authority to Hold Management Responsible**

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- ◆ **FD&C Act - Section 704(a)(1)**
- ◆ **21 CFR 820.20**
- ◆ **Case Law - Dotterweich & Park**
- ◆ **FDA will determine authority and responsibility to the highest level of the firm as well as the corporation or organization.**

# **Delegation by Management with Executive Responsibility**

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- ◆ **Establishment of quality objectives**
- ◆ **Translation of objectives into methods and procedures**
- ◆ **Implementation of quality system**

# Responsibility of Highest Level of Management

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- ◆ **Establish Quality Policy**
- ◆ **Ensure that it is followed**

# **How to Demonstrate Compliance**

- ◆ **Procedures ...**
- ◆ **Verbal Communications**
- ◆ **Written records and documents**

# **Establish [21CFR 820.3(k)]**

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◆ **Define**

◆ **Document**

◆ **Implement**

# What FDA Evaluates

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- ◆ **Duties**
- ◆ **Responsibilities**
- ◆ **Authorities**

# **Procedures ... FDA Looks At**

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- ◆ **Quality Policy**
- ◆ **Quality Plan**
- ◆ **Management Review**
- ◆ **Quality Audit**
- ◆ **Quality System Procedures and Instructions**

# **Verbal Communications FDA “Looks At”**

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- ◆ **Management with Executive Responsibility**
  - **Commitment to quality**
  - **Dialogue during daily “wrap-ups”**
  - **Commitment to correction and prevention**



# **Verbal Communications FDA “Looks At”**

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- ◆ **Management Representative**
  - **Interviewed prior to review of each subsystem**
  - **Provide overview of each subsystem**
  - **Demonstrate knowledge and understanding of each subsystem**
  - **Dialogue during daily “wrap-ups”**

# Verbal Communications FDA “Looks At”

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## ◆ Employees

- Familiar with the Quality Policy
- Other dialogue

# **Written Records/ Documents FDA Looks At**

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- ◆ **Organizational Structure**
- ◆ **Appointment of Management Representative**

# Written Records/ Documents FDA Looks At

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- ◆ **Documentation that audits were conducted as scheduled.**
- ◆ **Documentation that management reviews were conducted as scheduled.**

# **FDA Access to Audit and Management Review Reports**

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- ◆ **FDA's policy relative to the review of quality audit reports is stated in CPG 7151.02 (CPG Manual subchapter 130.300).**
- ◆ **This policy restricts FDA access to a firm's audit reports.**

*more...*

# **FDA Access to Audit and Management Review Reports**

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- ◆ **Under the Quality System**

**Regulation, this restriction extends to reviews of supplier audit reports and management reviews.**

*more...*

# **FDA Access to Audit and Management Review Reports**

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- ◆ However, the **procedures** that show conformance with 21 CFR 820.50, Purchasing Controls, and 21 CFR 820.20(3)(c), Management Reviews, and 21 CFR 820.22, Quality Audit, **are subject to FDA inspection.**

# **FDA Access to Audit and Management Review Reports**

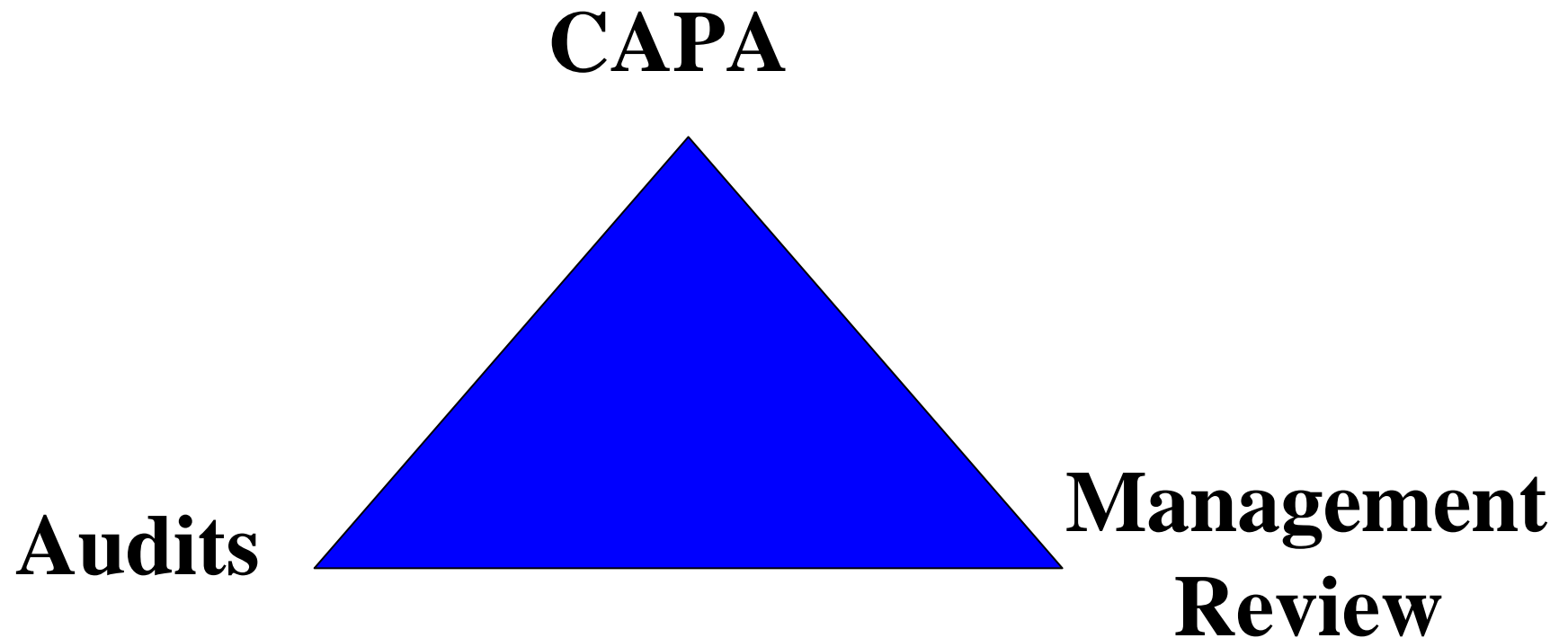
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- ◆ **FDA may look at those portions of these audit reports and reviews that contain corrective and preventive actions if these are the only places these action decisions are documented.**



# How does Management Assure an Effective Quality System?

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# At the Conclusion of the Inspection ...

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**“Evaluate whether management with executive responsibility ensures that an adequate and effective quality system has been established and maintained.”**

# Exercise

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