

QSIT Management Controls

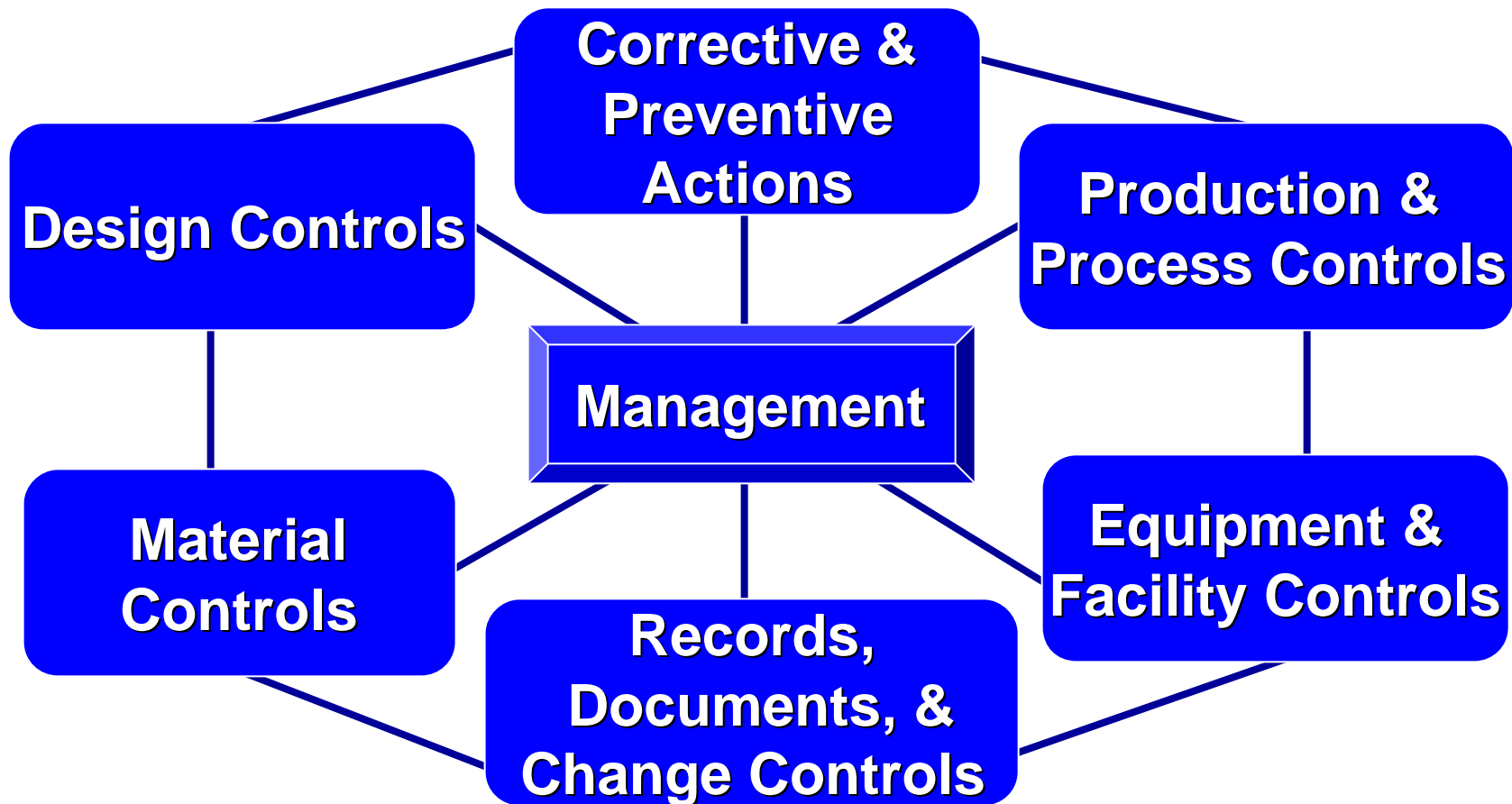
QSIT Workshops



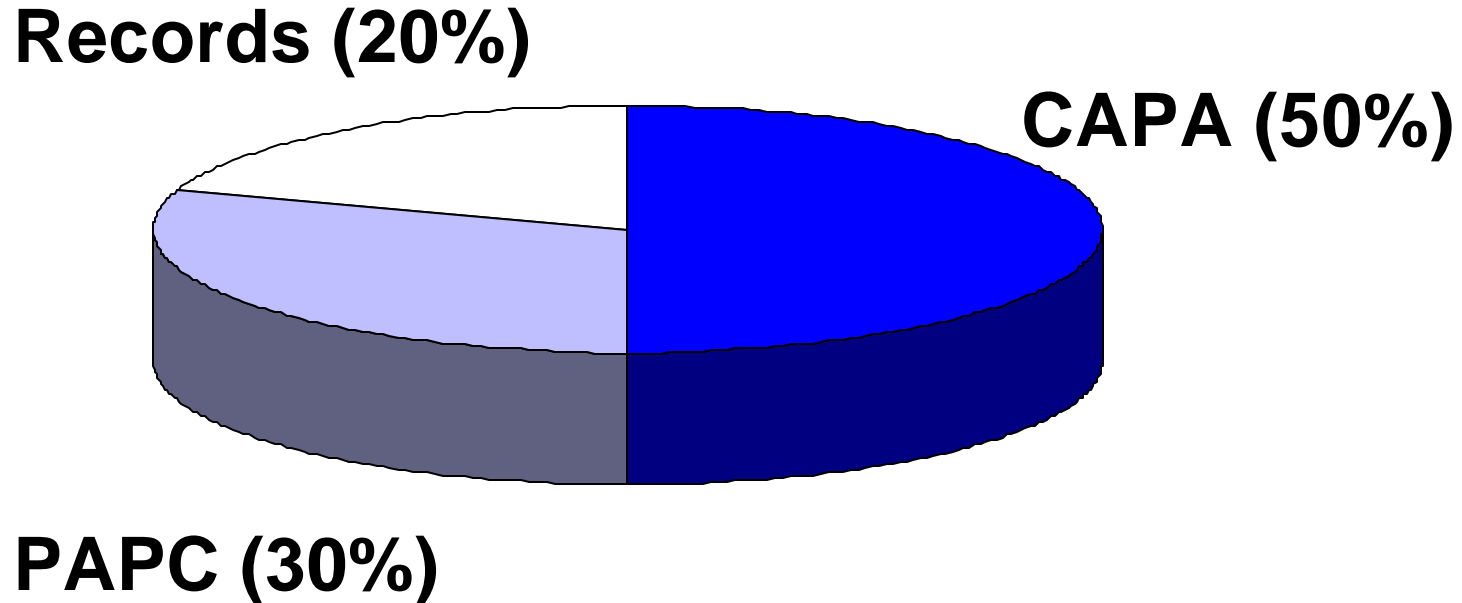
Management Controls

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

Quality System

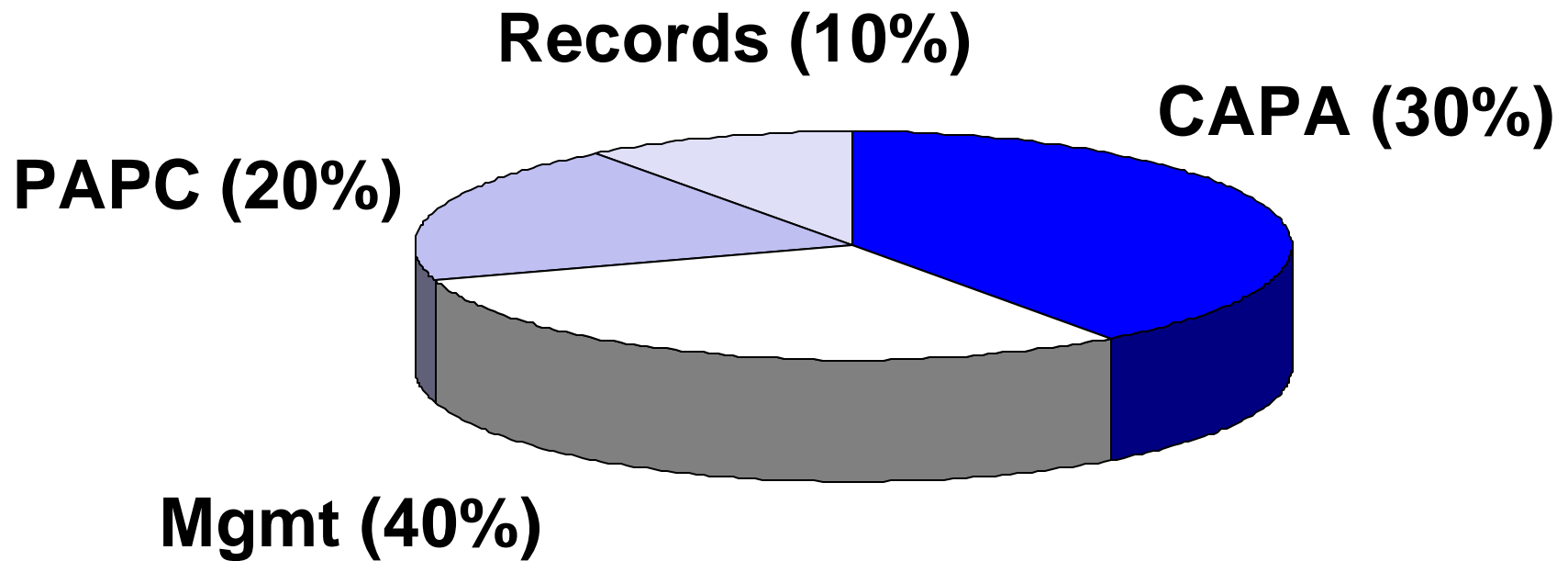


Top Ten FDA 483 Items



Non-QSIT Inspections

Top Ten FDA 483 Items



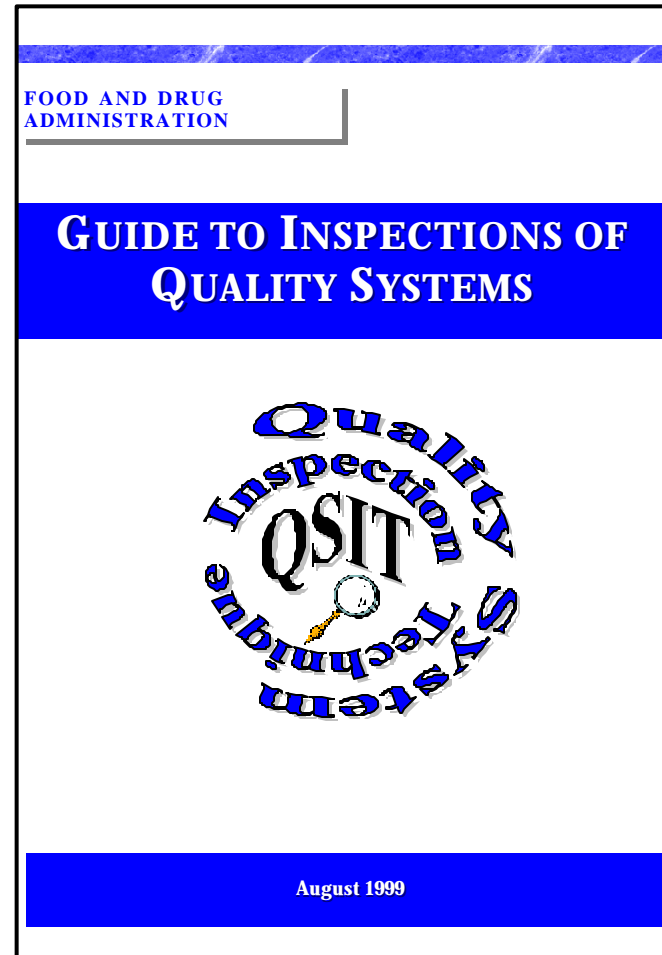
QSIT Inspections

QSIT Progression

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

How Will Management be Inspected?

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



Assessment

“Top Down” - *Defined and Documented*

1. Quality Policy

Management Review Procedures

Quality Audit Procedures

Quality Plan

QS Procedures and Instructions

Assessment

“Top Down” - *Implemented*

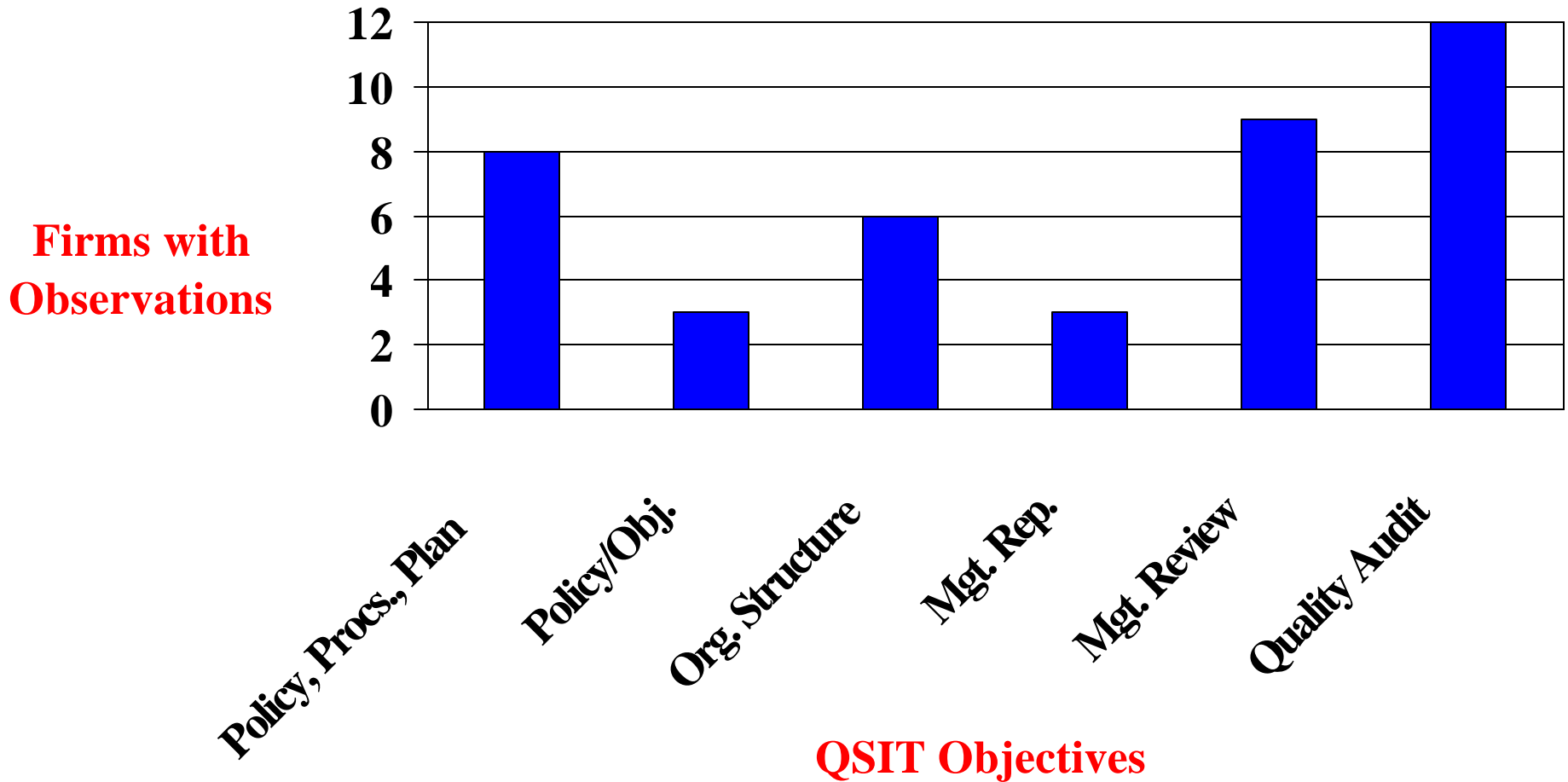
- 2. Quality Policy and Objectives**
- 3. Organizational Structure**
- 4. Management Representative**
- 5. Management Reviews**
- 6. Quality Audits**

Assessment

“Top Down” (At Inspection Conclusion)

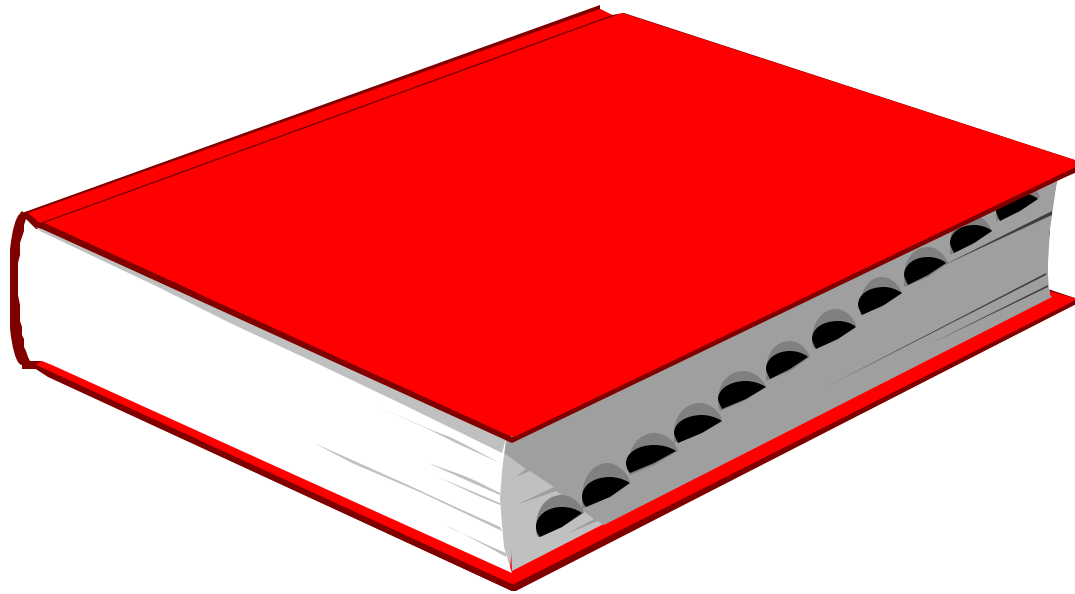
7. Quality System Established and Maintained

QSIT Study Findings



(Population = 42 Firms)

Terms and Definitions



Management with Executive Responsibility - 820.3(n)

- ◆ **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)

- ◆ **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)

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

Quality System - 820.3(v)

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

FDA's Authority to Hold Management Responsible

- ◆ **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

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

Responsibility of Highest Level of Management

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

How to Demonstrate Compliance

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

Establish [21CFR 820.3(k)]

◆ **Define**

◆ **Document**

◆ **Implement**

What FDA Evaluates

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

Procedures ... FDA Looks At

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

Verbal Communications FDA “Looks At”

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

Verbal Communications FDA “Looks At”

- ◆ **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”

◆ Employees

- Familiar with the Quality Policy**
- Other dialogue**

Written Records/ Documents FDA Looks At

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

Written Records/ Documents FDA Looks At

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

FDA Access to Audit and Management Review Reports

- ◆ **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

- ◆ **Under the Quality System**

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

more...

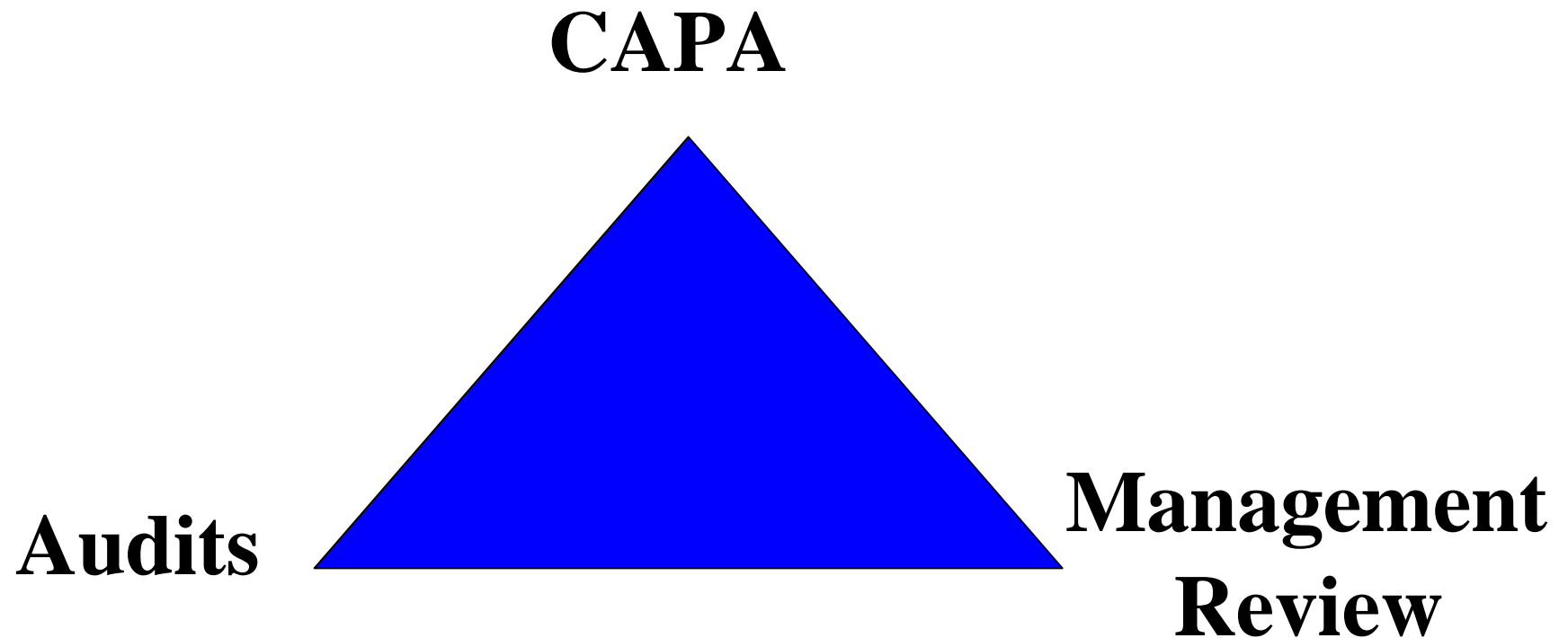
FDA Access to Audit and Management Review Reports

- ◆ 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

- ◆ **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?



At the Conclusion of the Inspection ...

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

Exercise

