

QSIT Corrective & Preventive Actions

QSIT Workshops



Corrective & Preventive Actions (CAPA)

- ◆ **Importance**
- ◆ **Assessment**
- ◆ **Data**

Management

Design Controls

Production &
Process Controls

Corrective &
Preventive
Actions

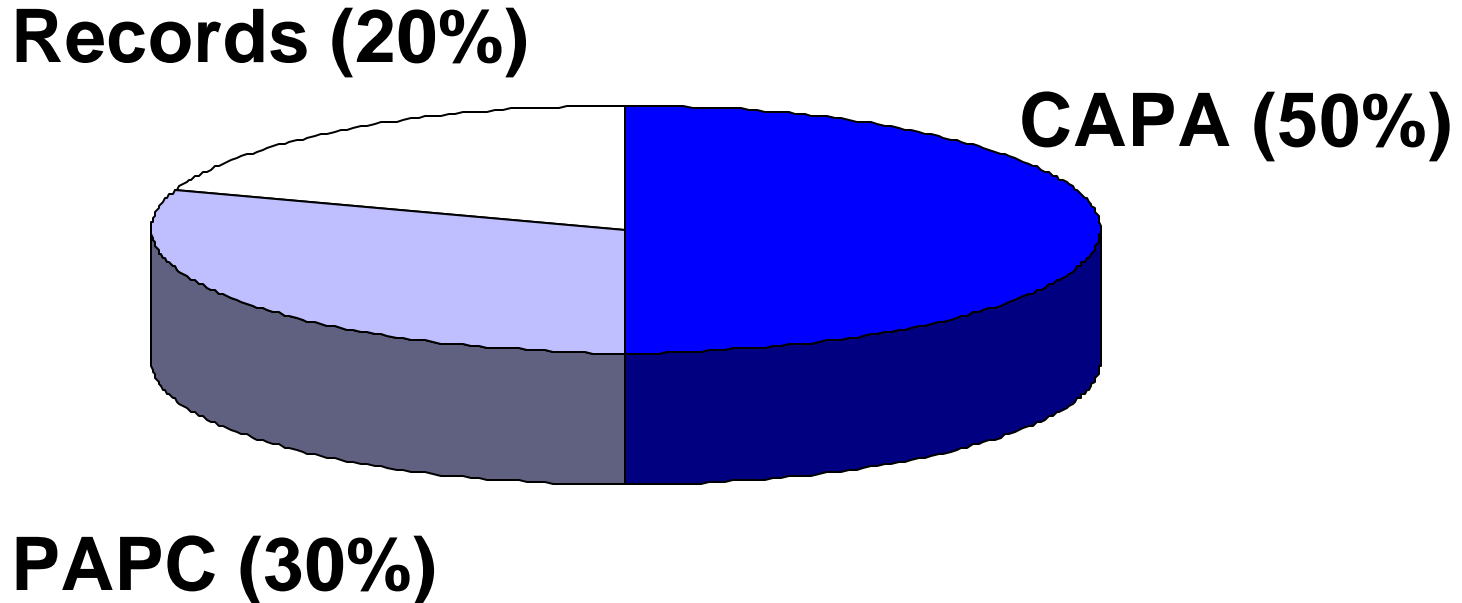
Material
Controls

Equipment &
Facility Controls

Records,
Documents, &
Change Controls

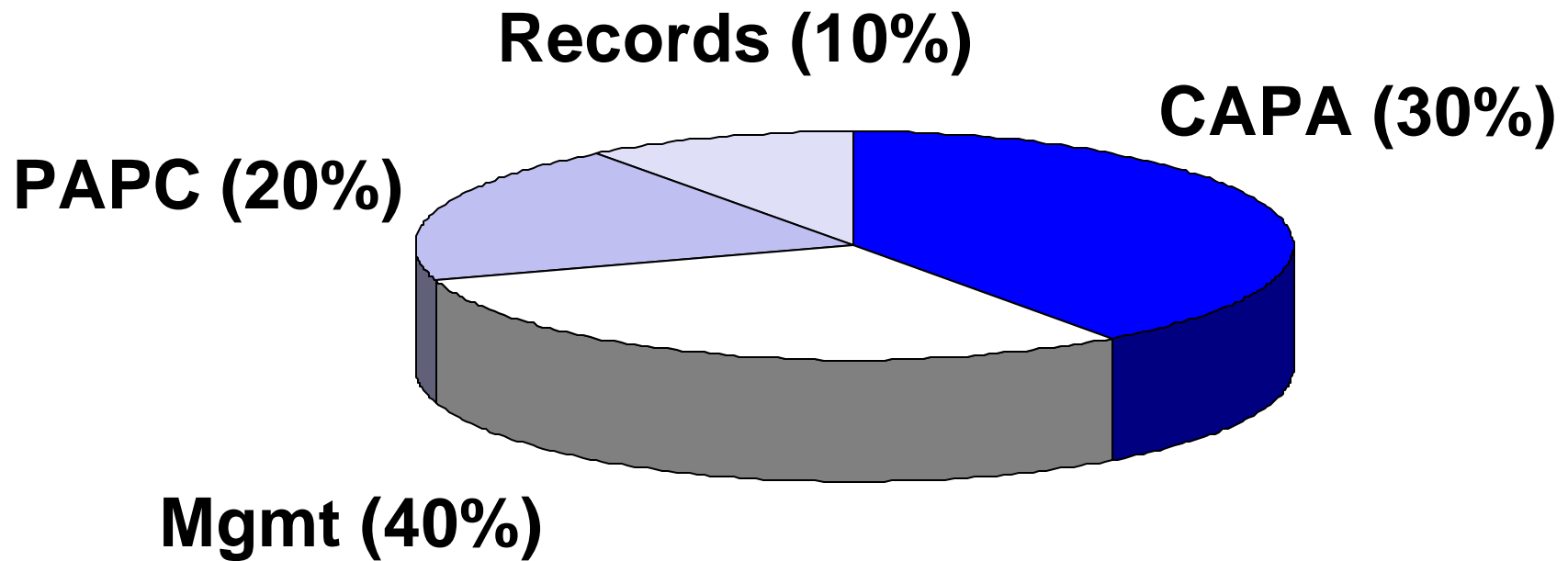
Controls

Top Ten FDA 483 Items



Non-QSIT Inspections

Top Ten FDA 483 Items



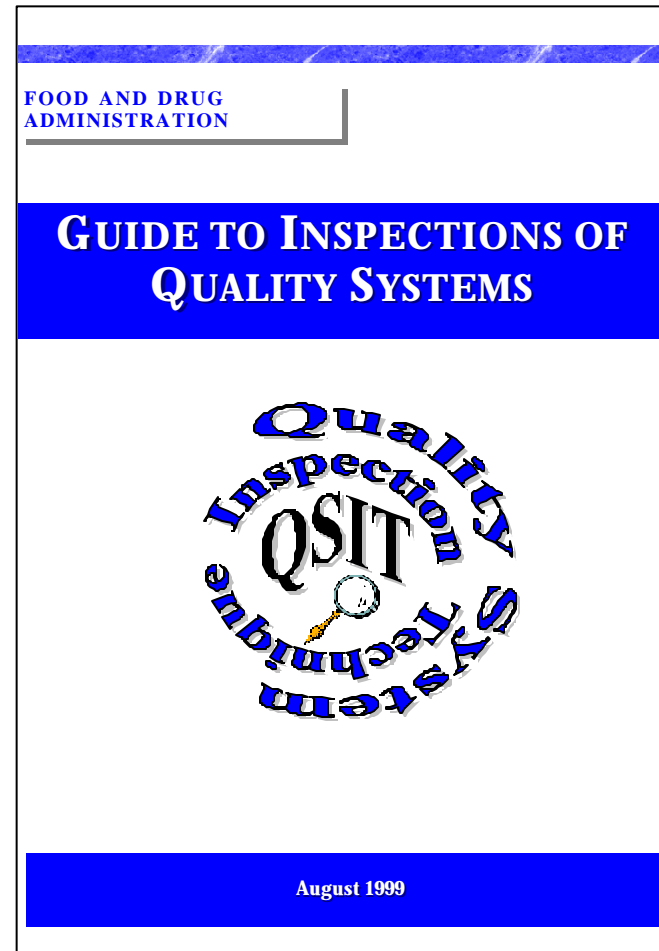
QSIT Inspections

QSIT Progression

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

How Will CAPA be Inspected?

- ◆ **QSIT Guide**
 - Purpose and Importance
 - Objectives
 - Flow charts
 - Narratives
 - **Sampling Plans**



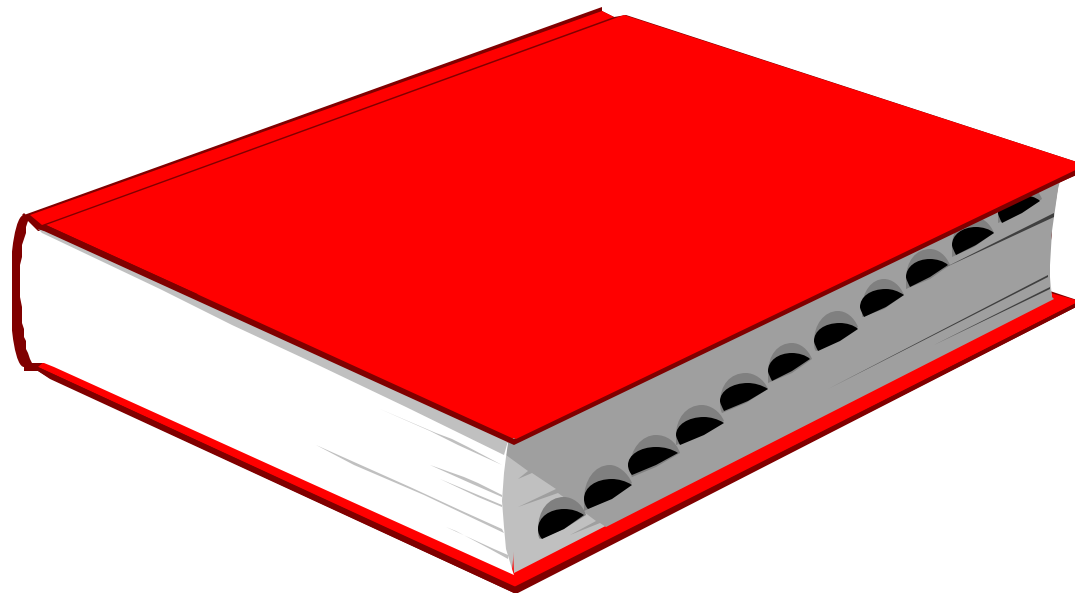
Assessment

“Top Down” - *Defined and Documented*

1. CAPA system procedures

- Address the requirements of the regulation**
- Management provides definition and interpretation of words or terms**

Terms and Definitions



Corrective Action

- ◆ Action taken to eliminate the causes of an **existing** non-conformity, defect or other undesirable situation in order to prevent recurrence.

[ISO 8402]

Correction vs. Corrective Action

- ◆ **“Correction” refers to repair, rework, or adjustment and relates to the disposition of an **existing** nonconformity**
- ◆ **“Corrective action” relates to the elimination of the causes of nonconformity [ISO 8402]**

Examples

- ◆ **Correction: Devices returned because of out-of-box failures are repaired and put back into inventory**
- ◆ **Corrective action: Defective components damaged by ESD during assembly caused out-of-box failures. ESD controls instituted; operators are trained in ESD controls**

Preventive Action

- ◆ Action taken to eliminate the cause of a **potential** non-conformity, defect, or other undesirable situation in order to prevent occurrence [ISO 8402]

Example

- ◆ **SPC charts indicate process is drifting *toward* upper limit for diameter of injection molded part. Investigation determines cause of drift is wear to mold. Replace mold, and verify/validate that process yields parts meeting specs.**

CAPA [21CFR 820.100]

Includes Actions Needed To:

- ◆ **Correct (“correction”) nonconforming product and other quality problems**
- ◆ **Prevent recurrence (“corrective action”) of nonconforming product and other quality problems**
- ◆ **Eliminate the cause of potential (“preventive action”) nonconforming product and other quality problems**

Assessment

“Top Down” - *Implemented*

2. ID existing problems (*Corrective Actions*)

- Quality data sources are identified
- Data from sources are analyzed

3. ID potential problems (*Preventive Actions*)

- Quality data sources are identified
- Data from sources are analyzed

Assessment

“Top Down” - *Implemented*

4. Data challenge

- Complete
- Accurate
- Timely

Assessment

“Top Down” - *Implemented*

5. Statistical and non-statistical techniques

- Detect recurring quality problems**
- Results of analyses**
 - » compared across different data sources**
 - » identify and develop extent of problems**

Assessment

“Top Down” - *Implemented*

6. Failure Investigation

- Procedures followed**
- Commensurate with significance and risk of nonconformity**
- Depth to root cause, where possible**
- Control to prevent distribution of nonconforming product**

Assessment

“Top Down” - *Implemented*

7. Appropriate action taken

8. Actions

- Were effective
- Were verified or validated
- Do not adversely affect the finished device

Assessment

“Top Down” - *Implemented*

9. Actions

- Implemented
- Documented

10. Information dissemination

- Individuals directly responsible for
 - » assuring product quality
 - » prevention of quality problems

more...

Assessment

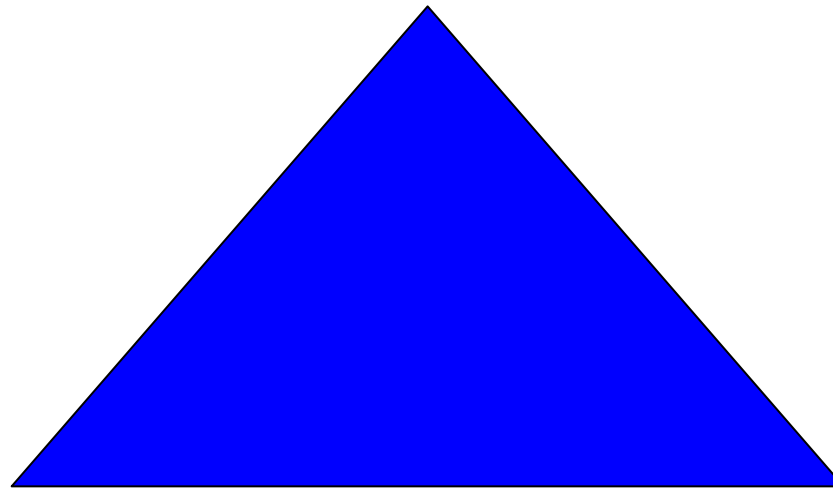
“Top Down” - *Implemented*

– **Management Review!**

Remember?

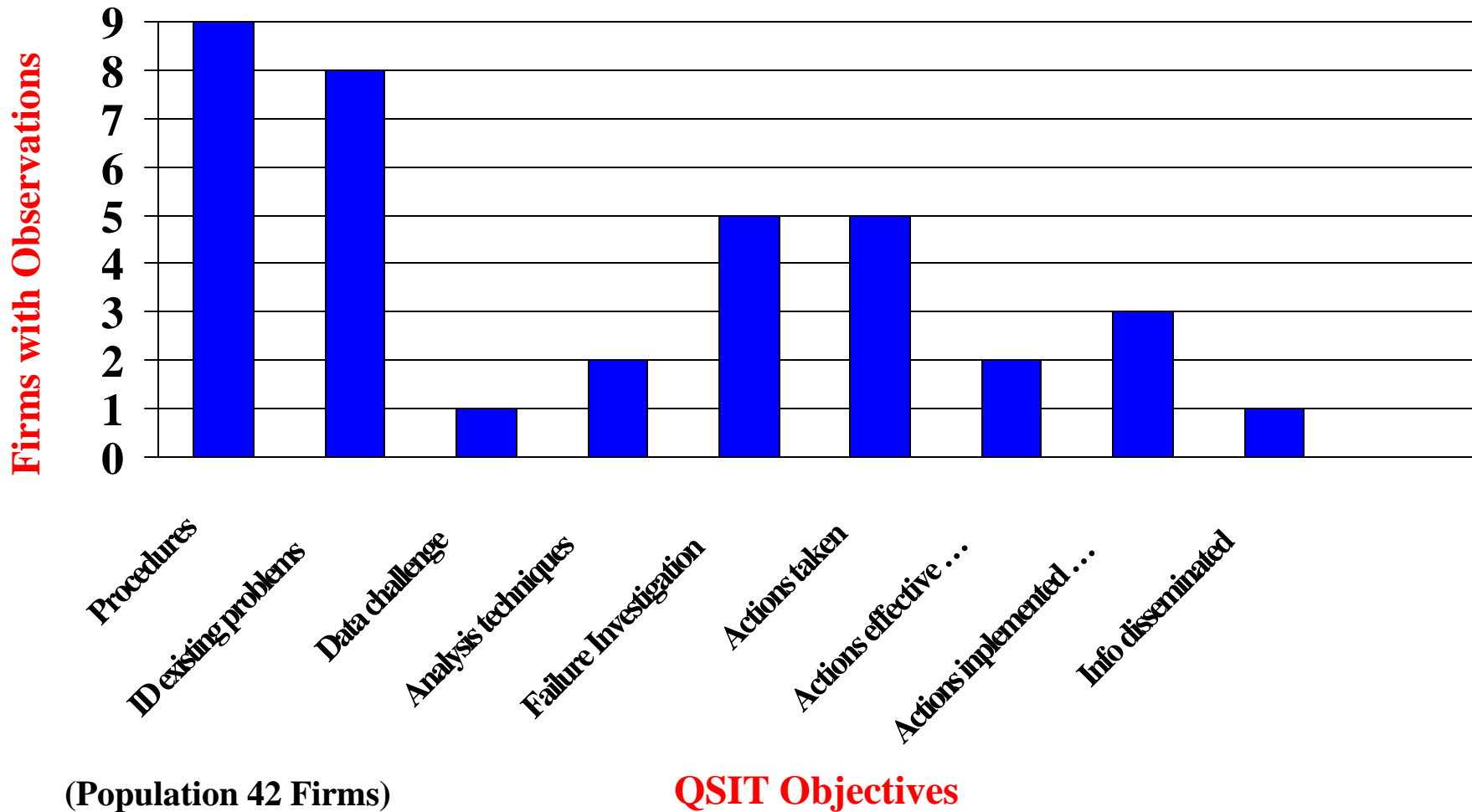
CAPA

Audits



**Management
Review**

QSIT Study Findings



Data Sources

- ◆ **Internal Feedback**
- ◆ **External Feedback**

Internal Data Sources

- ◆ **Inspection/Test Data**
 - **In-Process**
 - **Final**
- ◆ **Scrap/Yield Data**
- ◆ **Process Control Data**

Internal Data Sources

- ◆ **Incoming Components**
 - **By Part Number**
 - **By Supplier**
- ◆ **Equipment Data**
 - **Calibration**
 - **Maintenance**
- ◆ **Internal Audits**

more...

Internal Data Sources

- ◆ **Device History Records**
- ◆ **Training Records**
- ◆ **Change Control Records**
- ◆ **Rework**
- ◆ **Nonconforming Material Reports**

more...

External Data Sources

- ◆ **Complaints**
 - **Customers**
 - **Employees**
 - **MedWatch**
 - **Field Service Reports**
 - **Journal Articles**
 - **FDA**

more...

External Data Sources

- ◆ **Field Service Reports**
- ◆ **Legal Claims**
- ◆ **Product Warranty**

more...

Approach to Data Analysis

- ◆ **Rank areas from major to minor**
- ◆ **Select items with major impact to business**
 - **Product related**
 - **Process related**
- ◆ **Proceed to items with less impact**
- ◆ **Assure that eventually all areas are addressed**

Statistical Techniques

- ◆ **Statistical methodologies**
 - **Pareto charts**
 - **Run charts**
 - **Control charts**

Reminder!

- ◆ **21CFR Part 11 - Electronic Records;
Electronic Signatures**

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



... After Lunch