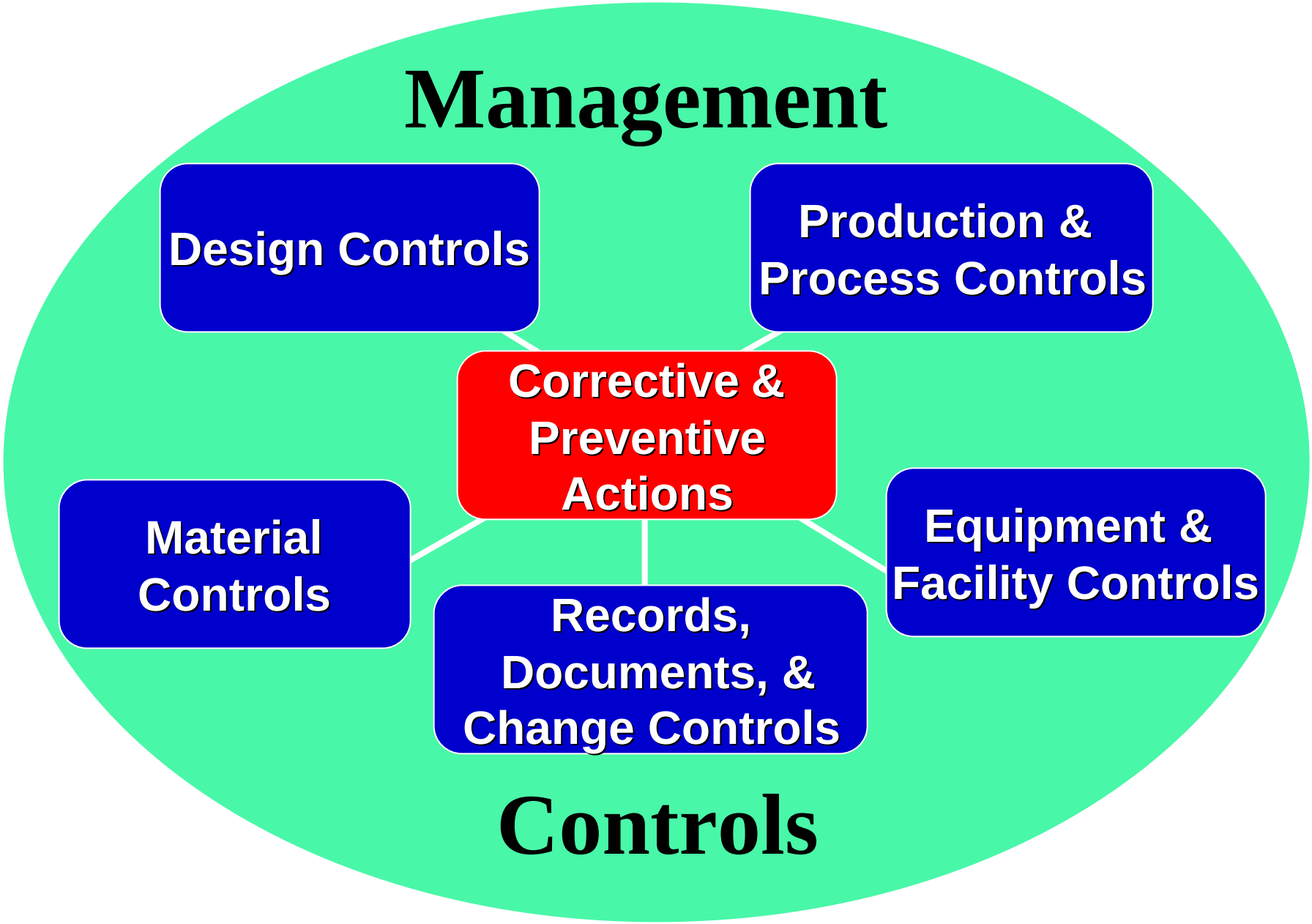
QSIT
Corrective & Preventive Actions

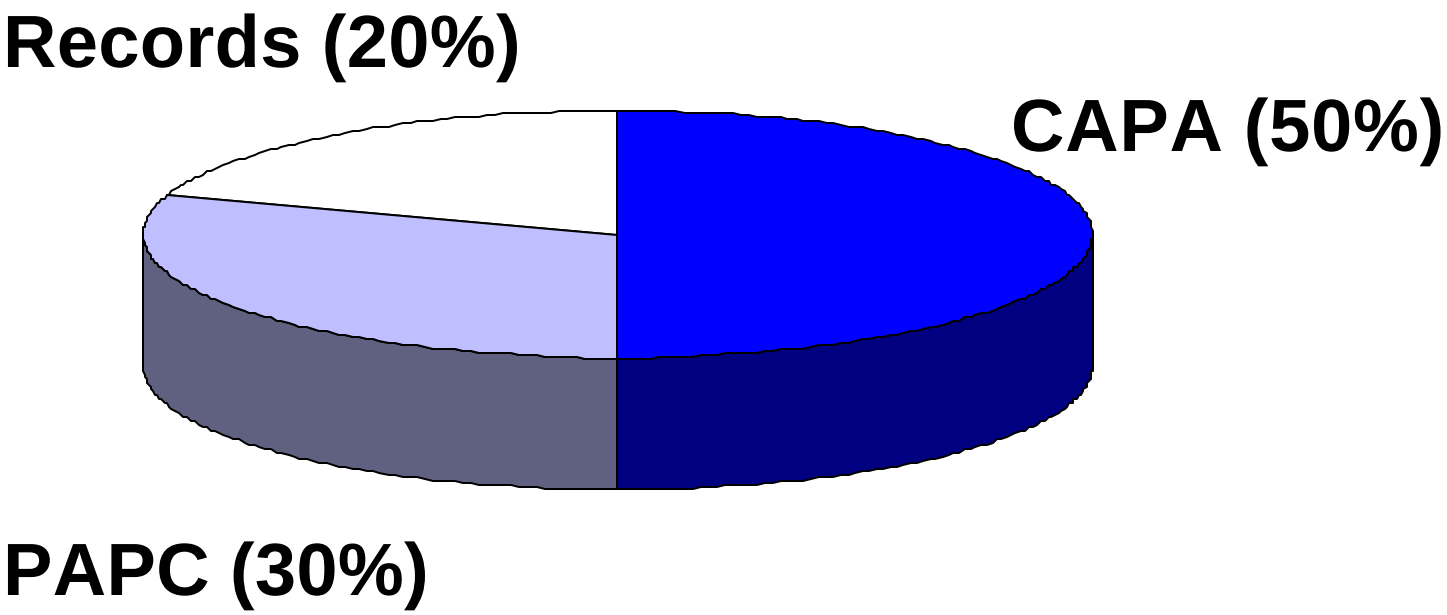
QSIT Workshops

Corrective & Preventive Actions (CAPA)

- Importance
- Assessment
- Data

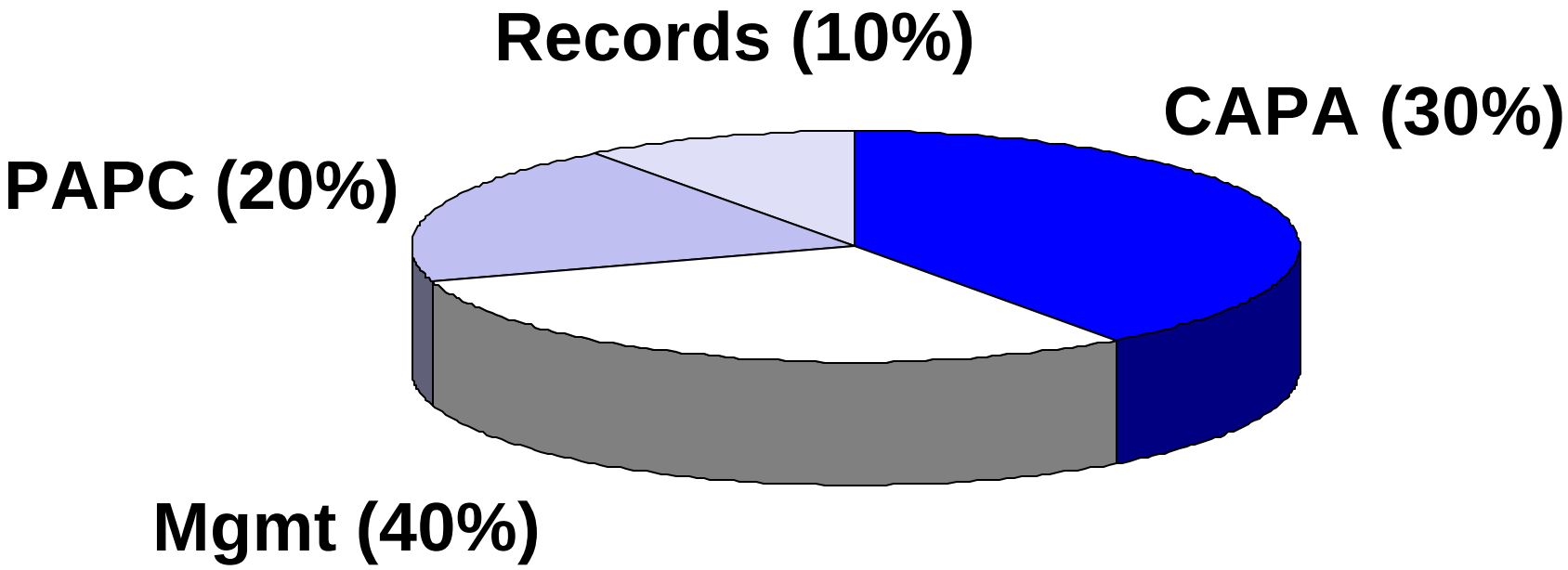

Management
Design Controls
Production & Process Controls
Corrective & Preventive Actions
Material Controls
Equipment & Facility Controls
Records, Documents, & Change Controls
Controls

Top Ten FDA 483 Items



Non-QSIT Inspections

Top Ten FDA 483 Items



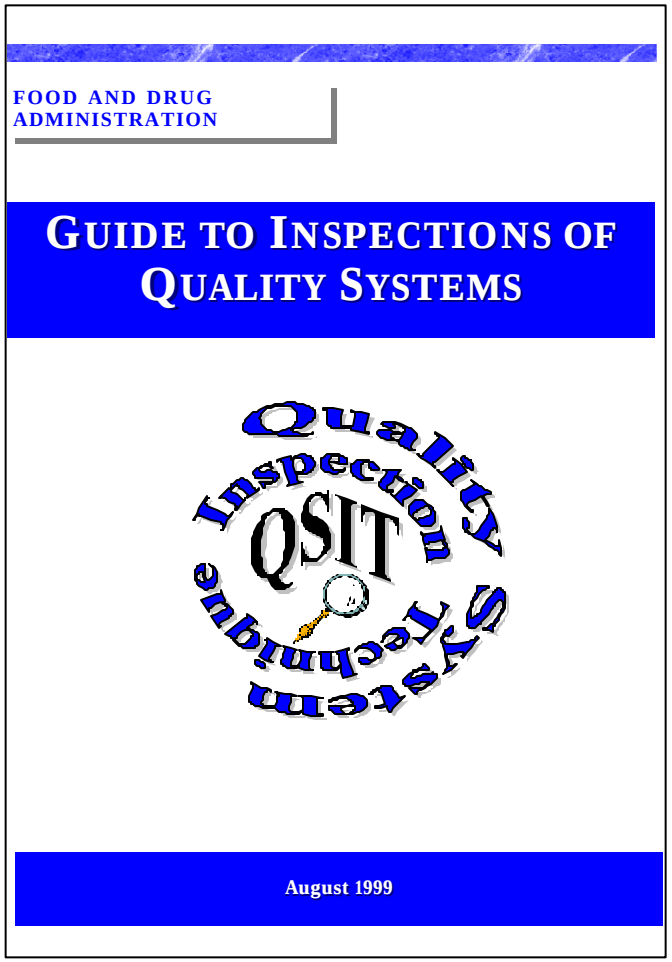
QSIT Inspections

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**

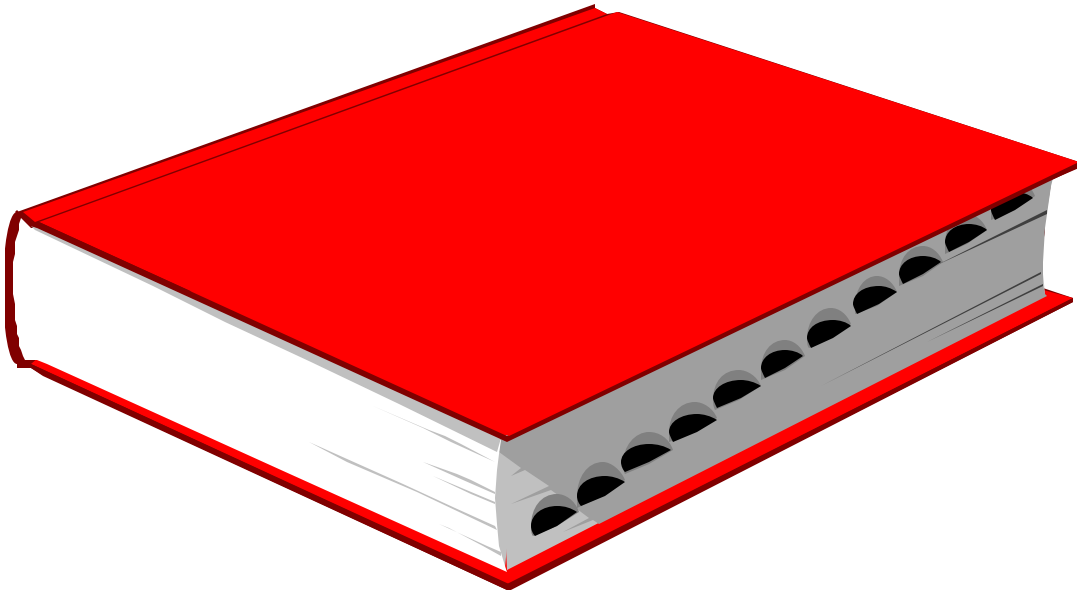


Assessment

"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**

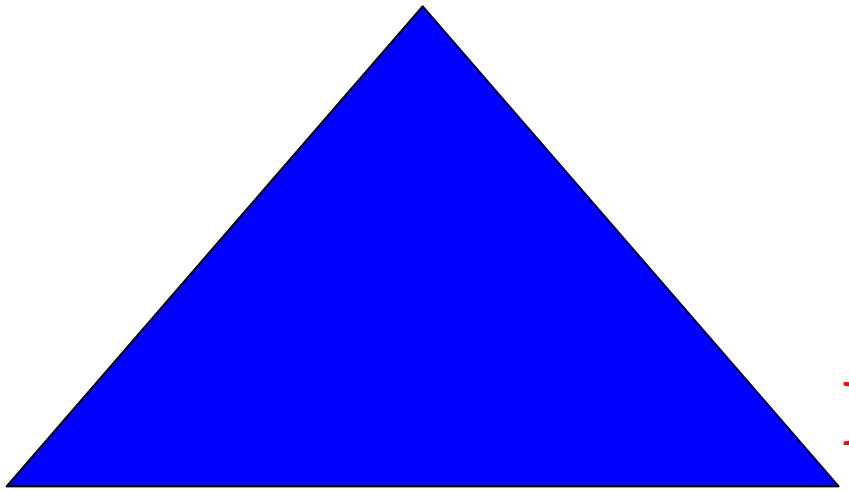
more...

Assessment

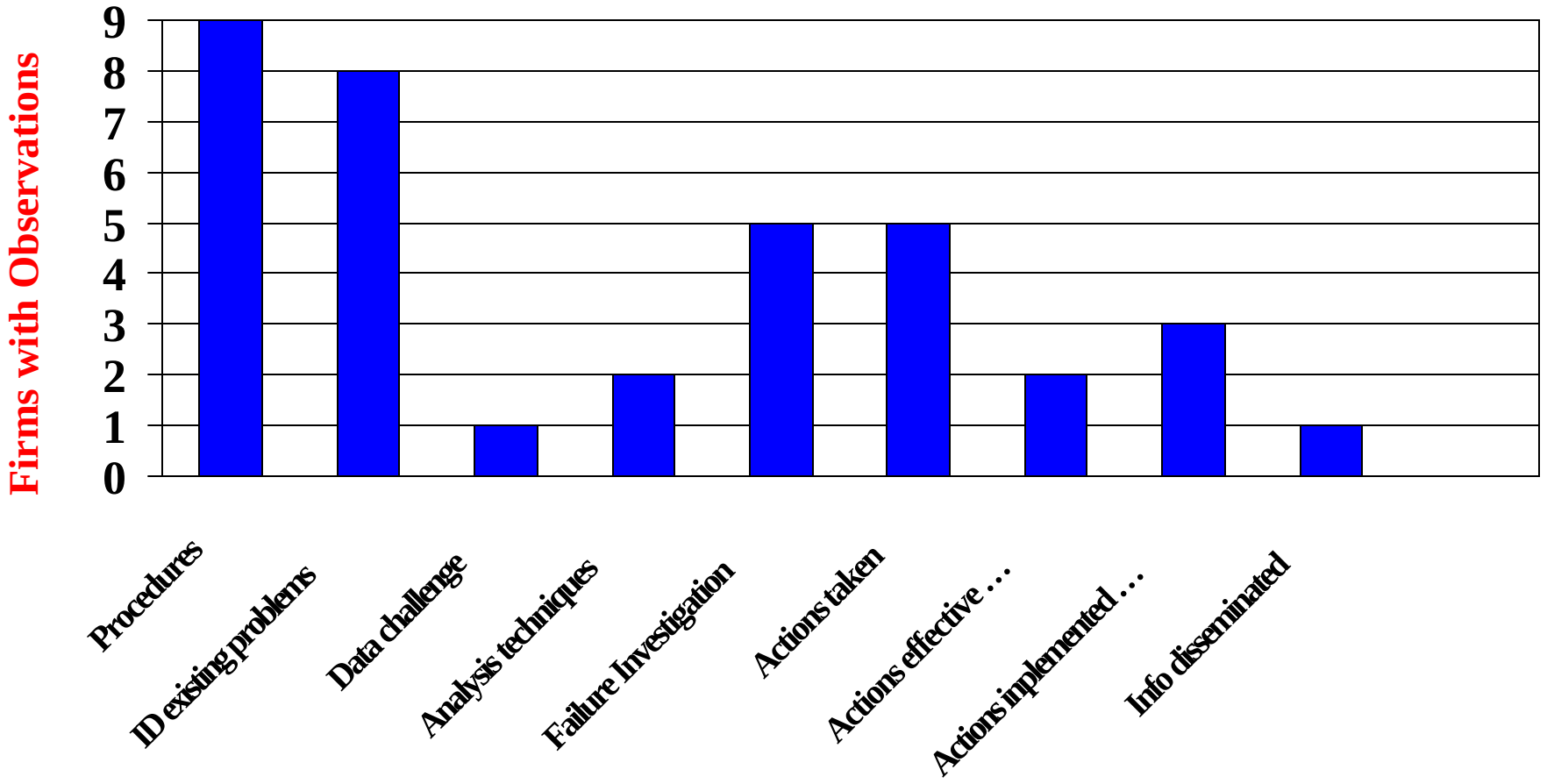
"Top Down" - *Implemented*

– **Management Review!**

Remember?



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
- Nonconfoming 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