

# LifeSciences BC CAPA Best Practices



Presented by: Bruce Haggar



Adding Value...Period

MedQ Systems, Inc.  
329 Berner Ave.  
Hazleton, PA 18201  
USA  
[www.medqsystems.com](http://www.medqsystems.com)

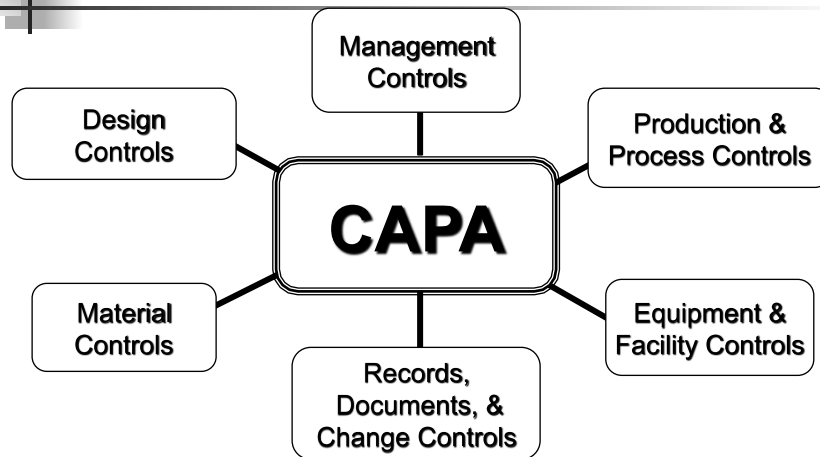
MedQ Systems  
Inc.

## Common Challenges

1. Recognizing links to other quality system elements
2. CAPA documentation does not reflect current status
3. Competing resources
4. Complex CAPA process
5. When to initiate CAPA
  - Action Limits
  - Speeding Tickets
6. Problem definition
7. Investigating Cause
8. Ineffective follow up
9. Timeliness
  - Aging CAPAS & Metrics
10. CAPA Software  
*"the automation solution"*
11. Inconsistency across Global companies

*CAPA links to all other quality system processes*

## 1. Links to CAPA



MedQ Systems Inc. 2008

3

## 2. Documentation

- CAPA documentation does not reflect current status
- Level of documentation is not commensurate with the work performed
  - *Investigation completed*
  - *Documentation changes complete or underway*
  - *CAPA file lacks documented evidence of work performed*
  - *Documentation rules: forward and backward traceability*
- Extensions
  - Are they overused?
  - Are they defensible?

MedQ Systems Inc. 2008

4

## Documentation

- Well defined problem statement
- Correction or containment measures
- Data reviewed  
*data sources, records*
- Investigation defined
  - method
  - dates of investigation
  - records *objective evidence*
- Results of investigation include statement of cause
- Action plan
  - who, what, when, deliverable
- Forward – backward traceability
- **CAPA file is maintained to reflect current activity level**

## 3. Resources

- More work - fewer resources
  - CAPA is "Quality" ... *let them do it*
- CAPA often competes for resources
  - Complaint Investigation
  - New Product Development
  - Manufacturing Improvements
- Conflicting priorities, changing priorities
- Avoid competing for the same resources by aligning CAPA with quality and business objectives





## 4. Complex CAPA Process

---

- Complexity impedes ability to act appropriately
  - Multiple approvals
  - Unnecessary signature requirements
  - Software tool is driving the process
  - CAPA Committees
    - Are participants prepared?
    - Are meetings effective?

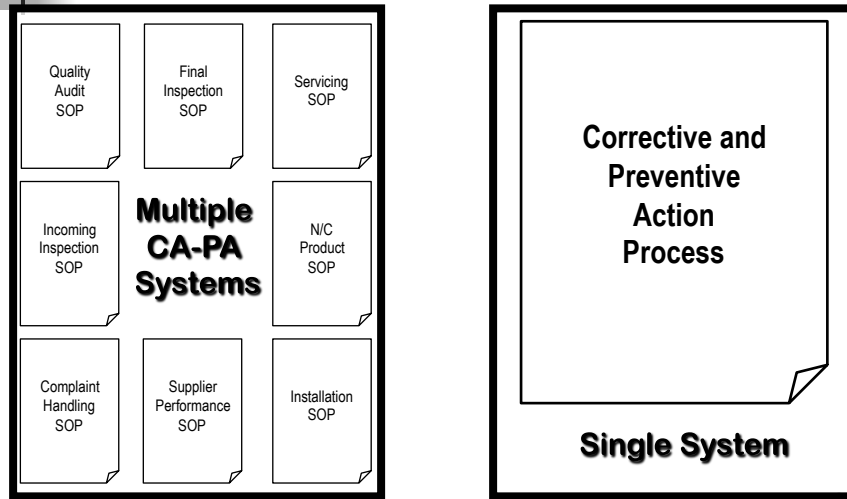


## Complex CAPA Process *(cont.)*

---

- A complex CAPA system contributes to aging CAPAs
- Risk unknown
  - CAPAs enter the system carrying the same weight
  - Sense of urgency is not conveyed
- Multiple CAPA systems

## Single vs. multiple CAPA Systems?



MedQ Systems Inc. 2008

## Pro's and Con's

### Multiple CAPA systems

- Difficult to detect similar issues and recognize problems early **"Silo's"**
- Prioritization problems
  - When multiple systems link to a bigger CAPA process
  - CAPAs are initiated and carry the same weight
  - Consistent use of risk prioritization is lacking
- Decentralized CAPA management typically necessitates oversight by the quality function

### Single CAPA System

- Improved ability to establish Action Limits that align with
  - Quality Policy, Quality Objectives, Business Objectives
- Managed by dedicated CAPA resource(s)
- Improves ability for early detection
- More likely to determine cause
- More effective actions

MedQ Systems Inc. 2008

10



## 5. Action Limits

---

- "Speeding Ticket" syndrome
- Perception that
  - ... all nonconformities require CAPA
- Alignment with *Quality Policy, Quality Objectives* and *Business Objectives* often lacking



## Action Limits

---

- Identify CAPA data sources
  - product, process, and quality system
- Define criteria (action limits) for CAPA
  - Consider frequency and severity across multiple data sources
  - Define a risk based approach for prioritization
    - patient/user safety, business, regulatory, employee
- Leverage the output of Design Control to drive CAPA
  - Risk Analysis: Design FMEA, Process FMEA

## 6. Problem Definition

- Often ambiguous and subjective
- The problem statement is the difference between what is and what should be
  - Focus on
    - facts – *not emotions*
    - **what** is wrong, not **why** it's wrong
  - A clear problem statement will establish investigation boundaries ... *avoid "scope creep"*

MedQ Systems Inc. 2008

13

## Problem Definition (cont.)

- State the problem in measurable terms
  - how often, how much, when, and where
- Emphasize the effects of the problem
  - safety, death, injury, rework, cost, etc.
- Avoid
  - using negative descriptors
  - inflammatory statements
  - words that are broad and do not describe the conditions or behavior such as *careless, complacency, neglect, oversight*

MedQ Systems Inc. 2008

14

## 7. Investigating Cause



- Implementing a solution that addresses the ***symptom... not the cause***

- Costly implementation of a solution that does not address the cause of the problem



MedQ Systems Inc. 2008

15

## Investigating Cause (cont.)

- Determine WHY the problem occurred
- Phases of Investigation
  - Presumptive Cause
    - apparent during early investigation, hypotheses that may explain the effect but needs validation
  - Contributing Cause
    - secondary and possible causes
  - Root Cause
    - primary reason for the problem which if corrected will prevent recurrence

MedQ Systems Inc. 2008

16

## Documenting the Investigation

- **Define method of investigation**
  - Include quality tools used
    - Is/Is Not,
    - Cause and Effect,
    - 5 Why's, etc.
- **Document**
  - Dates of investigation
  - Data reviewed (data sources, records, dates)
  - Corrections or Containment measures
  - Results: Statement of Cause

	IS	IS NOT
WHAT		
WHEN		
WHERE		
EXTENT		

Is / Is Not Diagram

## 8. Ineffective Follow-Up

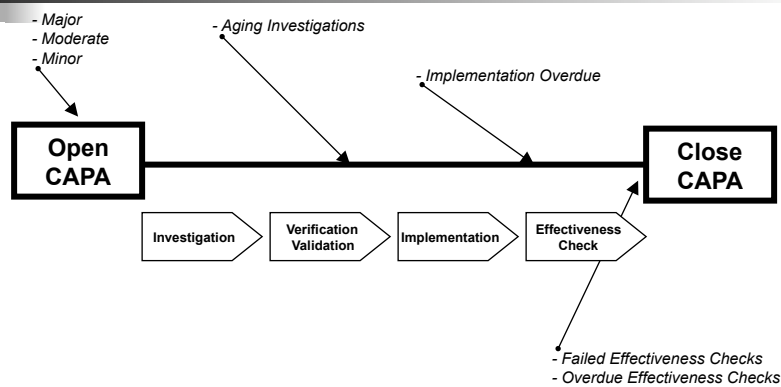
- Effectiveness Checks fail when
  - They are not planned specific to the CAPA
  - An inappropriate data source is selected to monitor for recurrence/occurrence
  - The same criteria is applied to all CAPAs

## 8. Ineffective Follow-Up

- What do you do when a effectiveness check fails?
- What are the consequences?
  - *Close the CAPA and open a new one?*
  - *Get an extension?*
  - *Leave the CAPA open and investigate why?*

## 9. Timeliness and Metrics

*Not all CAPAs are created equal*



## 10. CAPA Software

- **AUTOMATION** is a **TOOL** *...not a solution*
  - Define your CAPA process *first*, then automate
  - Walk before you run
  - Recognize the CAPA process is fundamental



## 11. Global Companies

- Global companies must overcome perceptions
  - Our businesses are different
  - Our methods are different
  - Our terminology is different
  - Our cultures are different
  - A sense that each
    - product,
    - process, or
    - quality system*...is unique*

## Global Companies (cont.)

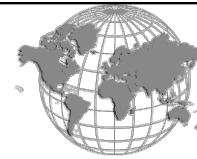
- CAPA processes should be same/similar to meet regulatory obligations and business objectives



- **WHY?**

It makes good business sense to leverage success!

## Global Companies (cont.)



- Opportunities exist to consider similar issues across multiple facilities
  - Share product, process and quality system information from various locations, sister facilities, manufacturing plants, to emphasize both *problems* and *solutions*
  - Act on information



## Best Practices

---

- Documented procedure
  - Risk based
  - Defined responsibility and authority
  - CAPA feeders (inputs)
    - Single process, or multiple processes
  - Process flow with decision points
  - Criteria defined
    - Initiation
    - Closure
    - Management review



## Best Practices

---

- Containment
  - Control nonconformity while investigation is underway
- Investigation disciplines
  - Planned and resourced
  - Method defined and documented
  - Status reports
  - Conclusion statement
  - Records



## Best Practices

---

- Verification and/or validation
  - Before implementation
  - Impact assessment, Design or Process



## Best Practices

---

- Well defined action plan
- Metrics - ability to monitor progress
- Effectiveness checks
  - Planned
  - Appropriate
  - Timely
- Management escalation



# Thank You!

---



**Adding Value...  
Period**

**Bruce Haggar  
PO Box 699  
Friday Harbor, WA 98250  
916.835.0774**

MedQ Systems Inc. 2008