

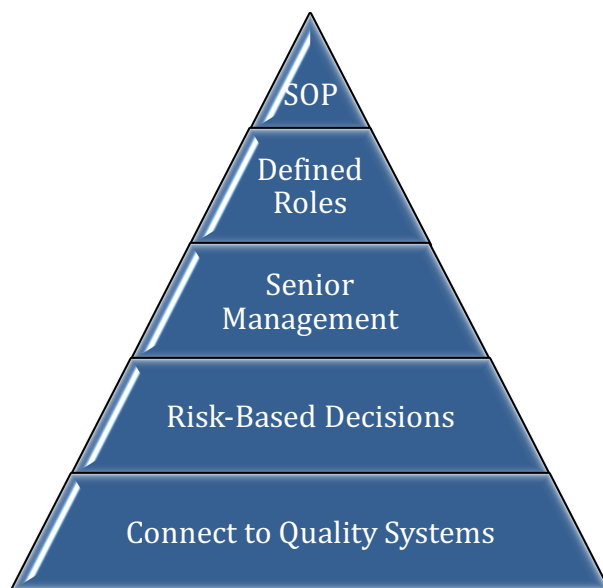
Topics for Establishing a Compliant and Effective Risk-Based CAPA System

NOTE: This Quick Reference Guide is intended to provide a high level overview of topics for establishing a compliant and effective risk-based CAPA system to improve risk actions.

Topics covered:

- Identify critical components of an effective CAPA System
- Determine where, when and how to assess risk throughout the process
- Verify Root Cause
- Mistake Proofing

Overview of the Critical Elements of an Effective CAPA System



Establish a CAPA Standard Operating Procedure (SOP)
Specify escalation / de-escalation conditions
Use a compliant software package
Assign dedicated investigation and CAPA staff
Define roles for all Investigation and CAPA staff
Analyze and use quality system metrics
Assure appropriate communication
Establish an Investigation & CAPA review board
Make risk-based decisions
Connect investigations and CAPA to other quality systems

Risk Assessment

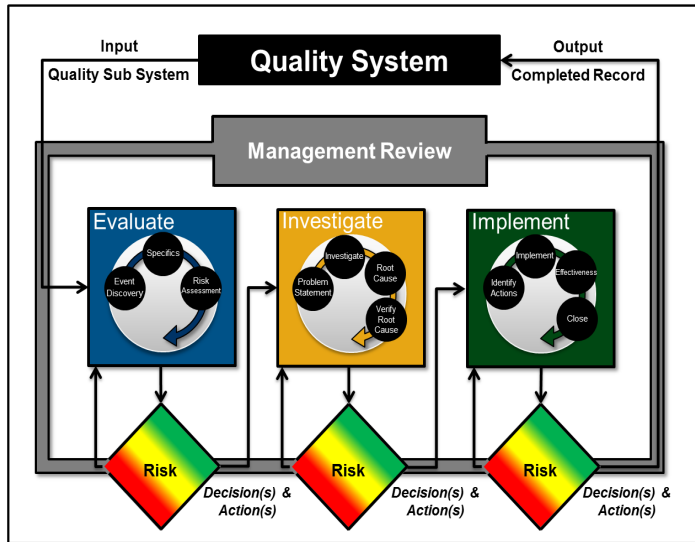
Risk Assessment is important because it meets regulatory requirements and helps the organization address resource allocation. When assessing risk it is important to know:

- What is the risk?
- What is the impact and frequency?
- Where will the event be recorded, dispositioned, and addressed in the quality system?

Where to Assess Risk in the CAPA System

There are 3 major areas to assess risk in the CAPA System:

1. Event disposition
2. Investigation completion/Root Cause Identification
3. Implementation of Corrective Action and Preventive Action activities



How to Assess Risk in the CAPA System

Questions to ask when assessing Risk in each phase:

- Evaluation – Does the event become an investigation?
- Investigation – Does the investigation support CA/PA activities?
- Implementation – Is a formal project for implementation activities required?

Root Cause Verification

Verifying the root cause ensures the correct Root Cause has been selected and is agreed upon by all stakeholders. Root Cause verification also determines the next steps of the investigation and the activities prior to implementation phase.

Key Questions to ask when verifying a Root Cause are:

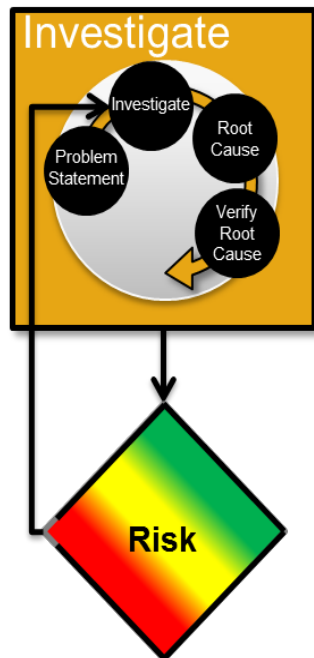
- Who are the stakeholders?
- Is the root Cause of the problem agreed upon by all the stakeholders?
- What are the next steps?

The table below is an example of the action taken when the Root Cause is verified:

Document	Plan
Correction Implemented	Measure and Monitor
Additional Actions Needed SOP not followed	Corrective Action(s)
	Preventive Action(s)

ROOT CAUSE VERIFIED

If the Root Cause cannot be verified then it is necessary to start the investigation over. For this situation, the Investigation and CAPA System must have a documented section illustrating what to do and with whom to communicate.



ROOT CAUSE NOT VERIFIED

Mistake Proofing

After completing all of the work to determine root cause you may not be able to identify actions to eliminate the root cause. One general type of solution that may be identified related to the verified root cause is to ensure that the error or mistake cannot occur again.

Mistake Proofing is the use of any method that makes it impossible for an error to occur or makes the error immediately obvious once it has occurred.

- PREVENTING the defect from ever occurring is true mistake proofing
 - This eliminates the potential for the error in the first place
- DETECTING the defect every time it occurs
 - This activity must be able to detect the root cause and shut down the system every time

Levels of Mistake Proofing:

- Level 1: Detects defects before proceeding to next step
- Level 2: Detects defects while in process at an operation
- Level 3: Prevent defects from occurring at all

Mistake Proofing Methods:

Facilitation is used to reduce the potential for the problem to reoccur or occur. The use of symbols is an example of facilitation.

Mitigation is a technique that reduces the consequences if the error were to reoccur or occur. An example of Mitigation is a spare tire stored in an automobile.

Detection involves a system or method to notify someone if a problem were to reoccur or occur. Carried out by the warning lights in your car i.e., the check engine light in your car dashboard. This light notifies the driver that there is a problem with the engine.

For additional information please visit www.pathwise.com.

ABOUT THE AUTHOR:

Kenrick Harrigan, is a highly skilled facilitator and training professional with over 11 years in FDA regulated industries including life science and biotech industries providing Management, Training, and Sales/Marketing Support. Kenrick has led global training initiatives, and received 2009 Project Award for serving as lead trainer and QIAGEN liaison for Mexico RCS Integration Project. He received his Bachelor of Science from Howard University.

© PathWise Inc., 2016