

Implementing a Successful Corrective and Preventative Action Program

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- Setting up an Effective Corrective and Preventative Action (CAPA) Program
- Important Definitions/Concepts
- Applying the CAPA model
- Examples on conducting an investigation and teaching others to perform root cause analysis
- Recommendations on responding to audit and inspectional findings

Corrective Actions:

- The process of reacting to an existing product problem, customer complaint or other nonconformity/non-compliance and fixing it.

Preventative Actions:

- A process for detecting potential problems or nonconformance's and eliminating them.

- Both FDA and ISO have requirements for a good quality system
- A poor quality system can result in financial, regulatory and loss of business impact
- Having the ability to correct existing problems or implementing systems to prevent potential problems boost confidence and increases customer satisfaction

What are the basics of writing a CAPA?



- Requires following an established problem-solving process
- Must understand how to conduct Root Cause Analysis
- Requires thorough documentation of each step
- Usually requires training on how to conduct an investigation.

How do I get started?



- Define the issue
- Evaluate the impact of the noncompliance
- Conduct an Investigation
- Perform root cause analysis
- Create, Implement and Execute an Action Plan based on your investigation
- Conduct Follow-up assessment to verify effectiveness

- Root cause defined as a fundamental breakdown or failure of a process which, when resolved, prevents a recurrence of the problem or non-conformance
- Root cause analysis is defined as a method used to address a problem or non-conformance

Step 1 – Define the Issue



- Clearly define the issue or potential issue to include:
 - Discover the source of the information
 - Obtain a detailed explanation of the issue
 - Collect supportive documentation to support that the noncompliance exist.

Step 2 - Evaluate the impact



- Evaluate the noncompliance action
 - In terms of the immediate need for action
 - Level of action
- Assess the potential impact of the issue to include:
 - Regulatory /Liability concern
 - Financial concern
 - Immediate or long-term CAPA

MEMO TO FILE [TEMPLATE]

- **DATE:**
- **TO:**
- **FROM:**
- **RE: (LIST ISSUES)**
- **Issue Identified:**
- **Background:**
- **Investigation Conducted:**
- **Root Cause Analysis:**
- **Corrective and Preventative Action Plan (CAPA):**

The Investigation should include...



- Who reported the issue
- How you became aware of the issue
- Who conducted the investigation
- What did the investigation consist of
- Where did the investigation take place
- When was the investigation conducted
- How was the investigation conducted.
- State the process used at the time the issue was discovered
- Your investigation should describe what your investigation consisted of..
- Be sure and review the original source documents when conducting an investigation and include a list of the documents reviewed.
- In your write-up, be sure to be objective

Step 4 – Conduct Root Cause Analysis



- The Root-Cause Analysis (based on your investigation) should document all possible reasons that led to the issue. For example:
- Employee not following current procedure (be specific what part of the procedure was not followed); The current process not addressing this specific situation (interpretation of procedures);
- Employee not trained on current process

Understanding Root Cause Analysis



Analyzing the Symptom	Analyzing the Root Cause
Assumes Employees are the cause	Is process driven Employees are one part of the process
Assumes issue is due to poor employee training	<ul style="list-style-type: none">•Conducts investigation to find out why the noncompliance occurred.•Implements corrective and preventative action to reduce chance of error recurring
Assumes no time or resources to address cause of the noncompliance	Management sees this as a critical issue that requires an effective solution to prevent it from happening again.

Step 5: Document CAPA



- Document what corrective actions were taken to prevent this issue from happening again including details on how it was implemented. For example:
 - A new procedure was required to be written and implemented as a result of the corrective action
 - Retraining of employees due to failure to follow or understand process
 - Extra quality checks put in place to ensure monitoring visits completed approved and provided to the sponsor on time
- The CAPA should give the auditor some type of assurance that this type of issue will not happen again.

CAPA Quality System includes:



Documentation Method (forms, tracking system)	ID solutions (Corrective/Preventative)
Define prioritization of CAPA	Conduct Impact Analysis (Define risk)
Procedures must be documented	Verify and Validate processes and procedures
Investigate to find root cause	Implement, Measure, Monitor progress
Determine source of input	Obtain management review/support
Decide how to analyze inputs	Includes Corrective Action Plan
Define measure for containment	Distribute/share info (Lessons learned)

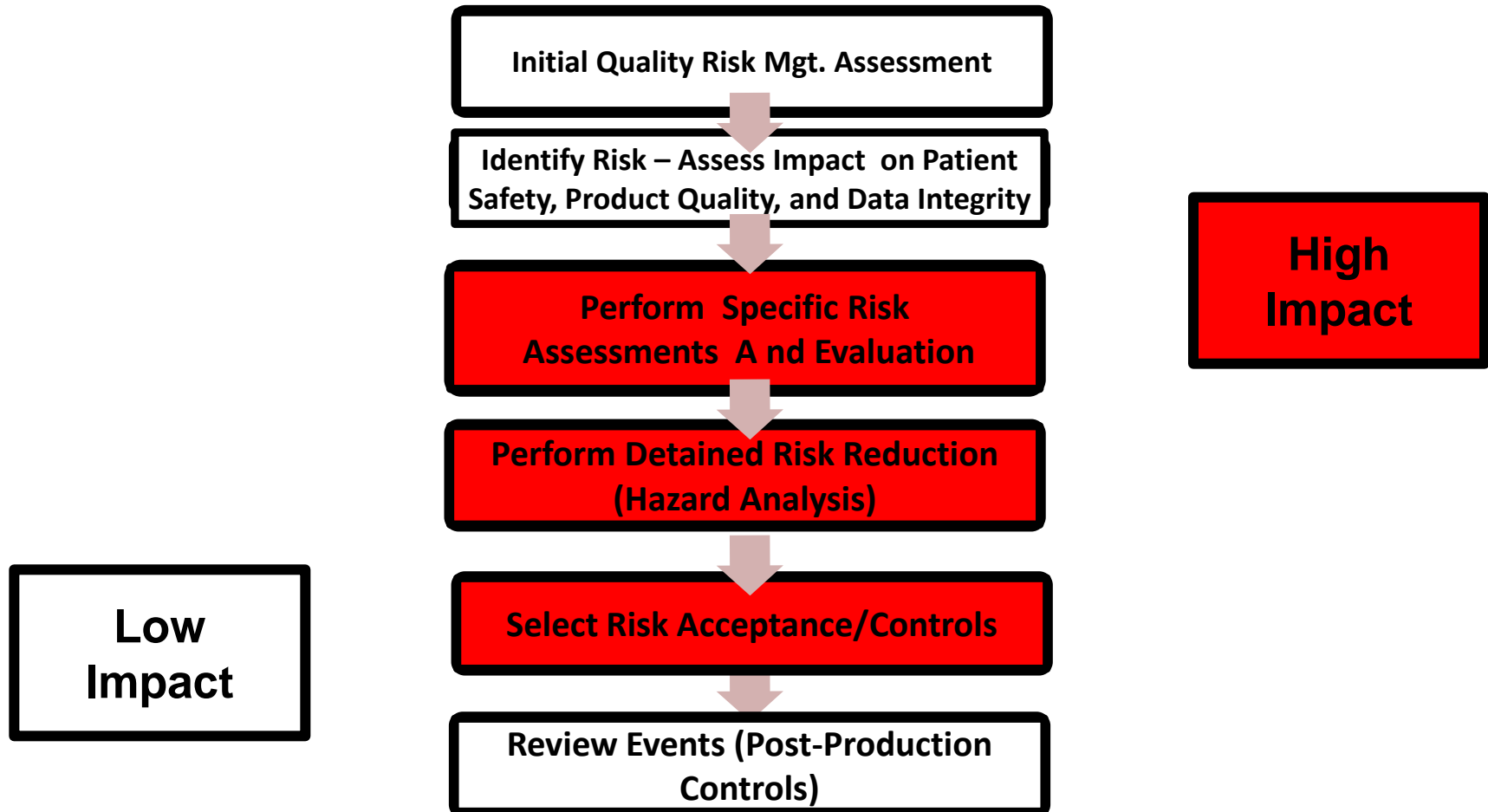
- Verify and assess effectiveness of the CAPA by conducting internal assessments/audits to verify:
 - That actions documented in the CAPA report were completed as promised
 - That supportive documents are available as evidence, i.e., training records, SOP modifications, updated data management plans or essential document trackers
 - For employee retraining, conduct checks to ensure that processes are being followed

- Step 1: Begin by collecting information from stakeholders, in-house specialist, external consultants
- Step 2: Ask questions to identify risk
 - What is the cause of the risk?
 - What can be done to prevent the threat from occurring?
 - If the threat does occur, what is the plan of action?
 - How will the plan for dealing with the threat be implemented?
- Step 3: Measure the risk
- Step 4: Make adjustments to the project plan to eliminate threats (risk) & identify opportunity to add value
- Step 5: Define & follow action plan & post-review

Q9 Risk Mgt. Concepts



Implement Q9 Risk Mgt. Process



QA RISK INDEX



RISK CONTROL INDEX	LOW RISK	MEDIUM RISK	HIGH RISK
FREQUENCY OF USE 3 = Used often 2 – Medium use 1 = Seldom use	A one-off process or vendor used on a small Study	Used on >1 or 2 studies	Preferred Provider or part of a SOP within CRO
REGULATORY RISK 3 = High risk 2 = Medium risk 1 = Low risk	Minor findings	Major findings	Critical Findings patient safety, data integrity
BUSINESS RISK 3 = High risk 2 = Medium risk 1 = Low risk	Small one-off studies with smaller sponsors	Studies with mid to large pharma	High Income Study with Large Sponsor



QA RISK EXAMPLE



RISK CONTROL INDEX	VENDOR A	VENDOR B	VENDOR C
FREQUENCY OF USE	Used rarely for archiving FDA regulated records = 1	Used on >1 or 2 studies for monitoring = 2	Preferred Provider - Assigned highest score of = 3
REGULATORY RISK	Original training record lost, but scanned copy available; Minor finding = 1	Major findings – some monitoring visit reports were missing = 7	Critical Findings on unreported SAEs, data integrity issues = 9
BUSINESS RISK	Small one-off studies with smaller sponsors, but not all processes documented = 2	Critical Risk – Risk for company not using qualified/trained monitors = 9	High Income Study with Large Sponsors and FDA reportable = 9



In Summary...



- Having an effective CAPA systems allows organizations to develop systematic risk systems to reduce probability of known risk and to identify emerging risk at the lowest levels
- Implementation of risk assessment allows organizations to understand and be prepared for:
 - Questions on what might go wrong
 - Probability of reoccurrence
 - Consequences of severity
 - Proactively identifying and preventing recurring issues
- Anyone can be taught how to perform root cause analysis
- Don't forget to conduct quality checks to ensure CAPAs are implemented and effective

Questions????

