CAPA Process

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What is CAPA ?
(CAPA =Corrective and Preventive Action)

Corrective Action

- It assumes that the incidence/undesirable event has happened

- Action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence after the issue/non conformance has happened.

- Reactive Approach

Preventive Action

- It assumes that the incidence/undesirable event has NOT happened

- Action taken to eliminate the cause of a potential nonconformity, defect, or other undesirable situation in order to prevent occurrence before the issue/non conformance has happened

- Proactive Approach

What is CAPA?
(CAPA =Corrective and Preventive Action)

• CAPA Risk Assessment
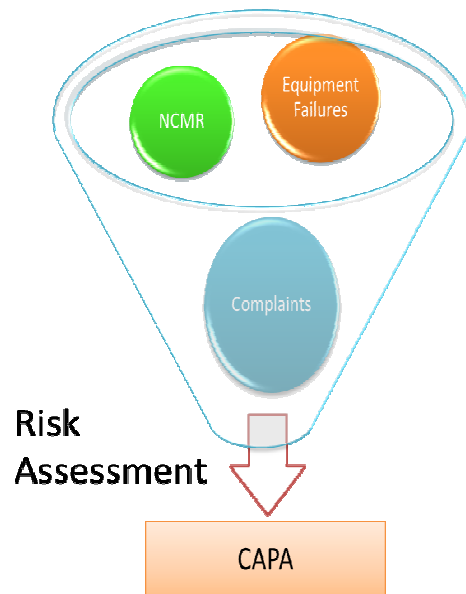
• CAPA System

- CAPA is a Sub System for Quality/Process Improvement with in the Quality System

- The significant and/or systemic issues are managed and documented in the CAPA system

- The system approach to manage the CAPA ensures effectiveness and produce business benefits (reduced complaints and increased revenue)

What is the Purpose of CAPA?

- Creates a system for fixing the issues and to prevent the issues

- CAPA system is a requirement for ISO standards (ISO 9001:2008 and ISO 17025)

- Also a requirement for FDA QS Regulations (e.g CFR 820, CFR211)

How to Implement?

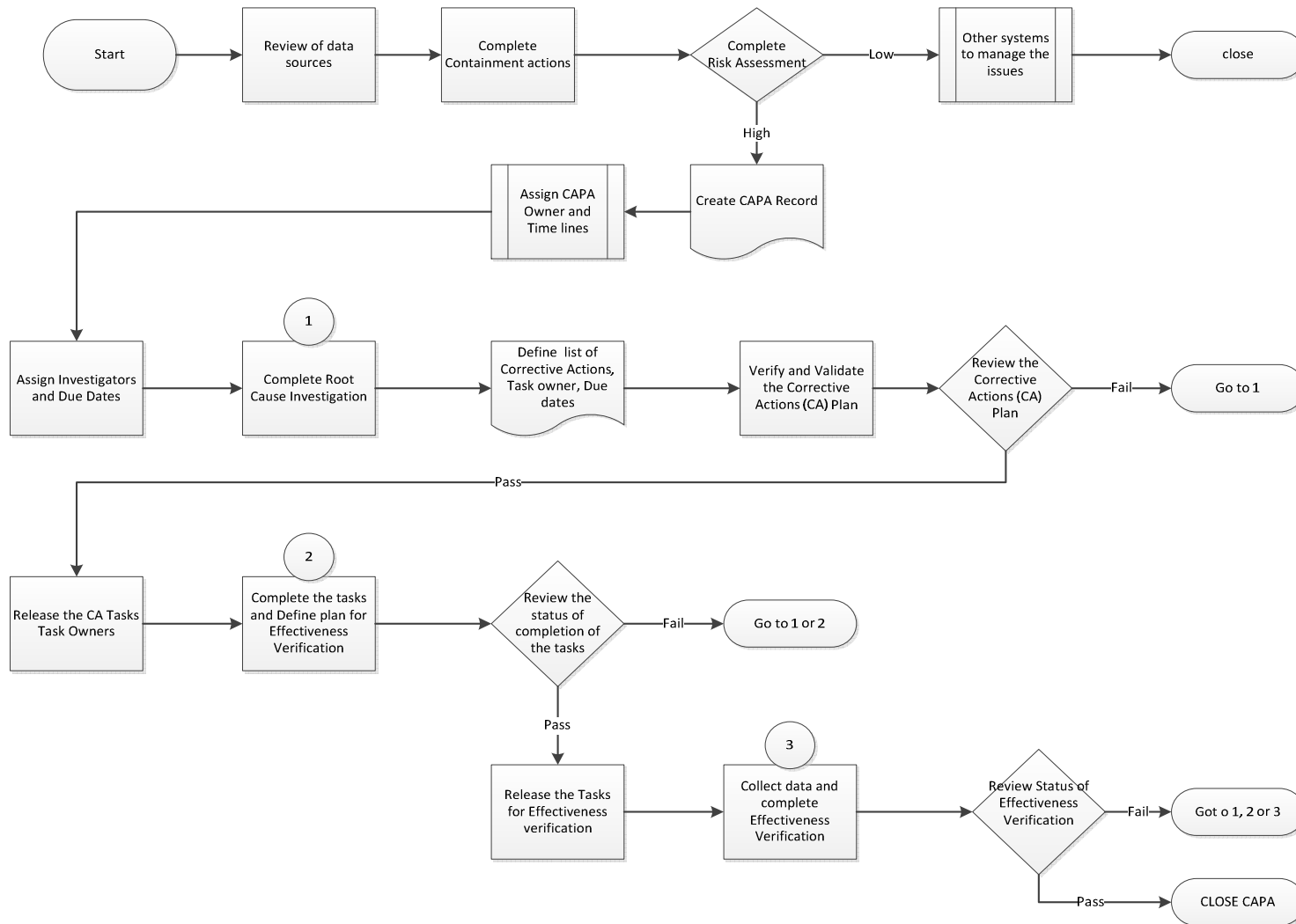- Define the high level process with a process map or flow diagram (see the next slide)

- Define the individual steps

- Defines the roles and Responsibilities

- Measure and report effectiveness of the CAPA process

Note: Create a SOP (standard operating procedure to document the details)

Define/Create CAPA	Root Cause Investigation	Action Plan Implementation	Effectiveness Verification

CAPA Process Map

qualcy
Systems Inc.

Start → Review of data sources → Complete Containment actions → Complete Risk Assessment —Low→ Other systems to manage the issues → close

Complete Risk Assessment —High→ Create CAPA Record → Assign CAPA Owner and Time lines → Assign Investigators and Due Dates

1 Complete Root Cause Investigation → Define list of Corrective Actions, Task owner, Due dates → Verify and Validate the Corrective Actions (CA) Plan → Review the Corrective Actions (CA) Plan —Fail→ Go to 1

Review the Corrective Actions (CA) Plan —Pass→

Release the CA Tasks Task Owners → **2** Complete the tasks and Define plan for Effectiveness Verification → Review the status of completion of the tasks —Fail→ Go to 1 or 2

Review the status of completion of the tasks —Pass→ Release the Tasks for Effectiveness verification → **3** Collect data and complete Effectiveness Verification → Review Status of Effectiveness Verification —Fail→ Got o 1, 2 or 3

Review Status of Effectiveness Verification —Pass→ CLOSE CAPA

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Measure Effectiveness

Collect data and review the following the metrics

- Number of Corrective CAPAs vs. Preventative CAPAs
- Time to complete the RCA, time to complete CA and time to close the CAPAs
- Number of failed CAPAs vs. Number of CAPAs opened

Summary

- The objective of the CAPA system is to fix the issues to prevent reoccurrence.

- The CAPA system should be utilized as a necessary business system to minimize the risk of full blown disasters from process and product failures

- The use for proper computer systems (e.g Qualcy eQMS- CAPA system) ensures the effective implementation and functioning of the CAPA system.