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

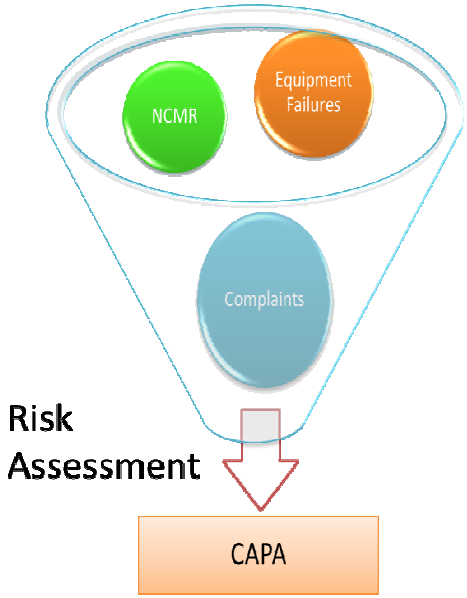
Preventive Action

- 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)

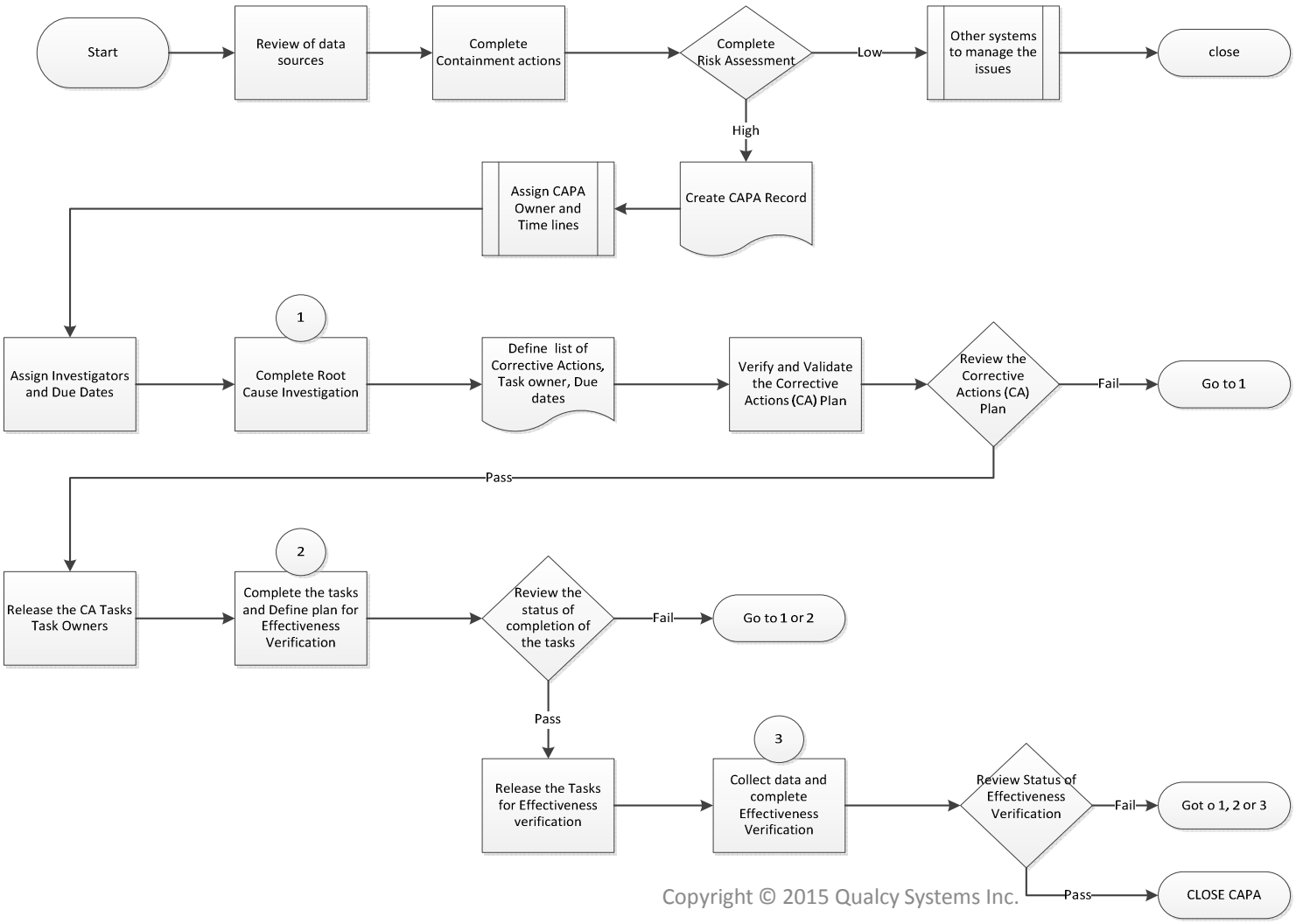
- Also a requirement for FDA QS Regulations (e.g CFR 820, CFR211)

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)

CAPA Process Map



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.