

Managing Change

Part 3 of 4

CAP A
Corrective and Preventive Actions



Agenda



Corrective and Preventive
Action (CAPA)

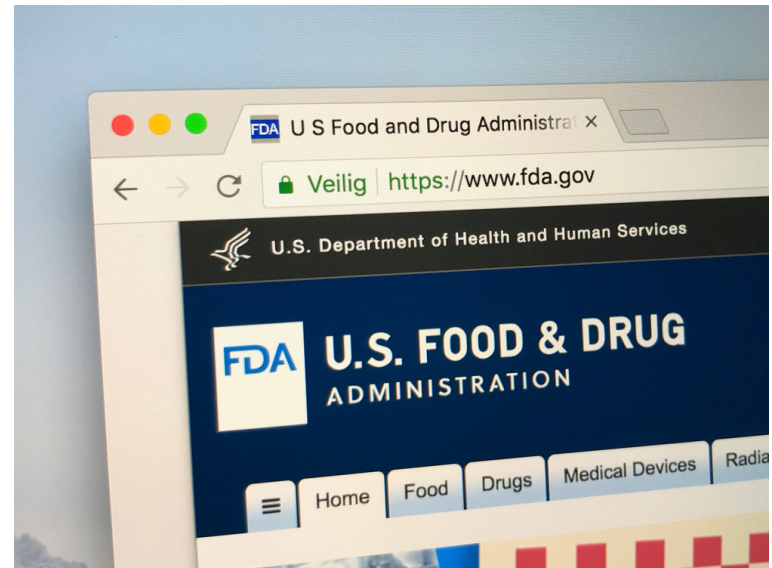
What is the CAPA
system for ?



Regulatory Requirements for CAPA

21 CFR 820 Regulatory Requirement - Procedures

- ❖ *Establish and maintain procedures for implementing corrective and preventive action.*
- ❖ *21 CFR 820.100(a)*
- ❖ **50%** of actions taken in organizations by the FDA were related to CAPA and therefore it is important for you to understand CAPA and follow the system.



PART 820 -- QUALITY SYSTEM REGULATION

Subpart J--Corrective and Preventive Action

(a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

(1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems.

Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

(2) Investigating the cause of nonconformities relating to product, processes, and the quality system;

(3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

(4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;

(5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

(6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

(7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

(b) All activities required under this section, and their results, shall be documented.

ISO13485: 2016 Medical devices — Quality management systems — Requirements for regulatory purposes

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered.

The organization shall document a procedure to define requirements for:

- a) reviewing nonconformities (including complaints);
- b) determining the causes of nonconformities;
- c) evaluating the need for action to ensure that nonconformities do not recur;
- d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
- e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
- f) reviewing the effectiveness of corrective action taken.

Records of the results of any investigation and of action taken shall be maintained (see [4.2.5](#)).

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems.

The organization shall document a procedure to describe requirements for:

- a) determining potential nonconformities and their causes;
- b) evaluating the need for action to prevent occurrence of nonconformities;
- c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
- d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
- e) reviewing the effectiveness of the preventive action taken, as appropriate.

Records of the results of any investigations and of action taken shall be maintained (see [4.2.5](#)).



Key concepts

Key definitions

“ Correction “

Repair, rework, or adjustment and relates to the disposition of an existing non-conformity

Repair the
puncture.



Key definitions

“Corrective action” action to **eliminate the cause** of a detected non-conformity or other undesirable situation.

- ❖ There can be more than one cause for a nonconformity.
- ❖ Corrective action is taken to prevent **recurrence**.
- ❖ There is a difference between correction and corrective action. *ISO 9000:2005(E)*

Replace tyre and replace it **before** it becomes bald again.

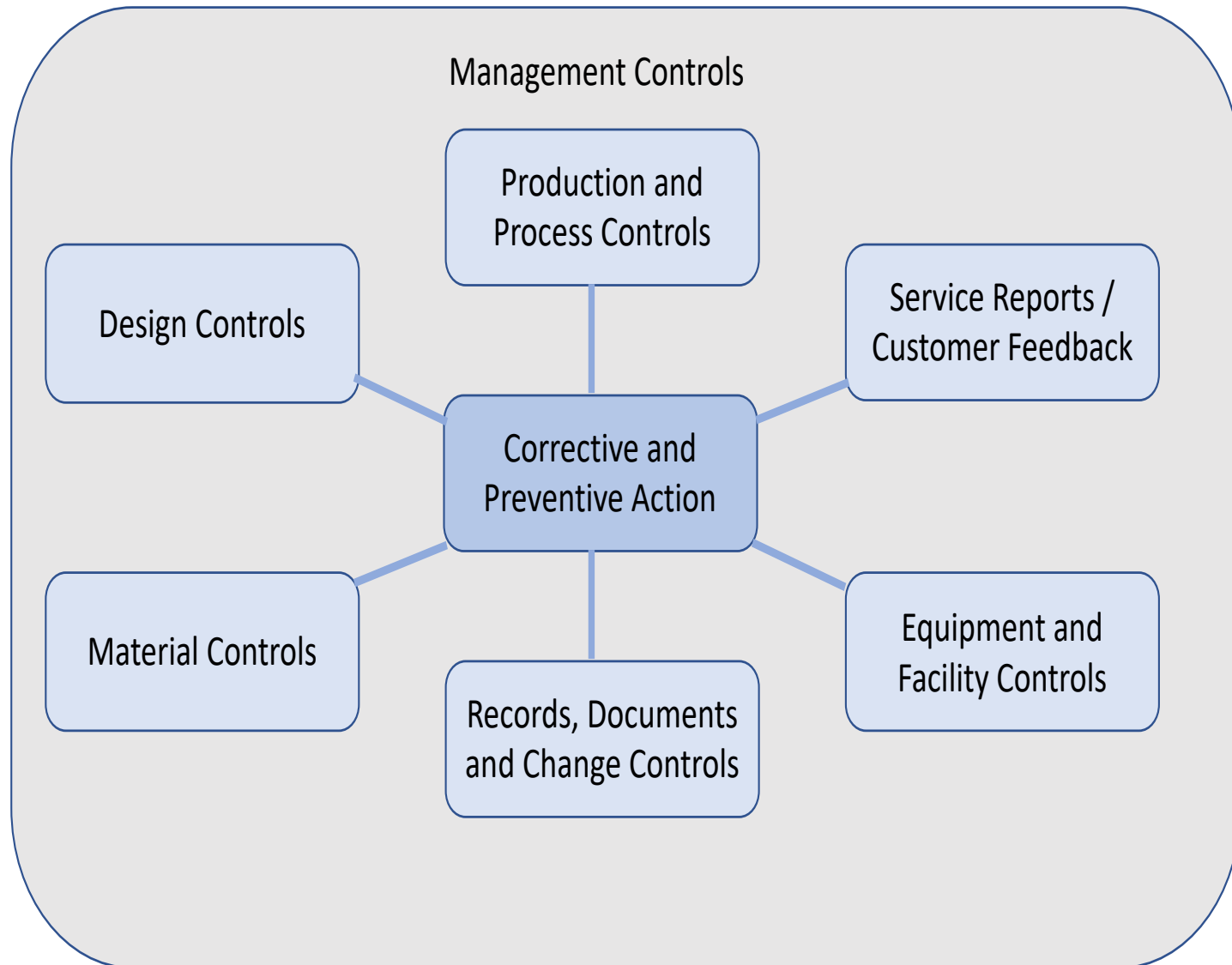


Key definitions

- “**Preventive action**” action to **eliminate** the cause of a **potential** non-conformity or other undesirable situation
 - There can be more than one cause for a potential nonconformity.
 - Preventive action is taken to prevent **occurrence**.
 - *ISO 9000:2005(E)*
- Replace tyre before it becomes bald and **before** it punctures.

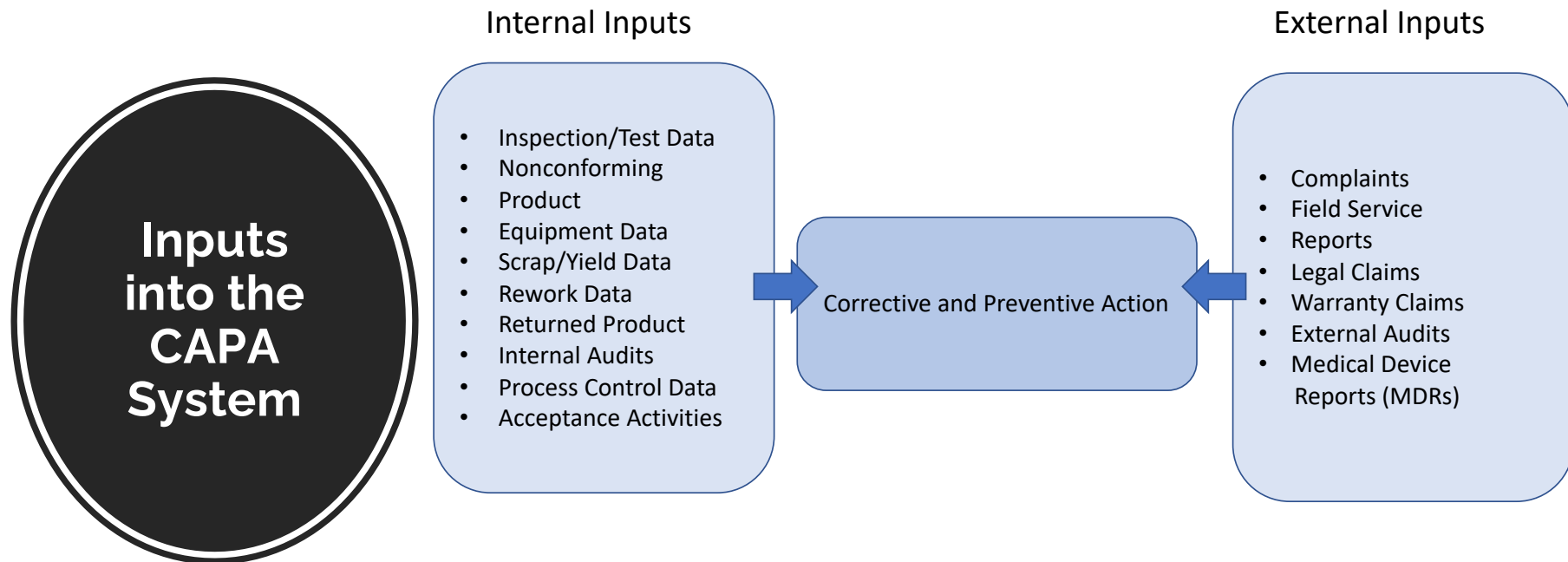


Relationship between CAPA and other QMS sub-systems



What are the inputs
into the CAPA
system ?





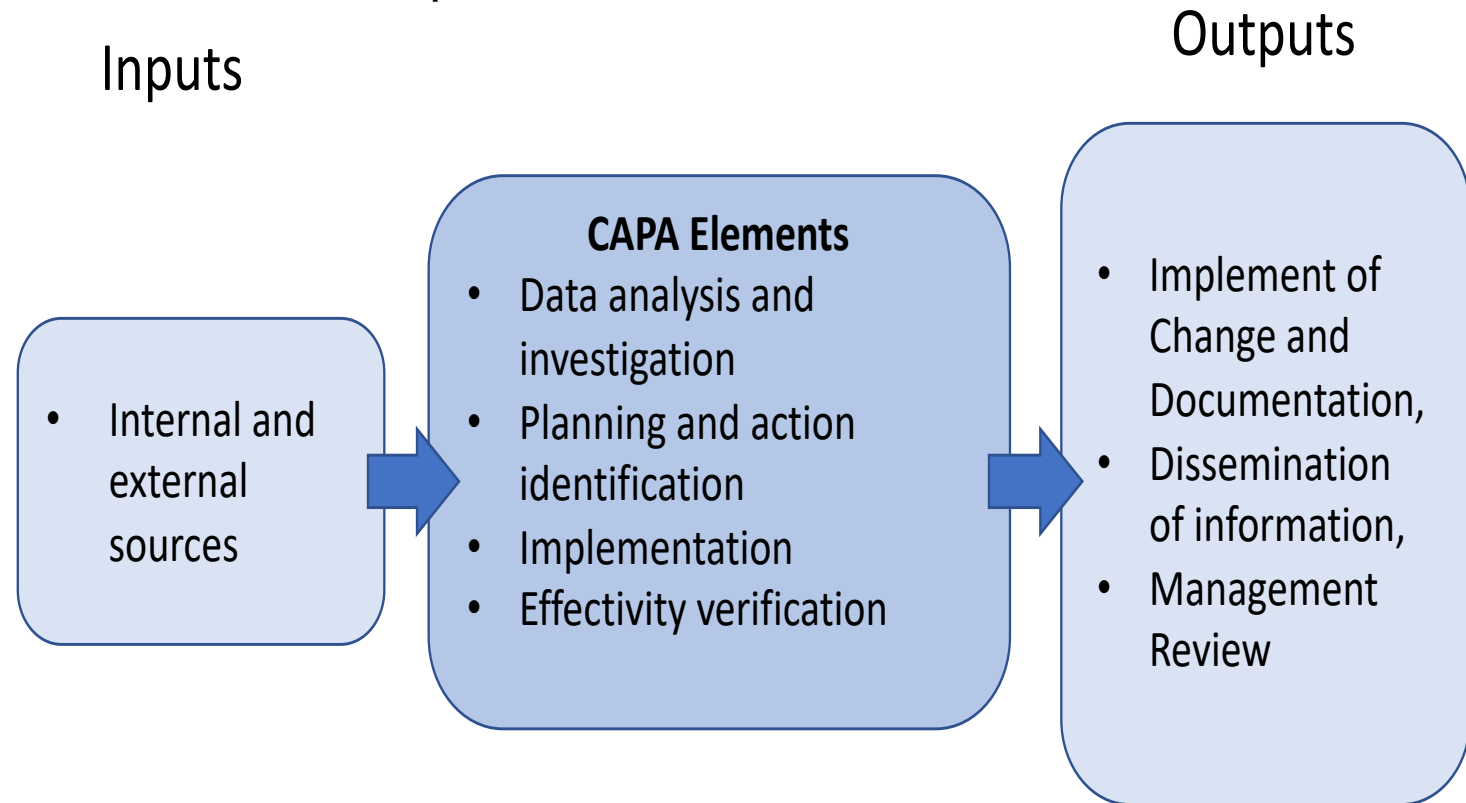
The CAPA System is not just about addressing nonconformities.

- ❖ **The CAPA System is a business improvement process and goes beyond just compliance.**
- ❖ The data gathered during CAPA can be used to improve decision making in other areas of the business: manufacturing, marketing, customer satisfaction, people development and ultimately, to help build overall business success.

SUCCESS



Outputs of the CAPA Process



As part of the CAPA process, data is analysed, root cause investigations are performed, actions identified and implemented, and the effectiveness of these actions verified.

Phases of the CAPA System

Initiation

Planning

Implementation

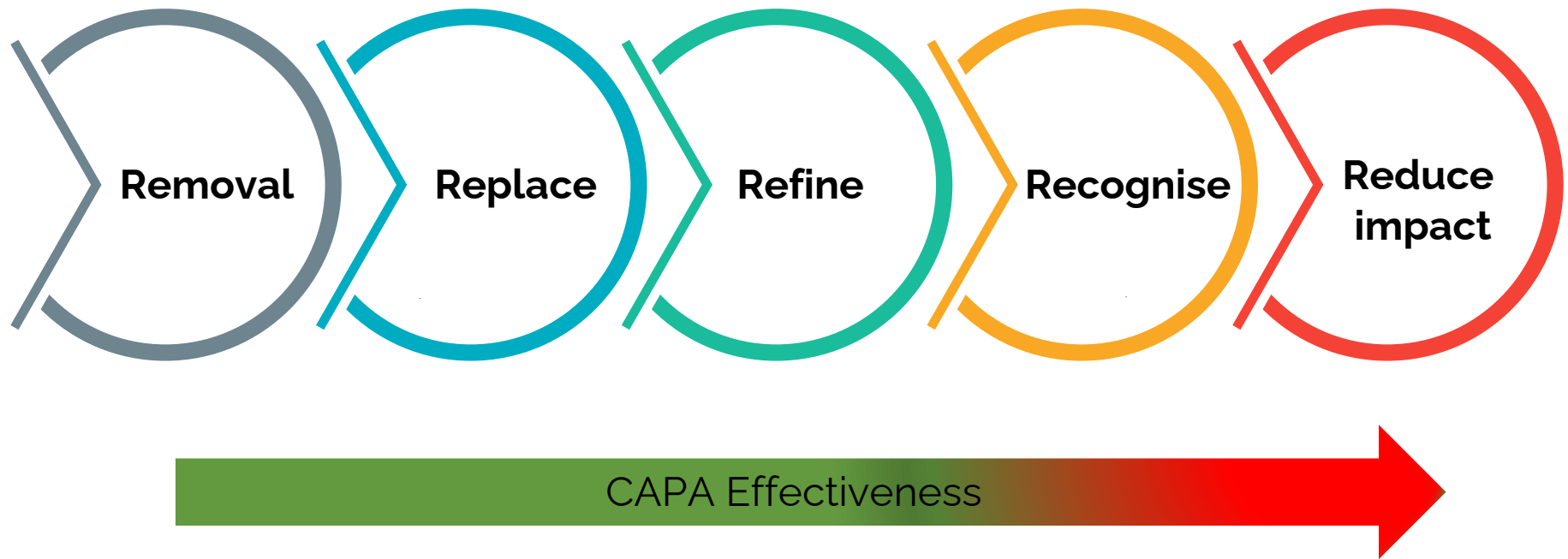
Effectivity check

Phase 2 : Planning

- An output of the Investigation will be the identification of an appropriate CAPA action plan that on implementation will prevent the occurrence or reoccurrence of the quality issue. The following will be used in order of priority.

Phase 2 (Planning): Hierarchy of effectiveness

The 5 Rs



- ❖ The extent of CAPA should be proportionate to the risk of the issue.
- ❖ CAPA that arise from Critical non-conformities or Recalls need to to focusing on Elimination or Replacement options for CAPA.

Sources of CAPA for Corrective Action

Source
Non-conformity
Audit deficiency
CAPA for Supplier
Customer complaint
Management Review

CAPA can also be created as a stand-alone event.

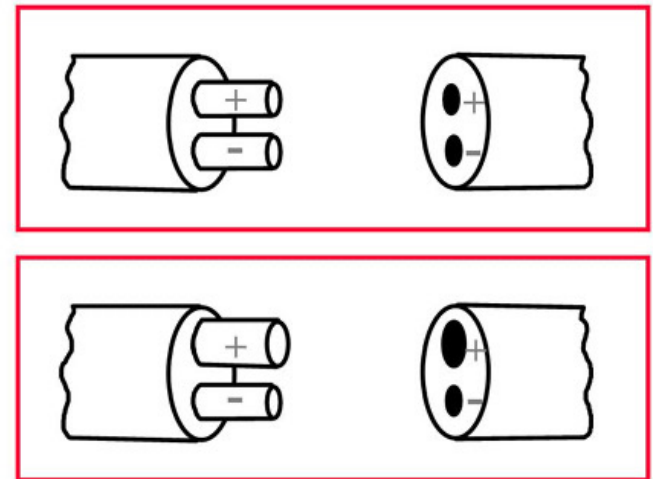
Sources of CAPA for Preventive Action

Source
Trend reviews
Scrap / yield reviews
Process control data
Specification reviews
Management Review
Product Reviews
Internal performance reviews

- ❖ All actions that constitute a form of CAPA, whether arising from non-conformities, audit observations, Supplier Corrective Action Requests, customer complaints, any form of Management Review or other source **must** be documented and managed in the CAPA Process.
- ❖ Even if changes are also being controlled and implemented via the Change Control or Nonconformity processes.
- ❖ The FDA will assess whether you are using the CAPA system appropriately.

Removal

- ❖ Eliminate the possibility of the error. Examples include elimination of the task through automation or application of error-proofing (poka-yoke) such that the task cannot be performed incorrectly.



Replace

- Alter the current process with one that is more reliable by design.
- Make it simpler and less complicated.

Simplicity
is the ultimate
sophistication.




-Leonardo
da Vinci



Step 8

Edit 

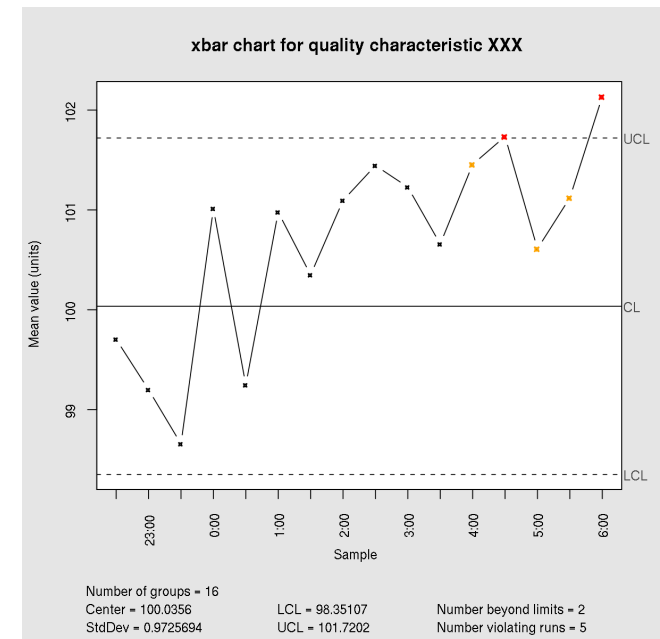
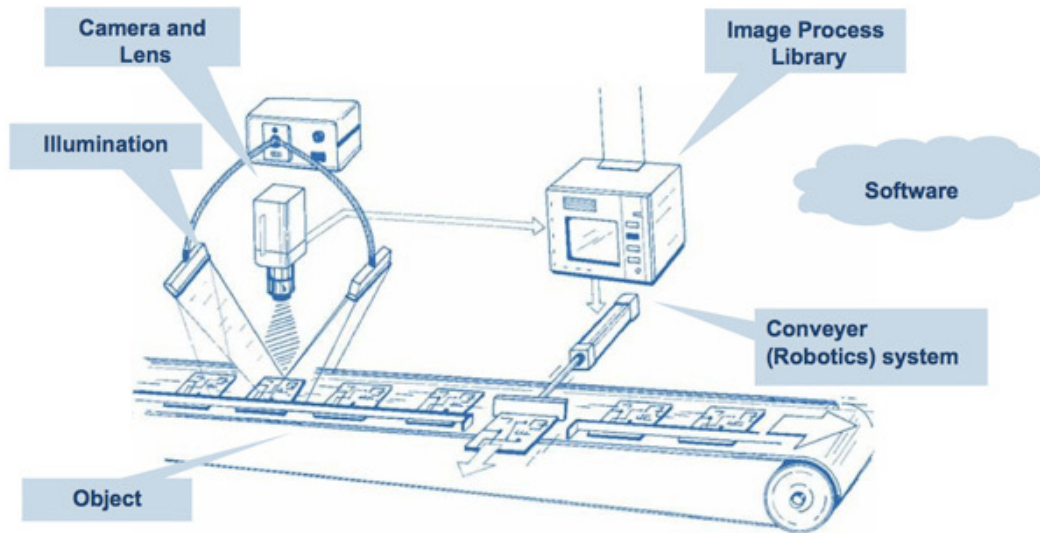
- On the probe body, loosen the two upper LOCKING set screws slightly, and then lightly tighten them.
- **WARNING:** The four lower sets of screws adjust the position of the stylus mount. Very small adjustments have a large effect on the stylus runout. 
- Decide which direction the stylus needs to be adjusted to reduce runout.
- Loosen and then slightly tighten the two (2) opposing screws which are NOT inline with this direction to add some friction.

Refine

- Make the process easier to perform. For example, use 5S or colour coding to make errors more obvious, redesign forms making them easier to complete or add pictures to procedures.

Recognise

- ❖ Improve how the error is detected and contained.
Examples include vision systems or use trend reviews to detect changes before a process goes out of specification.





Reduce impact

- Minimise the impact of the error. Examples include rework or sorting.
- This is weakest form of CAPA.



Training

- Training or retraining alone should **not** be used as the sole CAPA action and should only be used in combination with one of the CAPA hierarchy categories described.
- Question whether the deviation or error is a result of an unclear process or documentation rather than human error.



Phase 2 (Planning): Common Mistakes

1. Too narrow a scope of investigation. Are other processes, products or equipment impacted ?
2. Poor bounding. When did the issue start and stop ?
3. Lack of a cross-functional team.
4. Inadequate root cause investigation.
5. Lack of clarity how the effectivity will be assessed.

Phase 2 (Planning):

- The due date for implementation of the CAPA actions should be proportionate to the risk level of the issue.
- For any given quality issue, it is appropriate there may be multiple CAPA actions both correction and corrective in nature that can be implemented to reduce the risk of repeat events reoccurring.
- For high risk issues implementation of short-term risk reduction actions should run in parallel with more longer-term solutions.

Phase 2 (Planning):

Determining how
effectivity will be
assessed

- During the planning phase **how** the effectiveness of the CAPA will be assessed should be documented.
- The effectiveness of the CAPA should be assessed based on objective evidence. What will be measured, who will perform the activity and over what time frame should be documented.
- All measurement, sampling and acceptance criteria should be based on a valid statistical rationale.


Phase 2 (Planning): Determining how effectivity will be assessed

Common Mistakes in detailing the Effectivity Check

- ❖ Effectiveness checks are not specific to the root causes.
- ❖ Effectiveness check acceptance criteria are not measurable and well defined.

Phase 3 (Implementation):

- During the Implementation phase the agreed actions are completed. An assessment should be made that the actions do not have a detrimental impact on the quality of the products, detrimental impact on process or introduce new risks.
- Failure Modes and Effects Analysis or similar risk assessment should be used to identify any additional failure modes and potential risk mitigation actions before any process change is made.



Phase 4 (Effectivity check):

- Common methods to determine Effectivity
 - Trend analysis
 - Sampling
 - Audit
 - Periodic checks



CAPA Effectivity

- Aligning CAPA Effectivity with the CAPA Plan
 - Moving CAPA Effectivity Upstream

Requirements of CAPA effectivity

1: Verify that the CAPA meets the expectations of the CAPA plan.

This may or may not be complete elimination of the original issue.

It is important in the CAPA plan to be clear how much the risk will be reduced. When this is unclear it will be difficult to verify the effectiveness of the CAPA.

A CAPA that still reduces incidence of the error to the level expected can still be deemed effective.

Requirements of CAPA effectivity

2: Verify that the CAPA does not cause any unforeseen failure modes.

3: There should be a **rational** for the effectivity plan dependent on the type of CAPA that was implemented.

4: It is better to have data supporting how effective the CAPA will be **prior** to implementing the CAPA than **verifying** after implementation.

The verification should not be an experiment.

5: Effectivity must be based on data. Ideally numeric data that is **statistically** based. This does not always mean sampling.

6: CAPA effectivity has to be **reasonably practical**.

Information to be detailed in the Effectivity Plan

- ✓ Who will perform the effectivity assessment ?
- ✓ What will be measured and documented ?
- ✓ When will it be measured ?
- ✓ What will be the acceptance criteria and why ?
- ✓ What will be the course of action if the acceptance criteria are not met ?

Effectivity of various CAPA types

Removal

- If the risk is eliminated through a change in the process there is no logic in assessing the effectivity through sampling.
- Verify that the change has been appropriately made through referencing the change control order.
- It may be necessary to monitor for a period after the change to ensure a different failure has not been created on making the change. This applies to all CAPA types.

Effectivity of various CAPA types

Replacement

- Replacement involves replacing the current process with one that is more reliable by design.
- Documents that can be used to verify the effectivity of the CAPA generated through change control can include:
 - Capability studies on the new process
 - Validation reports for the new process.
- In the absence these documents it may be necessary to sample to demonstrate that new process is more reliable.
- Consider tests such as proportion-tests to demonstrate the new process is statistically different to the previous process.

Effectivity of various CAPA types

Refine

- Facilitation does not change the process but makes it easier to perform through error-proofing.
- It will be necessary to sample to demonstrate that new process is more reliable.
- You need to set criteria in the CAPA effectivity plan around how more reliable you want the process to be.
- Consider tests such as proportion-tests to demonstrate the new process is statistically different to the previous process.

Effectivity of various CAPA types

Recognise

- Detection improves how the error is detected.
- Documents that can be referenced as part of the effectivity check generated as part of the implementation include gage R & R studies that demonstrate the effectiveness of the detection system.
- The effectivity assessment may require monitoring for a period of time to demonstrate the defects are being contained.

Effectivity of various CAPA types

- Mitigation often used with Detection minimises the impact of the error. For example through detecting, sorting and removing the defects.
- Documents that can be referenced as part of the effectivity check generated as part of the implementation include gage R & R studies that demonstrate the effectiveness of the detection system.
- The effectivity assessment may require monitoring for a period of time to demonstrate the defects are being contained and appropriately removed.

Sampling

- Statistical based sampling should be used except where it is not reasonably practical
 - Where lots / events occur at too low a frequency to make the effectivity check unachievable in the short / medium term (0-6 months).
- Other forms on non-statistical sampling
 - Review of trend data. Is the process now stable or moving in the correct direction ?
 - Periodic checks / audits

What to do if the effectivity criteria are **not** met.

Ideally the expectations of the CAPA plan will be met and the CAPA deemed effective.

However we do not live in a binary world where CAPA actions deliver fully or not at all.

If this is the case you can either:

- 1) Deem the CAPA ineffective and apply further actions to reduce the risk.
- 2) Make a risk based decision that the level of risk is now acceptable and further efforts do not justify the further gains in risk reduction. – Partially effective / Effective and close.

This can only be assessed on a case by case basis.

CAPA Type	Documents that can be referenced as part of the Effectivity Check
Removal	Change Control orders
Replacement	Capability studies, Validation – Qualification reports Training assessments
Refine	Capability studies, sampling
Recognise	Gage R & R studies
Reduce impact	Gage R & R studies, process monitoring

CAPA Management

❖ Some organisations have a specific CAPA Board

- ❖ The CAPA Board is a cross functional team responsible for oversight of the CAPA process.

CAPA Board
Quality Assurance
Quality Control
Production
Technical Support
Research

Some responsibilities of a CAPA Board.

- Monitoring of the status of all open CAPA records.
- Review of key performance metrics such as CAPA closure, cycle time and overdue CAPA events.
- Approval of due date extensions requested by CAPA Owners.
- Management review of items that may be preventing effective and efficient execution of the CAPA process.
- Monitoring and assessing the effectiveness of the CAPA process based on a range of inputs.
- Approval of CAPA due date extensions.
- Communicating output of the CAPA process.



CAPA

Corrective and Preventive action