Guidance on CAPA Plans

Quality Management Systems Subcommittee
Science & Policy Workgroup

NOTE: This guidance is not legal advice. It is intended to assist licensed marijuana businesses to better understand elements of a CAPA plan. Please consult an attorney or quality management professional if you have any questions regarding the requirements that apply to licensed marijuana businesses.

What is CAPA?

CAPA stands for Corrective Action and Preventive Action. It is a systematic approach that is part of the Quality System used to document deviations and nonconformances, investigate root causes, and implement actions to prevent recurrence. CAPA plans can be used to communicate corrective and preventive actions to the appropriate people, to provide information for management review, and to document activities for trackability.

What terms do I need to understand to implement a CAPA plan?

Correction means an immediate fix implemented to eliminate the one instance of a nonconformity or deviation.

Corrective action means a reactive action implemented to eliminate the root cause of a Nonconformance and to prevent recurrence.

Nonconformance or deviation means a non-fulfillment of a requirement or departure from written procedures, work instructions, or quality system.

Preventive action means a proactive action implemented to eliminate the cause of a potential Nonconformance or other quality problem before it occurs.

Root cause analysis means a problem-solving method aimed at identifying the root cause of a nonconformance or deviation. It involves asking “why?” until you reach the root cause.

What Is the difference between Corrective Action and Preventive Action?

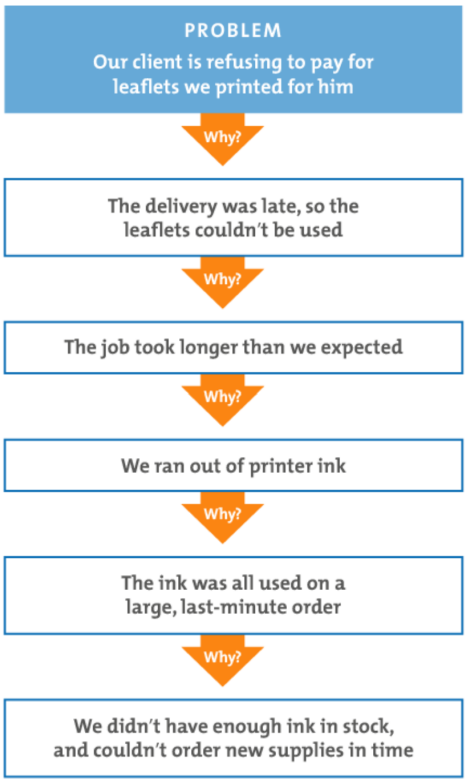
Corrective is reactive. Preventive is proactive. Although these two actions use similar processes and some of the same analytical tools, they are not necessarily used together.

What is the CAPA process?

1. ***Description of the event.*** Describe the nonconforming event. What is the requirement that is not being met? What evidence exists? What batches were involved, if any? What were the dates, times, and people involved in the event?
2. ***Event response and investigation***. Document the immediate correction to eliminate the one instance of nonconformity and list the investigation steps used to determine the root cause(s). What processes or data were reviewed? Which staff were notified? Was any process repeated or halted?
3. ***Determination of root cause*****.** A root cause is the identification of the source of the problem where the problem, system, process, or external factor is identified as the cause of the

nonconformity. One way to identify the root cause is the "5 Whys Method." Keep asking "why" until the root cause is determined.

3.1. *Example:* [5 Whys | What you need to know to pass your Six Sigma certification exam (sixsigmastudyguide.com)]



4. ***Identify corrective action(s)***. List all the corrective actions to be taken to eliminate the root cause(s) of nonconformity. What is the corrective action? Who is responsible for implementing it? When is the proposed implementation date? Which stakeholders are involved in the corrective action?

   4.1. *If the corrective action is to recall affected product, reference your internal Recall Plan* and notify the MED.

5. ***Implement and communicate corrective action(s).*** Ensure everyone is aware of the changes to be made and provide ample training on the changes. Document when each corrective action was completed and what evidence exists to prove the corrective action was implemented.

6. ***Identify and Implement Prevent Actions:*** Determine if there are any preventive actions that should be taken to prevent the nonconformity from occurring again in the future.

7. ***Evaluation of the corrective action(s) and preventive action(s)***. Supervisors or management should evaluate the significance of the nonconformity and if the corrective actions are sufficient to prevent recurrence. Are there any other corrective actions that need to be implemented?

8. ***Verification of the effectiveness of corrective action(s) and preventive action(s)***. Supervisors or management should verify if the corrective actions were effective. Allow a

sufficient amount of time to pass with the new corrective actions in place. Did the changes have their desired effect (more than once) and did they have any adverse effects?

Source: smartsheet.com

How can a business implement a CAPA plan into their processes/workflow?

To implement a CAPA plan, a business can create a CAPA SOP, so employees know the process to respond to and investigate problems that cause nonconformances. This SOP should include important definitions, the protocol employees should follow, and who should be notified. The best way to document CAPAs is to create a CAPA form for employees to fill out and management to sign for approval. An example is provided on page 5.

What are some misconceptions about CAPA?

Although CAPA plans are required in several industries, companies often have doubts and misconceptions about CAPA including:

1. ***It's a punishment for when something goes wrong.*** For a company to successfully thrive, someone must implement a CAPA process to ensure root causes of problems are effectively handled and documented as internal memory for the future. Human error is rarely the root cause of problems, people implement processes that continually need improvement. Depersonalize CAPAs by letting your employees know that a CAPA report is not a write-up or an indictment of an individual. It should be used as a learning experience to continually improve processes.

2. ***It's extra work.*** SOPs are put into place for a reason, to ensure processes are performed the same way each time. If there is a deviation or nonconformance, it will likely happen again if it is not investigated and fixed. By identifying and eliminating root causes of problems as opposed to using 'band-aid' fixes, it will in turn prevent the problem from occurring again, creating less work.

3. ***Training staff on CAPAs is too expensive.*** Implementing a successful CAPA plan involves training. If you think training is expensive, how much do you think a recall will cost you? CAPAs can help your business determine where problems are occurring to fix them in a timely manner

and may help prevent quality problems or recalls in the future. Organizations that train are the ones that sustain.

Where can I learn more about CAPA plans?

1. ASTM Standard Guide for Corrective Action and Preventive Action (CAPA) for the Cannabis Industry. https://www.astm.org/Standards/D8229.htm

2. U.S. Food and Drug Administration PowerPoint on Corrective and Preventive Action Basics. https://www.fda.gov/files/about%20fda/published/CDRH-Learn-Presenation--Corrective-and-Preventive-Action-Basics.pdf

3. U.S. Food and Drug Administration PowerPoint on Corrective and Preventive Action. https://www.fdanews.com/ext/resources/files/Conference/MDQC14Presentations/Jariwala-CAPA-JVJ-FDAnews-v20---Clean.pdf

4. Learn about GMP: 8 Process Requirements the FDA wants in your CAPA system. https://learnaboutgmp.com/good-manufacturing-practices-cgmp/8-process-requirements-the-fda-want-in-your-capa-system-video/

5. Master Control Simplifying CAPA: Seven Steps. https://www.mastercontrol.com/capa-software/capa/plan/

6. Med Device Online The 5 Most Common Problems with your CAPA Process. https://www.meddeviceonline.com/doc/the-most-common-problems-with-your-capa-process-0001

7. R.M. Baldwin, INC Preventive/Corrective Actions (CAPA) Guidelines. http://www.rmbimedical.com/RegulatoryAffairs/capa%20guidelines.pdf

8. Wellness for Business Conducting CAPA Investigations. https://www.rcainc.com/wp-content/uploads/2017/10/CAPA-Webinar-Final-Slides_9.21.16.pdf

ABC Company Example Corrective and Preventive Action Form

CAPA No:	Testing nonconformity	QC Failure	Suggestion for improvement	From complaints/notices/external parties		Other
Category	Testing failure	System failure	Wrong instructions	Training	Client fault	Other
Raised by:		**Assigned to:**		**Date:**	**Remarks:**	
Description:						
Proposed immediate action (correction):						
Root cause analysis required: **Yes** **No**						
Underlying / root cause:						
Proposed action for long term solution (corrective/preventive action):						
Completed by:		**Date:**	**Remarks:**			
MANAGEMENT USE ONLY						
Comments on effectiveness of action taken:						
Closed out by:		**Date:**	**Remarks:**			