

COVER STORY: Corrective or Preventive?



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Corrective or Preventive?



By: Jose Rodriguez-Perez, Ph.D.

One of the most sterile debates one can witness is the discussion between two CAPA professionals about whether a specific action they are working on should be considered corrective or preventive. The debate is pointless because what really matters is whether the action would attack a root cause.

To add even more confusion, one only needs to read the formal definition of corrective action. ANSI/ISO/ASQ Q9001-2008 section 8.5.2 defines corrective action as “action to eliminate the causes of nonconformities in order to *prevent* recurrence.” ANSI/AAMI/ISO 13485-2003 contains the same definition, and FDA regulation for medical devices (Title 21 CFR § 820.100) establishes that each manufacturer shall identify “the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems”. They use the word prevent as part of the *corrective* action definition.

To avoid any confusion, I do recommend to substitute the word *prevent* with the word *eliminate*, and therefore the definition of corrective action will read “action to eliminate the cause(s) of a detected nonconformity or other undesirable situation. The corrective action should eliminate the recurrence of the issue.”

A second common source of confusion and misunderstanding is deeper and more philosophical. Let’s say that company A has a situation where root cause Z is creating a potential dangerous upward trend but the result is still within specification. Someone can argue that because the result is still *within conformance*, the action to be taken can be categorized as preventive. Others may perfectly well argue that it is a corrective action because the cause was already acting, even though the final result is still in conformance. My opinion is that it is a preventive action but whatever you choose is fine, because the really important issue is to implement the action as soon as possible.

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For the sake of clarification, Table 1 contains the rules followed in my book **CAPA for the FDA-Regulated Industry**:

Table 1: Corrective or Preventive?

Situation	Examples
Name it <i>corrective action</i> only if you already have a product nonconformance or process noncompliance	<ul style="list-style-type: none"> • Product failing specifications • Confirmed customer complaint • Use of obsolete or un-approved documents • Audit finding of product nonconformance or process noncompliance
Name it <i>preventive action</i> whenever the product, process, or system is still in conformance but you discovered root causes with the potential to create nonconformities	<ul style="list-style-type: none"> • Developing adverse trends from a monitoring system (run chart or control chart) <ul style="list-style-type: none"> • Shifts • Trends • High variability, and so on
Name it <i>preventive action</i> if it is purely a recommendation to enhance or improve any product, process, or system	<ul style="list-style-type: none"> • Changing to new material or new design • Implement new (enhanced) processes

A typical situation often found during nonconformance investigations is the discovery of both existing and potential root causes simultaneously. In those cases, actions taken to eliminate the cause of the nonconformance will be corrective actions, while actions taken against the identified potential causes will be considered as preventive actions. It is possible to have both categories of actions within the same CAPA Plan.

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A third controversy occurs when the same action can be considered as both corrective and preventive when applied to different situations. Some CAPA professionals believe that once you have a corrective action (because you already had a nonconformance) to whatever product, process, or system you extend it, it will always be a corrective action. On the other hand, other professionals, including myself, believe that if the same action can be extended to other product/process/system not yet affected by this root cause, then it should be considered as a preventive action for them. ■

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'PICK ME UP' QUOTE

"Pleasure in the job
puts perfection in the work."

Aristotle

Submitted By: Dan Gowers