
Corrective and Preventive Actions: A Framework For Effective Solutions



Introduction

When it comes to implementing corrective and preventive actions (CAPA), responsible leaders struggle with creating the right solutions. For manufacturing industries, making the right change is important. Whether it's related to safety, quality, or something entirely different, once a CAPA is implemented it should leave the operation better than it was before, and leave you with peace of mind. Done correctly, it ensures the sustainability of the improvements and prevents future issues from occurring. But several questions remain.

What are the right actions? How do I know they'll make the desired impact? How can I ensure they'll be sustained?

Manufacturing leaders often find themselves grasping at straws to come up with actions that will truly correct, contain, and prevent future errors from occurring. Despite their ability to define and understand the problem, its seriousness, and its risks, leaders still struggle in producing solutions that make a lasting difference. There is a lack of understanding of what makes one action better than another.

In this guide, I'll break down the "Goodness of Solutions" framework so you can see and understand why some solutions are much better than others. This framework will allow you to finish CAPAs quickly with highly sustainable, highly impactful results.

The roadmap for this framework comes from the sentiment best expressed by W. Edwards Deming, who said, "A bad system will beat a good person every time."

The framework demonstrates concrete ways that countermeasures, corrective actions, and preventive actions can be improved to decrease human error. By taking the pressure off of individuals and building quality into the system and environment, the impact and sustainability of your CAPAs will be greatly increased.



Lowest Tier. “Retrain the operator”

The first tier of solutions solely relies on communicating information. The recipients of this type of CAPA are usually on the front lines (front-line workers, maintenance staff, etc.). Often the very person who failed to detect an error will be the sole recipient of the message. This is a very common corrective action that you’ll be familiar with. I’ll call it “retrain the operator” and you can smirk and nod your head, because you know how many times you’ve been a part of such a “retraining”. If you did smirk, the reason you did was because you understand that this solution doesn’t really solve the root cause. Was the operator really trained insufficiently to begin with? Will making them read a standard operating procedure really make a lasting impact and prevent us from similar failures in the medium and distant future? Probably not.

Shop Floor Example:

Consider a manufacturing process. At various stages in the process the product is weighed. If previously some issue with the product weight was identified and a CAPA was put in place, it is important to improve standards, specifications, and retrain operators to the correct procedures for weighing the product (including how often, how to work the scale equipment, and how to select a product sample). As a corrective action, it’s an important step, and I rather do it than not. Yet so many CAPAs end here. Everything is put on the individual to make the correct decisions and yet nothing is really improved.



Middle Tier – Visual aids, Warnings, Sirens

You can make a very big difference to the impact of your CAPAs simply by adding things I like to call “signal enhancers.” Signal enhancers don’t take much more work or effort either. Most human error is not caused by malicious intent or sabotage, but simply honest people making honest mistakes; somebody did not realize an error had occurred. They didn’t “catch” the error until after all the consequences were realized. What signal enhancers aim to do is improve the detectability of errors. This still puts the individual at the center of the solution. The CAPA still relies wholly on the individual to do the right thing. But now they are supported by their environment.

Could you imagine driving a car without stop lights, turn singles, and brake lights? Or have you ever seen what happens to a parking lot when a light dusting of snow covers all of the parking spaces?



Adding small improvements like 5S, visual management, bells, whistles, sirens, and other tools to aid employees in detecting errors is a highly impactful way to improve any solution. Even better, it has an oversized impact, since many of these solutions cost very little too.

Shop Floor Example:

Continuing the production line example, imagine that in addition to instructing the operators how to properly weigh the product, real-time product quality data, warnings, and alarms were added as well. TV monitors on the shop floor that reflect “green” quality data vs “red” quality data could signal the need for supervisor involvement to ensure consistent product weights throughout the shift. Meanwhile visual aids detailing possible workflows can be posted at the weigh station to assist the operator in determining what to do if the product weight was too high or too low.

Integrating real-time data and alarms that monitor common quality issues is an easy way to enact this. In food processing, in-line metal detectors are widely used to ensure no metal shavings from machinery falls into the food product. Freezer temperatures are monitored and signals alert operators when there is a problem to ensure the cold chain is maintained.

Upper Middle Tier – Downstream Inspection

Above the tier of signal enhancement is downstream inspection. This technique is usually implemented because of a government regulation or only for a short amount of time, like in response to an acute issue such as product recalls, or when training new employees. Downstream inspection can be expensive and promote a rework mentality instead of in-process quality.

However, having a dedicated person inspect work and process, and finished goods, is still a very effective way to mitigate the risks of upstream human-error. Two eyes are better than one. So, if the resources are available, this type of corrective action can produce immediate results.

Shop Floor Example:

As part of the production run process, automated tasks and verifications built into quality check workflows can add an additional layer of protection against inconsistent product weights. Line supervisors who have to “sign off” on an operator’s quality check eliminate any risk associated with lack of training or guesswork.

Highest Tier – Error-Proofing

At the highest level of corrective solutions is error-proofing. As its name implies, error-proofing prevents any issues from occurring in the first place. As a result, solutions that incorporate error-proofing ensure right-the-first-time, in-process quality and have a very high impact on the final outcome of the CAPA initiative.

Many people think that because error-proofing has such an oversized impact on the outcome of the system that it will entail high costs like the development of new software or engineering designs. While error proofing may use these technologies, it doesn't necessarily rely on them. In fact, error-proofing provides an opportunity to think creatively about the problem and solutions.

For instance, consider that you've never stuck your power cable into your headphone jack. You've probably never tried. And unless you're my grandma, I bet you've never connected an ethernet cable into a USB port. The reason is error-proofing. Simply by creating unique shapes for different cables, computers have prevented almost all of their users from incorrectly connecting cables which could have devastating consequences for the machine hardware. The solution is extremely low cost, they're just using different shapes, yet it has a tremendous impact on the customer experience.



Shop Floor Example:

Using our production line example, we can see how easy it would be to error-proof the product weight process as well. The line could be automatically set to stop at specific intervals if a weight measurement is not input to the system, ensuring product quality and preventing unmitigated risks of producing bad products. With slightly more elegance, it's easy to conceptualize an error-proofing solution that checks to see that the correct workflow, based on the product weight, is completed before the product is moved to the next step in the process.



Likewise, you've never forgotten your card at the ATM. Never. The ATM has also incorporated error-proofing into the cash-dispensing sequence to ensure this. You must first take the card before cash is dispensed. This prevents the ATM user from driving away in haste after receiving the cash. This simple feature, a logical sequence of steps, costs ATM manufacturers and banks nothing. Yet, this sequence of steps saves untold amounts of time and headaches from bank employees asked to retrieve forgotten cards, to say nothing of potential risks related to identity theft. Process sequence is a great errorproofing technique that facilitates an extraordinarily high level of error prevention.

Improving your CAPA Caliber today

You can get acquainted with this framework and begin using it even before the next time you need to complete a CAPA.

- Take a look at all the CAPAs completed. Categorize them based on the tiers of this framework. Where do they fall? You may find that many of them look similar and rely on retraining of the operator and updating the standards.
- Scrutinize these actions to determine if more couldn't be done to move the CAPA into a higher tier, either through integrating signs, warnings, or error-proofing.
- Foster an ongoing commitment to reviewing all new CAPAs through the Goodness-of-Solutions framework.

As the need for CAPAs continues to pop up, you will not always have time to think about and generate the best solutions that use the best practices of the model. This is OK. But as you complete CAPAs, denote which tier the solution falls into.

Conclusion

CAPAs are an important and necessary part of operations management. In many cases, the effectiveness of a CAPA is the only thing protecting employees from ongoing safety concerns, or customers from product quality issues. Whatever spurred the need for CAPA, the desired result is always the same: prescribe changes so this never happens again.

This guide has walked through the "Goodness of Solutions" framework to help you understand what makes for a good solution. The framework is effective at demonstrating what is missing from current CAPA plans, and also prescriptive in what can be done to make future prescriptive actions more effective, impactful and sustainable, all while being sensitive to common operational constraints like manpower, capital, and time.

Informed by Michael Parent

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