PathWise

Corrective Action vs. Correction- Which is it?

I am sure most of you have heard that there are corrections and corrective actions and the two are not the same thing. What I am also sure of is that our industry struggles with the difference. Having travelled around the US and overseas training many companies on this subject it has become apparent that the distinction between these two specific terms is not well understood, which leads to many bad habits and issues with the CAPA system. In this situation misunderstanding these terms has led many companies to feel they are implementing corrective actions, when they are only implementing corrections. When used correctly, the CAPA system is one of the most powerful systems available to drive major improvements and decrease waste. This is only the case when taking actions (corrective and preventative) and not just implementing corrections.

The importance to the CAPA system and misunderstanding of what a correction is became so apparent that ISO standards added the definition for corrections in 2008. To understand the difference let's look at the definitions and where the issues can occur.

Corrections and Corrective actions can be defined as the following:

- *Correction is taken to rectify a known nonconformance;*
- *Corrective Action is taken to prevent recurrence of said nonconformance.*

The first thing that clouds the issue is the interpretation that all corrections are immediate. While many corrections are, others can take a period of time to define and implement. Take, for example, a situation where water is found on the floor. An immediate correction may be to clean

the water off the floor (or even to just isolate the area while it is determined if this is just water). Let's assume a little used pipe has a crack in it that has caused the water to be on the floor. It may take some time to identify the source of the water since the pipe is not in constant use. The response would be obvious, fix the crack in the pipe. Ask yourself, is this a correction or a corrective action? Let's come back to the answer to that question later in this paper.

Another interpretation that can lead to how corrections and corrective actions are implemented would be the definition of nonconformance. We look at most nonconformance as individual events or symptoms and define our nonconformance as the single result that lead to a deviation or CAPA. The failed result or unexpected observation may be what lead us to initiate a quality event, but defining this as the nonconformance or as the problem statement drives us to an incomplete Root Cause Analysis. Let's dig into that a little.

The FDA defines corrective actions as those actions that address the root cause of an issue, whether it be a deviation, a nonconformance, an expected result or whatever your organization calls it. The corrective action addresses the ROOT CAUSE of the issue, not the outcome or symptom. But is this where we put our effort and due diligence? In general, the answer is no. Our focus and motivation typically is to eliminate the outcome (symptom) quickly and with minimal effect on scheduling and cost. So, while we may hope to get to root cause, our primary goal is to address the symptom. By defining our nonconformance as the symptom, we set ourselves to only go deep enough to eliminate that result. Unfortunately, this is systemic in our industry. We try our hardest to eliminate the non-conformance and tend to call any result of an investigation a corrective action, when we are often simply correcting the result.

For our pipe example, we repair the pipe and call it a corrective action. We can even defend that by saying the cause of the water on the floor was the cracked pipe. We neglect the second half of the definition of corrective action which state "to prevent recurrence." Does this action really prevent recurrence? We must start to think deeper, to the root. The cracked pipe caused the

water, but what caused the cracked pipe? If we dig down to that level we can prevent this pipe from cracking again, and even may prevent other pipes from cracking depending on what the root cause is. Digging deeper allows us to get past the cause down to the root. Can you see how the correction may just get us back up and running, while the corrective action may save us lots of work in the future?

As mentioned earlier, some of the confusion around corrections versus corrective actions can go back to defining the nonconformance and drafting a problem statement. We will cover that in more detail in a future paper, but for now we can understand that the better we define what to eliminate, the better the chances are to identify a true root cause.

One example I have seen is a clean room that has a bioburden above action level result during environmental monitoring. For those of you who don't work in clean rooms this is a way to say there are more microorganisms than we want in our cleanroom. What we forget sometimes is that *we* set the action level. The Microorganisms themselves don't know what that level is. The natural response at most companies is to state "On 25 FEB there was an action level excursion for Bioburden" since that is what triggered us to initiate a quality event. What we neglect to look at is the data for that room. In many cases, there is a trend of increasing bioburden leading up to the day the action level was exceeded. What if the data was below the action level, but had an obvious and statistically supported increase that started last June? If we stay with the 25 FEB problem statement, we will most likely clean the room and then take our best guess at what changed in February and address that as our corrective action. In the second case, we will look at what started the increase in June and have a much better chance at finding root cause and implementing a true corrective action.

One other typical example again ties back to our inability to dig deep enough. A final product has an out of range product result. We do a root cause analysis and determine the equipment used for

processing the product was not validated to the correct process range. We revalidate the process to the correct range and the product passes. We even perform an effectiveness check and the product passes for the next 5 batches. We have a pizza party for all involved and celebrate what a good corrective action program we have. But can we and should we do more? What if we ask "why" a few times? Why did we validate wrong? It was a new process added to already existing and validated equipment. We ask why this is important and we find that our policy for new process implementation states "ensure existing equipment has been validated." Based on this information we implement a corrective action to change the statement in our policy for new products to state "ensure existing equipment is validated to the proper range." This leads to a more robust policy that will prevent recurrence not only for this individual result, but for future products.

Hopefully you have a better feel for the difference between corrections and corrective actions. What I haven't said yet is there is a time and a place for both. There are times where we have a nonconformance that is medium to low risk and we decide through a formal risk analysis that because risk is low, a correction is okay as an outcome of the root cause analysis. Any of the cases I stated above may fall into that category at one time or another based on risk. When we have higher risk, it is important to really get down to the root cause and implement corrective actions.

SUMMARY

In summary, I would like to rephrase the definitions a little bit and add details that will address issues a lot of companies and individuals in our industry deal with.

A correction is taken, immediate or after some analysis, to eliminate the symptom or result of the event that triggered the nonconformance. It may even eliminate the cause of this nonconformance

but not the cause of the cause. It will generally only prevent recurrence of the identified nonconformance and not have any impact on other results or products.

A corrective action addresses the root cause of the nonconformance and prevents reoccurrence. It may address the cause of the cause, for example an issue with systems, procedures, and/or equipment that lead to the symptom or nonconforming event. In general, a true corrective action will often, but not always, address a certain class of nonconformance, not just the single one observed at this time.

About the Author:
Mike Murphy has 20 years of experience in manufacturing. He has a Six Sigma Masters certificate from Villanova University. He also has a Quality Improvement Certificate from Worcester Polytechnic Institute, where study included Failure Mode and Affect (FMEA) Analysis, Introduction to Six Sigma, Root Cause Analysis, and Building the Team Concept for Continuous Improvement. He also has his own patent: Murphy, Michael, et al. 2010. Bioengineered tissue constructs and methods for producing and using thereof. U.S. Patent 7,824,913, issued November 10, 2010.