Kepner-Tregoe

KT CAPA: Skills are Not Enough

The Challenge:
There is a recurring and troublesome scenario within the Life Sciences industry

Your average time-to-root-cause has increased beyond the regulated thirty days and shows no sign of decreasing. Your investigators spend most of their time on recurring problems you thought had already been solved. You're getting complaints from the functional managers because a high percentage of their people's time is being spent thrashing through problems when they could be getting product out the door. Your new drug application has just been stalled by the regulators. And sales and customer service are blistering your ear because one of those investigations has taken so long that a critical drug, of which you are the only supplier, is close to going on back-order.

Some of the consequences of this scenario — to both the organization and its shareholders — are obvious:

- Until you find and validate root cause, you can't make or sell the product
- Since you can't sell, revenues may drop, raising concerns externally
- With work stalled, raw material supplies back up and order cycles get out of sync, undermining your efficiency
- As your people keep trying to juggle a dozen issues, their time and efforts are shifted towards non-productive activities, affecting overall efficiency

As the bottleneck ripples through your inventory system, supplier network, and marketing programs, less obvious effects begin to appear. A situation like this can harm your relationship with regulators, and the increased scrutiny can cause additional problems. Eventually, word gets out to shareholders and investors. As we've seen recently, just one highly visible incident can place at risk the trusting relationship you have built with your customers over the years. If you happen to be in the wrong place at the wrong time, it could cost you your job.

Some of this is about Skills:

As pioneers of root cause analysis training and consulting, having transferred these skills to millions of people in the last half century, Kepner-Tregoe has experienced that sometimes people simply do not have the individual capability of finding root cause.

This can show up in a number of ways:

- People involved in investigations may not be skilled in asking the right questions to the right people in the most effective way
- People may not know how to write a Standard Operating Procedure that can be effectively executed
- The teams assembled to analyze the problem may contain too few people, too many people, or the wrong people
- Investigation reports may be confusing and end with a list of CAPAs that sound like band-aids
- Problem-solving meetings may be hindered by a facilitator's inexperience in group settings or their inability to manage "challenging" individuals
- Those who manage investigations may approve CAPAs which do not really get to the heart of the issue, and can come back later to haunt them

Some of this is about Process:
While building individual skill is critical, there are additional factors to consider:

- The process by which you identify, prioritize, assign, manage, and close-out issues may be broken
- Time may be lost as hand-offs get dropped and reports get stuck in recursive loops
- Roles and responsibilities may overlap or change from issue to issue
- Individual reviewers may be looking at the data from different points of view, leading to time-consuming debates on which process to use and what data to consider
- All too often, politics can hijack the process

It may well be that your people are "A Players". However, if you put an "A Player" onto a "C Team", the "C Team" usually drags the "A Player" down to its level. Putting a highly skilled investigator into a broken workflow process can have the same effect.

Some of this is about Systems:

Sometimes this is not about the people or the process; it's about the systems. You may lack the data needed to explain batch discrepancies. The data might be available, but inaccessible, pushing your "30-days-to-root-cause" target out into the future. Maybe your deviation tracking database lacks depth, clarity, prioritization and analysis capabilities, making it impossible to tell if this is the same problem you had in a sister plant or some new deviation you've never seen before.

And some of this is about Culture:

The gap is often about the performance systems—the structured set of expectations, feedback, and consequences within which your people operate.

Asking a few questions can help determine your culture's shortcomings:

- Are people being encouraged to look for 'the cause of the cause', even if it takes a little longer?
- Are they being told to look for permanent corrective and preventive actions, not temporary band-aids, even if the long-term fixes cost a little more?
- Are your people rewarded for preventing problems, or do they receive more accolades for fire fighting?
- If you are a lead investigator, what's in it for you? Is this a part-time effort that takes away from your full-time responsibilities? Is it tied into your annual appraisals around bonuses and promotion? Or, are you just "taking one for the team?"

The brightest, most committed troubleshooter, if trapped in a culture that devalues problem-solving, may be doomed to failure. Research shows and common sense confirms that if you expect to change your employee's behavior, you have to change what they are being rewarded for. There will always be a dedicated minority who will do the right thing regardless of the personal consequences to them. However, does it really make good business sense to run such a high risk enterprise on the basis of heroic individual effort?

The Solution:

Clarity of systems issues need to be visible at the information level, identifying who needs to know what and when and, how they need to access the data. Working through existing processes, systems and people you need to drill down to diagnose how much pain there is, and where it is located. With the issues identified, a project plan can be crafted to meet the established objectives.

Processes and Systems First:

Without a process, all you have is chaos. The first task is to map the current investigation process from first notice to final disposition, to isolate problems with the way you are doing things, and set

measurable objectives for the process. We then work with you to develop a new process that avoids the problems you have encountered and meets the objectives you have set. Roles and responsibilities are then clarified, measures and metrics are established, and the process is rolled out.

Building a Structure of Support:

As new processes, systems and key documents are to be implemented, a structure for mentoring and coaching is essential to guarantee adoption and success. A key ingredient for sustained improvement is a system developed by management that provides expectations and consequences for investigators. This system should be designed to promote sustained use of re-designed processes and measurable results.

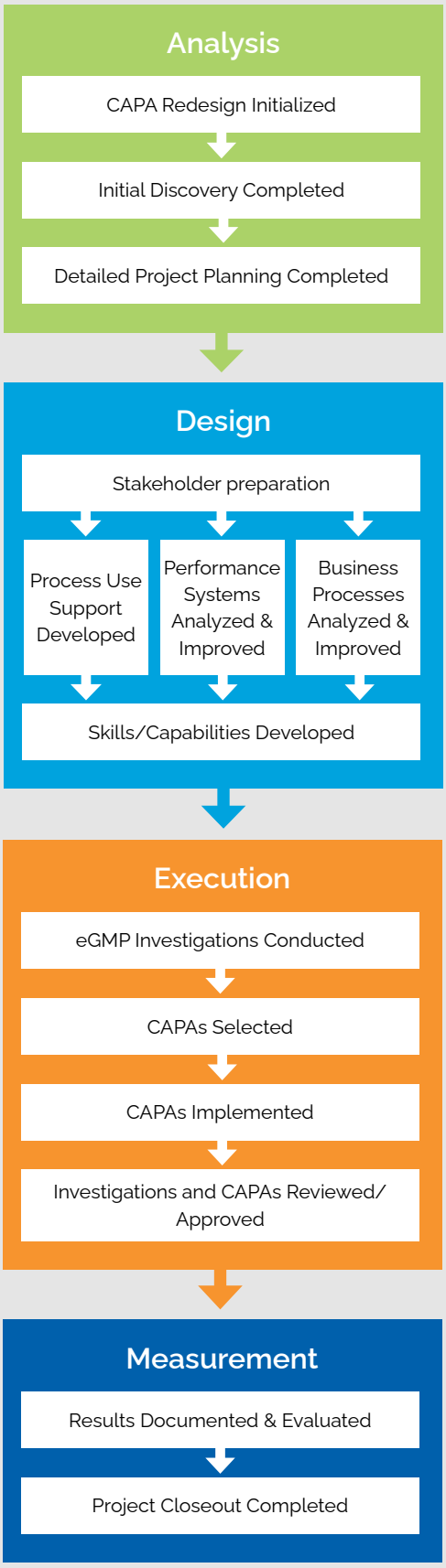
Building Mastery:

Once the processes and systems are aligned and attuned, it is time to transfer the skills to those who need them most. Identifying who gets trained in what, and to what depth, is all a direct outcome of the up-front diagnostic work. The goal should be to do just enough to make the results robust. These sessions should be tailored to your organization's unique culture and schedule.

Any new process should be adjusted to fit the organization's particular needs. Options should be considered to hire an outside firm to conduct the training or provide the needed training and resources for internal personnel to run it. To succeed, it is imperative to have expert coaches guide the work, facilitators to direct the investigations, and a clear template of what data is required to get to root cause—allowing people to put aside egos and rivalries and focus on the facts. With internal systems now assisting instead of hindering, the process is free to flow like water.

Measuring Results:

Finally, the results are measured and the project is complete. Successes are celebrated, lessons learned are captured, and next steps are assigned. If using an outside firm it is key to have personnel from your organization "in the instructor's seat," during this project. This will guarantee that improvements are sustainable beyond the current project.



Expected Outcomes:

Results can range based on the organization's current state and capacity for change. Some of the potential benefits are immediate and can be quantified within the root cause analysis process within the first six months:

- A reduction in time-to-root-cause
- A decrease in investigator time per incident
- Documented payback of greater than 10 to 1
- Decreased management approval time
- Decreased percentage of recurring problems

Other benefits are indirect, but still powerful:

- Reduced time to get back into production
- Improved resource utilization
- Reduced scrapped product
- Improved efficiency of escalation
- Reduced number of CAPA follow-ups required to implement
- Decreased time to implement CAPA follow-ups
- Improved risk management awareness

Other benefits are long-term, and take time to appear:

- Diminished percentage of product on back order
- Reduced negative publicity
- Lower product cost
- Lower maintenance cost
- Lower overtime cost
- Improved FDA profile
- Improved audit results, both internal and external
- Improved first-time-fix rates
- Increased device uptime
- Increased mean time between failures
- Improved utilization of technical experts
- Reduced validation costs and validation time

Conclusion:

There is a well-known Sufi teaching story about a wise man who comes across a fellow on his knees under the streetlight in front of his house and asks him what he is doing. The fellow replies that he is looking for his lost keys, so the wise man gets down on his hands and knees and helps him look, but to

no avail. Soon, feeling frustrated, he asks the man if he is sure he lost his keys in this precise spot, under the light in front of his house. “No,” the fellow replies, “I remember dropping them inside my house.” The wise man asks why they are looking outside, and the man replies that, “well, there’s more light out here.”

And, how does this apply to issue resolution systems? Because the light is shining on skills, it becomes the obvious place to look. We can measure how many people learned the skills, how well they were learned, how much time they spend learning them — all of this data is easy to find in your LMS. But focusing on skills alone just because there is light there ignores the areas where the problem may really lie, and may actually set your people up to fail. By investing time in analyzing processes and systems and creating a culture that supports required systems improvements you can achieve results far beyond those that can be achieved from just training alone—results that can be measured and celebrated.

About Kepner-Tregoe

Founded in 1958, and based on ground-breaking research regarding how people think, solve problems, and make decisions, Kepner-Tregoe provides a unique combination of training and consulting services to improve quality and effectiveness while reducing overall costs. The KT methodology is used at every level of client organizations: to implement strategy, achieve continuous improvement, increase customer satisfaction, and drive effective issue resolution throughout the organization.