The Fallacy of People Problems

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One of the most often cited statistics in pharmaceutical manufacturing is that 80 percent of all reportable deviations are “people problems,” deficiencies of human performance. Clients report similar internal estimates ranging from 40 to 90 percent. This statistic shows up in our studies of Corrective and Preventive Action or, CAPA processes and investigation reports. Despite the pervasiveness of people-caused problems the specific causes attributed are few in number: failure to follow standard operating procedures, skipped or mis-sequenced steps and improper documentation.

But do all of the problems classified as “human factors issues” really indicate a deficiency on the part of a person? Perhaps not.

The Root of the Cause

At a philosophical level, a colleague of mine has always claimed that, when you get down to the root cause there are only two options, human fallibility or God’s will. Neither is a cause we can do much about with effective corrective and preventive action. We need to work at a level of analysis where we can have an impact on the results. Human fallibility or God’s will is perhaps too deep to accomplish this objective. Too often it is not a lack of systematic analytical logic that prevents effective action. But more mundane concerns, such as a worker’s fear of being reprimanded or blamed for the problem that occurred, rather than focusing on a solution or corrective action.

To Be Actionable Start by Being Specific

Even classic “people problems,” such as skipping a step in the standard operating procedure (SOP), needs to be examined. The standards of problem-analysis for a “mechanical problem” demands that we state problems with enough granularity to be actionable. Why should the analysis of a “people problem” be any less specific? If someone skipped a step, then who and which step? If someone touched a contaminated surface, then who and which surface? Does this happen a lot? What are the trends? Why is it always this surface? Why just at this time?

Precisely stating the defect or deviation, and who or what was involved, can help us visualize and understand what has happened. For example, “An Operator named Jim skipped step 4 in procedure 34-B.” “Maintenance Technician Amanda in the process of adjusting belt speed on line 3 brushed up against the fill-nozzle at station 15.” “Supervisor Tom entered the batch yield data for batch 040315B in kilograms instead of pounds.” These statements provide a concise starting point for analysis and follow a path that leads toward eliminating the deviation at its source.

A Model of Cause Analysis

Once we have a place to start, the causes may lie with the operator, the maintenance technician or the supervisor. Or they may not. To determine cause, we need a model. Classic Problem Analysis1 analyzes “special-cause” variation by asking:

What is it?

When is it?

Where is it?

What is the extent of it?

What is it not?

When is it not?

Where is it not?

What is the extent of it not?

Using this method may narrow the search toward a given person doing a particular thing at a specific time, but may fail to address the uniquely human sources around the question why?

Once we have narrowed the range of possibilities we need to turn to a model, not of mechanical cause-and-effect, but of human performance2. In this view, human performance is the result of a system of forces that act together to drive behavior.

This model offers different sources of performance problems. Let us start with the performer, and admit that there are people out there doing jobs they are not qualified to do. The test question is: “Could this person do this task if their job or their life, depended on it?” If the answer is yes, then there is no deficiency in the performer. However, for each of us some tasks are simply out of our capabilities and no amount of training would improve our performance. In this case, retraining is not the option, replacing is. People cannot be expected to do what is impossible for them to learn.

Next, consider the response. This asks, “How clear is the desired behavior that we want from the performer?” “Are we asking for a quantum leap in performance or just a slight tweak?” The response often exposes problems caused by changing the SOP. Perhaps the standards are unclear, the changes too drastic or the expectations unreasonable. If it cannot be changed, training will be required on a constant basis.

To test the situation, ask if the signal to engage in the desired response is clear and unambiguous to the performer or muddled with other priorities and expectations. In the world of pharmaceutical manufacturing, knowing when to call something a deviation and to begin the analysis can be murky. Employees may be told that quality matters, that precision is important and that documenting every deviation is necessary. But is this message delivered at even half the volume of the one that says: Keep the line running? Included in the situation factor is how well the environment supports the desired behavior.

Perhaps the most significant factor in the performance system model is indicated by consequences. This factor reminds us that people do what they do because they get rewarded for doing it and punished for not doing it. But the model is more subtle. It posits that there needs to be a balance of short-term and long-term consequences for both the individual and the organization. The same applies to organizational consequences.

Individual and organizational consequences also must be balanced. If the corporation always sacrifices meeting its objectives so that individual workers can feel better, it will not stay in business long. And if the individuals suffer constant, negative consequences so that the organization can prosper, they will seek employment elsewhere where more of their goals can be met.

The most subtle aspect of the model is in how it defines consequences. Not everything is seen as universally rewarding or punishing. Positive consequences must be regarded as positive by the performer. An employee recognition program that offers a personal lunch with the president as a reward might make as many people run screaming in terror as it attracts.

In pharmaceutical manufacturing, there are often consequences built into the system that punish spotting problems and engaging in root cause analysis. In many firms, whoever first notices the deviation owns it and is responsible for assembling a team, gathering data, doing analysis and in many instances writing up the investigation report. For many, these are seen as negative consequences or at very least, onerous tasks to perform on top of regular responsibilities. Additional risks are

management visibility, pressure from production to complete analysis and get back to making product as well as resistance from colleagues concerned that your analysis might not show them in the best way forward.

On the other hand, letting something slip has few, if any negative consequences for individuals in the short term. It is easy, and all too common for production people to think: As long as the batch meets specifications, who is to know if a step was skipped or reversed, or if a signature was affixed properly during the process or after review? Chances are it will be three to six weeks before the batch fails specifications, or two to 24 months before a patient complains. Whatever happened or didn't happen might well be long forgotten.

These abundant negative consequences and a lack of positive consequences in the short-term discourage the reporting of a deviation.

Finally, consider how feedback factors into the model. If nothing ever tells you about the consequences of your responses you will continue to do what you have been doing, assuming that it is working. If everyone knows production's average yield and no one has a clue what the reject rate is, the message is clear. If it is not clear in the standard operating procedures or SOP training on precisely why you can't skip a step and what impact it has not only on grinding but on mixing and encapsulation, then you have no reason to be especially vigilant.

Making Quality a Priority through Corrective Actions

The performance system model leaves room for retraining as a corrective action to a people problem, but only when the deficiency is in the performer and even then, only some of the time. Some people are simply not trainable, some skills are not transferable and the optimal solution is rarely "more of the same." Instead, most corrective actions for performance problems involve addressing the system itself. In short, the solution lies with management to communicate clearly that quality in all its aspects is the priority. This is not done with words and slogans but with rewards, measures, metrics and behavior. And finally, the solution lies with addressing the common people problem with as much rigor and analytical precision as the most challenging mechanical or biochemical problem.

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[1] http://www.kepner-tregoe.com/