The Fallacy of People Problems – and How to Resolve Them

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One of the most oft-cited statistics in pharmaceutical manufacturing is that 80 per cent of all reportable deviations are ‘people problems’ – deficiencies of human performance. This statistic shows up in our studies of Corrective and Preventive Action (CAPA) processes and investigation reports, and is even cited on the Food and Drug Administration website. Despite the pervasiveness of ‘people problems’, the specific causes attributed are actually few in number: failure to follow standard operating procedures, skipped or mis-sequence 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.

DEFINING THE PROBLEM

Even classic ‘people problems’ – skipping a step in the standard operating procedure (SOP), touching the wrong surface and not re-gloving immediately, not entering batch yield information at the right time or in the right format – need to be examined. The standards of problem analysis for a ‘mechanical problem’ demand 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 the wrong 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? If someone failed to document batch yield, who, where and when?

Precisely stating the defect or deviation and who or what was involved can help us visualise and understand what has happened. ‘Operator JW skipped step 3.2.5.4 in procedure 34-B.’ ‘Maintenance Technician AR, in the process of adjusting belt speed on line 3, brushed up against the fill-nozzle at station 15.’ ‘Supervisor JT 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 towards 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 Analysis (1) analyses ‘special-cause’ variation by asking:

◆ What is it?
◆ What is it not?
◆ Where is it?
◆ Where is it not?
◆ When is it?
◆ When is it not?
◆ What is the extent of it?
◆ 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 performance (2). In this view, human
Innovations in Pharmaceutical Technology

performance is the result of a system of forces that act together to drive behaviour (see Figure 1).

The model offers different sources of performance problems. Let us start with the Performer, and admit that there are people out there doing jobs that 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 beyond our capabilities and no amount of training would improve our performance. In this case, retraining is not an 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 behaviour 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. It is common to encounter 57-step SOPs that require the dexterity equivalent of patting your head and rubbing your stomach at the same time. They just cannot be accomplished easily or consistently – if at all. In these cases, the SOP needs to be changed. 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 behaviour. Are people expected to do a lot of writing in a room with no flat surfaces and little light? Is a problem-solving meeting working as well as it might when it is held in a space that requires goggles and earplugs?

REWARD AND PUNISHMENT

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. A truism in management circles states ‘To see what you have been rewarding, look at what results you are getting.’

But the model is more subtle. It posits that there needs to be a balance of short- and long-term consequences for both the individual and the organisation. For example, if the individual sees the desired performance as negative or punishing, he or she can be motivated to do it anyway if there is a reasonable expectation of positive consequences in the longer term. This is a classic trade-off: ‘it’s a pain to do this, and it’s going to make my life crazy for a while, but if I do it without complaint, it will be good for my career down the road.’ The same applies to organisational consequences. A serious problem in the first month of a multi-year production campaign can justify shutting down the line for a time, if it will produce a ten per cent increase in productivity for the campaign. In contrast, there is no long-term benefit of shutting the line for a complete revalidation on the last day of a multi-month run.

Individual and organisational 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 organisation can prosper, they will seek employment elsewhere, where more of their goals can be met.

A back-order situation encountered at a medical device company illustrates the effects of unbalanced consequences. Our consulting team was asked to analyse some issues in the shipping process. We discovered a huge back-order problem. Surprisingly, the products on back-order were not special orders, but common everyday products, the highest-volume SKUs (stock keeping units) in the product mix. No one knew why this occurred until we learned about the incentive plan in Production. It rewarded volume based on skewed criteria that drove them to produce odd lots of weird stuff. The consequences for Production were out of balance with those for the organisation, rewarding performance that harmed the company.

Figure 1: The human performance system model
The most subtle aspect of the model is 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 programme that offers a personal lunch with the president as a reward might make many people run screaming in terror. One client company recounted how they had tried three times to conduct such a programme, only to see it backfire every time because the rewards weren’t universally positive. Once, the rewards were too trivial (free magazine subscriptions); then they were too extravagant (a $5,000 reward that led to rampant fraud and corruption); and finally, they were just plain strange (pizza with the president, go figure).

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 the analysis and – in many instances – writing up the investigation report. For many, these are seen as negative consequences; onerous tasks to perform on top of regular responsibilities. There is the risk of management visibility, a constant push from Production to finish the analysis and get back to making product, and resistance from colleagues who are concerned that the analysis might not show them in the best light. The analysis itself can be less of a systematic process of gathering and arraying data, and more of a knock-down war among vested interests. Being caught in the middle can be unpleasant. Given all this, it is no wonder that many people are reticent to go out of their way to notice deviations: ‘Problem? I don’t see a problem.’

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 during the process or after review?’ Chances are that it will be three to six weeks before the batch fails specs, or two to twenty-four 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. A client recently received a patient complaint of a one-inch bolt in a sealed bottle of capsules. They traced it back to a hinge-arm on a cotonner machine, used right before the bottles are sealed and capped. It was a peculiar bolt; there was only one like it in the plant. It appeared that, if the bolt had worked itself loose, it could have fallen into a bottle before the cotton was inserted. The details of this are not worth troubling about here, but it was striking that the nut that attached to the bolt was never found. Someone must have found that loose nut, looked at it and thrown it away, without writing it up in the batch records or reporting it to anyone. And someone must have noticed that the cotonner wasn’t working correctly because the hinge-arm was missing a bolt and a nut, and then replaced it without noting what had happened. When the complaint supervisor was asked how probable it was that her people could have done this, she rolled her eyes and said, ‘Don’t ask, don’t tell.’ Because, to be blunt, what was in it for them?

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 SOPs or SOP training precisely why you can’t skip step 3.2.5.4, and what impact it has not only on grinding but on mixing and encapsulation, then you have no reason to be especially vigilant. Finally, if the only real feedback is a yearly list of generalities, followed by a modest monetary reward, what behaviour can be expected to change?

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 – its balance of consequences, its feedback mechanisms, and its stated goals, targets, and objectives. In short, the solution lies with Management making it clear that quality – in all its aspects – is the priority. This is not done with words and slogans, but with rewards and measures and metrics and behaviour. And finally, the solution lies in addressing the common people problem with as much rigour and analytical precision as the most challenging mechanical or biochemical problem.

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References