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To train or not to train? Too often training is seen as the primary corrective action for a quality deviation, but sometimes the root problem is something training can't solve. Performance analysis can help you track down the real source of a problem.

Performance: The Goal of Training or Why Training Is Not Always the Answer . . .

A revealing exercise to discover your company's real understanding of the role of training is to review your corrective responses to deviations and to quality and GMP audits. How often do the phrases "Will retrain the analyst" or "Will conduct training on the procedure" appear? How often does the same (or a similar) problem recur and recur and . . .?

Some companies point to the need for training in one-half to two-thirds of their corrective actions. When I see that, I make a heretical statement: Training is not the answer to most of those problems. Factors other than training must be addressed to correct the root cause of such problems or to supplement the "performance environment" before training can be useful.

Training is a powerful tool. It does have an important place. But using it inappropriately is a waste of time, money, and opportunity. When training doesn't work, you still have the real problem that can have significant regulatory and compliance consequences.

To determine whether training should be part of your solution, look at typical barriers that must be overcome before training can have its optimal effect.

High Monitoring Counts

A colleague told me of a case she was involved with: Environmental monitoring data from one of her company's aseptic filling areas showed a trend toward increasing particulate (nonviable) and microbial (viable) counts. Testing uniforms as employees entered the area showed that their uniforms were free of contamination at that point. So the assumption was that the contamination was generated by poor aseptic technique. After discussing the monitoring trend and quality, production management determined that the corrective action would be to conduct a refresher training course on proper aseptic technique, covering topics such as frequently sanitizing

hands with an alcohol solution or similar agents; avoiding large, fast movements in the room; minimizing time in the "critical zone"; and similar behaviors.

What would you do if you were the trainer receiving that assignment? Would you dust off the training course that you've already given, or would you develop a new one? Would you hire a consulting company with expertise in training? Or would you send the group to an off-site facility that provides training in sterile product manufacturing?

Is It a Training Problem?

Instead of those common responses, try another approach first. Be skeptical whenever people say that training is the solution. Although well intentioned, that is a conditioned response stemming from the repeated prescription: "Train and retrain."

Robert Mager suggests this classic question for determining whether training is an appropriate solution: Could the person do the job if his or her life depended on it? (1). If the answer is "yes," then you are in *the performance improvement solution zone*. That person does not need additional basic knowledge or skills; the employee may need encouragement, feedback, or something else, but it is not the most productive action to take in solving the problem.

As a skeptical training professional, you consider the root cause of a problem. If you encounter undesirably high monitoring results (as in the case above), first examine training records to see whether all people in that area were trained previously on aseptic technique and were involved in successful media-fill validations. If they were, then you know that they could, at one time, perform correctly. (This is the performance test that auditors and regulatory inspectors will ask for as evidence that the training was successful.) Even though people are typically the source of most contamination, you need to look for other possible causes of the problem as well.

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Fish-bone diagram. Several tools can be used to determine the root cause of a problem. One of the simplest (and yet very effective) tools is the fish-bone or cause-and-effect diagram (Figure 1).

As you expand on the “people” bone, consider items that are barriers to performance: seven performance structures in need of improvement (2).

Seven Performance Structures

People are capable of doing the job. Because each person successfully did the job in the past and can perform adequately when put in another, similar area, you can feel confident that each person is capable of performing.

The job or task is well designed. In talking with the workers in the area, you find that they are a little crowded as they do their jobs and that they have complained to their supervisor that the room is too warm. The supervisor recently made a change in the uniform and gowning requirements; you’ll pursue that later.

The desired or expected performance is clear. You learn that those in the area have significant experience making sterile drug products and have the knowledge and skills needed to perform correctly. They all know the rules for working in an aseptic fill facility.

Appropriate feedback is given. Individual monitoring results (rodac plating) are available to each person, but rather passively: The monitoring group charts room results, and each month it sends a color graph to the supervisor, who hangs it in the office. In your discussions, you find that workers in the area pay little attention to that chart.

Appropriate incentives are in place. An aseptic processing operator in your company is in a slightly higher pay grade than someone working in a less stringently controlled area, such as the “clean” (class 100,000) equipment preparation area. You find that no inappropriate incentives encourage taking shortcuts or doing things incorrectly.

Appropriate tools are provided. Through the observation windows, you watch people work in the areas, and they seem to have all the sanitizing agents, forceps, and other items they need. Procedures are available. The filling suite where the problems exist is identical to another suite experiencing no problems regarding tools and equipment. But someone mentioned that the sterile gowns worn in the areas are “itchy.”

Employees have the knowledge and skills to perform the task. In reviewing the training records, you find that everyone was initially trained in the general concepts of aseptic manufacturing and that all the relevant procedures are being followed.

Putting the Pieces Together

At this point, as the trainer, you probably feel a little frustrated: You think you aren’t much closer to solving the problem. But in fact, you are. You’ve come up with data

EXCESSIVE training, if repeatedly required, indicates that either the training is ineffective or that the root cause of the problem is being inadequately addressed.

showing that the difficulty really isn’t due to a training problem. The items worth exploring in more detail are the design of the job area where it is performed, the filling room itself, and the “itchy” sterile gowns.

At lunch that day, you run into one of the longer-term employees in the monitoring group, who asks when the new training course will be ready to present. She’s not very happy to hear that you are still looking into issues; she says that the problem needs to be corrected by training the people right away. You talk about all the monitoring that the environmental group does and the monitoring of other conditions (temperature and relative humidity) that is done by the plant engineering and utilities group. You walk over to the control room of the utilities plant, and the technician monitoring the control panels shows you temperature trends for different rooms. You notice that the

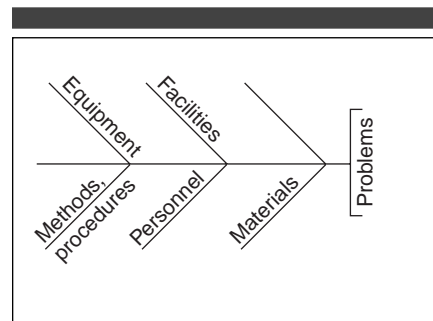


Figure 1. An example of a fish-bone (cause-and-effect) diagram

room temperature for the problematic filling room goes up from 65 °F to 75 °F when it is in use. The other filling room increases only two degrees to 67 °F. You think you might be on to something: People shed more particulates, particularly *viabiles* (cells capable of growing and proliferating), with increased temperature.

Back in the filling area, you talk more with the person who earlier said the room was warm at times. He says that the increase in temperature started about a year ago. He says that the temporary solution of not wearing the white uniforms under the sterile gowns helps a little, but not very much.

“What do the employees wear underneath their sterile gowns?” you ask. (You’re a little afraid of what you might hear.) A few months ago, the supervisor gave people permission to take off their uniforms and wear only their underclothes beneath their sterile gowns. Your source says that most people do just that. The original procedure was a little vague on specifying undergarments, and the supervisor felt that not wearing a uniform was a justifiable interpretation of the standard operating procedures.

You are uncertain, but you think you have found a major part of the problem. Wearing little under a sterile gown is not a typical industry practice. Cotton-blend uniforms are usually worn because they provide a barrier and help to absorb skin cells and bacteria that get sloughed off with perspiration.

As you walk back to your office, you recall that about a year ago (around the same time the room’s temperature started getting higher) you coordinated training for a new piece of equipment installed in the problem room.

You continue to learn more about the room, how it operates and how it has changed over the past few years. It was originally designed for two operators, but four people are typically present now when the equipment is running. Also, the equipment installed in the past year is larger than the previous machine, with faster throughput to meet market demands.

Presenting the findings. At the next staff meeting, you present your analytical findings: People have been previously trained and have demonstrated that they can successfully perform their tasks (the “test” that demonstrates the effectiveness of the training). Most people in the room do not wear standard uniforms under their sterile “bunny suits” because the room, when in use, is too warm. That change and the increased temperature could contribute to shedding. The room is too warm because the HVAC cooling system is incapable of handling much more than it was originally designed for. The two extra people and large filling machine generate more heat than the system can handle, causing discomfort — and excess perspiration — of those working in the room.

The consensus of the staff is that those are the issues that need to be addressed to decrease viable and nonviable particulate levels.

When Training Isn't the Answer

The example above is one of the more dramatic, complicated scenarios of a problem that may at first seem to require training but has its real roots elsewhere. We have all had contact with other, simpler misdiagnoses. For example, a company was having problems getting its personnel to document their work using the “official” pens with permanent black or blue ink. A look at the area showed that the “tools” available in the work areas included pens with red, green, and purple ink, many of which were water-based. The simple solution to that problem was to spend \$50 to buy several hundred of the correct pens, replacing those that people had previously used. Another example: In another company people were failing to record the time using “military” (24-hour) format. The problem was corrected not by teaching people how to calculate time using standard 12-hour clocks, but by replacing the usual 12-hour

clocks with digital clocks that showed the time in the correct, 24-hour format.

Joseph Juran, one of the gurus of quality systems thinking, states that only 10–20% of the quality problems in a company are due to line personnel. The remaining 80–90% of quality problems are traceable to management actions, particularly systems-related decisions (3).

Reinforcement Training

If many problems require solutions other than training, does reinforcement training fit into the picture? Although it might be a waste of time to go over topics or procedures that people already understand, periodic retraining in GMP principles is required by all regulatory agencies. Such training needs to be meaningful to people in their jobs. If you put them through the same simple program they went through their previous year, it will add little to the knowledge or skills. On the other hand, if you are trying to help motivate someone to perform correctly — shaping attitudes — you need to look for a new way to get the information across. You could build on topics covered earlier, but present them in a way that gives the learners new insights. The goal of procedure training might go beyond just reinforcing performance to also provide feedback (coaching) help to optimize performance or to demonstrate that employees can correctly perform as required. (Reinforcement training will be discussed in a future article.)

Looking At Your System

GMP auditors and regulatory inspectors are becoming more savvy about training and performance. They are asking to see evidence that the training was effective — performance tests, and in some cases, pen-and-paper tests. If they see that excessive training is required or that problems recur when the original solution was “retrain the operator,” they are observing in audit reports and 483s either that the training was ineffective or that the root cause was inadequately addressed.

Personal accountability and responsibility also can affect performance goals. In a unique consent decree requirement, FDA demanded that a company conduct training, including “procedures for disciplining employees who after training are found to not be following written procedures” (4).

The company evidently had been saying, “we’ll retrain, we’ll retrain, we’ll retrain” without achieving the desired results. The agency intended for the company to hold its personnel accountable for following procedures correctly.

Focus on performance. Penicillin was considered a miracle drug and continues to be a very effective tool for fighting specific infections. However, it cannot cure all conditions. It won’t do much to heal a broken arm. It also can cause serious reactions in those allergic to it. The prescribing health care professional must know the disease he or she is treating and the patient.

Frequently, a physician recommends more than just a drug product; the patient hears the famous words, “Drink plenty of fluids, and get lots of bed rest.” These are part of the total prescription and are needed together with the drug for the patient to regain health.

Training is a powerful tool to achieve performance, but it can be successful only if all other performance issues are addressed. Training must be geared to the needs of those participating in it. When you approach a problem, you must first understand the real root cause, and then if the problem involves people and performance, consider the seven barriers to performance that need to be eliminated for structures to improve.

In other words, before you say or agree that “training is the answer,” be skeptical: Consider that it might not be the answer. Then prove to yourself that it is.

References

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- (4) *United States v Steris Laboratories, Inc.*, “Consent Decree of Condemnation and Permanent Injunction,” 98–1630 PHX RGS (AZ, 16 October 1998). **BP**