

Training for Compliance Employing Scientific/ Skeptical Thinking

When a company trains its staff with the thought of compliance first and foremost in mind, it runs the risk of abrogating its scientific thinking in favor of the thinking done by those who wrote the relevant regulations/standards. Many of the best solutions to specific scientific issues are contextual, that is to say, dependent upon the specifics of the company's particular situation. This article presents an argument in favor of training to induce scientific / skeptical thinking along with how to go about it, and that by doing so, compliance, and indeed surpassing mere compliance, will be the natural result.

It is well known that when a regulator or auditor comes in to inspect your facility, your processes, your documentation, etc., part of what is expected is demonstration of compliance with the aforementioned. Compliance with applicable regulatory documents, internal documents (SOPs, protocols, etc.) is required. One mantra of cGMP and GLP is that you should say what you do and do what you say. Otherwise, you should expect a poor outcome from the inspection/audit.

Given the importance of compliance, it is not surprising that many training programs are based upon the need to comply, and demonstrate compliance, with relevant internal and external documents and procedures. The premise of this article is that training based first and foremost upon compliance does not adequately prepare people to handle the unexpected because that mode of training does not emphasize what should always be of paramount importance to technical people: asking scientific questions.

Common Training Methods

We have all probably sat through SOP training that went something like this:

The trainer stands in front of the trainees with a PowerPoint presentation on the screen. If you are lucky, the trainer uses the material on the screen as talking points. If you are unlucky, the trainer reads the material on the screen to you, thereby causing death by PowerPoint. Often, after enduring the training, a quiz may follow. More often than not, the expected answers to the questions may be lifted directly out of the training material, or from the included SOP. For example, let's say the training pertained to an SOP related to chapter 62 of the USP. The SOP includes in part a listing of the species of microorganisms described in the chapter. The quiz may ask what species of microorganisms are indicated in the chapter. The "right" answer is supposed to be the regurgitation of the listed species. It is unlikely that the quiz would ask why the particular species are indicated in the USP chapter. The first type of question requires a rote answer, the second requires thinking.

Here is another type of training you might have gone through. This form is

delivered via a computer, and is often based upon interactive software. The basic information is provided, often with oral material and an accompanying transcript. Sometimes you can choose the exact order of the material to be covered, sometimes not. There can be questions posed throughout, or in the form of a quiz at the end. Again, most often the questions asked would require answers that can be lifted directly from the material as presented. Rarely will the questions require reflection upon what was presented in order to synthesize an answer that was not directly presented in the material.

In either case presented above, the trainee will have signed an attendance sheet and/or submitted the quiz with an acceptable number of correct answers. This will be placed in the trainee's training file, and these files will be made available to inspectors/auditors upon request. The idea is that by having such training documented in training files, compliance with expected training requirements can be demonstrated.

Is Compliance Adequate?

Is there anything wrong with demonstrating compliance with training requirements in this manner? Through this method, it can be demonstrated that each person who needed to be compliant with various SOPs/etc. did receive training and satisfied whatever quiz requirements may have existed. The problem is that training along the lines of that described above does not require acquiring a detailed understanding of, for example, why the steps in the SOPs are what they are. Why is the incubator temperature to be set at 25 +/- 0.5C? Why should the USP Sterility Test be conducted even though method suitability could not be demonstrated? Why is it appropriate to use dedicated glassware in an analytical chemistry laboratory involved in evaluating multiple product types? Is it appropriate to set an environmental monitoring alert level at 1cfu and an action level at 2 cfu?

The types of questions posed above will rarely have the answers directly provided in the documents for which training was provided. However, when the trainee can provide answers to these questions, the trainee will be in a much better position to address unexpected circumstances, and to be able to suggest revisions to SOPs upon such reflection. For example, what should be done if an incubator temperature falls outside of the required range? If you don't use dedicated glassware in the analytical chemistry laboratory and unusual chemical "contamination" is observed, what should you inspect in the lab as possible culprits before assuming the problem in manufacturing? Is there scientific justification for setting an alert level at 1 cfu and an action level at 2 given the limitation of quantitative microbiology?

Consequences of Training for Compliance Alone

Imagine this circumstance: During a regulatory inspection of the data from microbial limit testing, no indication is found, ever, of TNTC (too numerous to

count) plates. It is highly unlikely that the microbiology laboratory never missed how much dilution would be necessary to ensure countable numbers of colonies. When asked how this could be so, the lab person responds “Our SOP states that plates with too many colonies to be countable should be discarded and no data recorded”. Therefore, the person was in fact in compliance with the company SOP. Their training record confirmed that they had been satisfactorily trained. As you might guess, an inspector would not be impressed with either the SOP or the training.

If instead of merely being trained to compliance, which our person in the example above had been, the person had been asked as part of the training to explain why not recording the data from the TNTC plates was appropriate, the SOP itself might have undergone revision. The fact that there may be an SOP, standards in a compendium, regulatory guidances, etc. should not mean that reflecting and questioning is no longer required.

What can happen given an SOP, regulatory guidance, compendial standards, etc., is that people will cease thinking about why they are doing what they do. Instead, using such documents as a crutch, when asked why they are doing what they do, they respond with “That’s what the document states we should do”.

Training for Thinking

If training for compliance is at the forefront, and this method is fraught with risk, what is an effective alternative that will ensure compliance and reduce the risks? A much more effective approach, one with which the trainer can induce thinking and reflection as opposed to merely rote processes, is one employing effective questions.

This approach requires much more interaction between the trainer and trainees, and between the trainee and the material being taught. The trainer must often ask: why? The questions asked most often should not be answerable by reading text back from the document being trained in.

This questioning approach should be employed in practical training as well. Often the trainee is paired with a person experienced in whatever method or procedure is to be learned. In that case, the trainer must remember to not simply demonstrate, but to ask why the method is performed as it is being shown. This requires thought by the trainee, and can help the trainer as well. A person who has been performing a procedure the same way for years may well have forgotten why it is conducted the way it is. It is possible that they were not trained to ask questions, but merely to replicate what was shown. The danger in this sequence is the potential for arriving at the situation where nobody remembers why a method is done the way it is. When asked, the response becomes “We’ve always done it that way.”

Online training can also be developed such that reflection upon the material presented would be necessary to answer posed questions. Such questions should not simply be based upon rote memory (e.g. "Who is responsible for that step?") but require thinking (e.g. "Why is that person responsible for that step?").

Additional Benefits of Training for Thinking

I believe it is essential for management to buy fully into the training for thinking versus training for compliance approach to achieve maximum benefit. When the company culture becomes one of questioning first, followed naturally by compliance, the ramifications can be vast. Compliance would follow naturally because those trained under the "training for thinking" system would have asked enough questions, and have answered enough thought provoking questions, to understand why they are doing what they do, and therefore also understand the importance of compliance. When an inspector asks why something was done, the response will not be "because that's what the (SOP/other document/etc.) required". Instead the answer will be based upon the underlying science.

When the culture is one of open questioning to the extent that people understand why the requirements are what they are, and they have been trained under a system that emphasizes questions, the interactions among them will also be more one of questioning rather than blind compliance. If people observe something unusual, something unanticipated, they will be far less likely to ignore it because documentation (internal, compendial, regulatory/etc.) did not mention it. If a trainee observes an experienced person doing something not precisely in line with what is written, they would be quick to ask why. It may well be that the experienced person is performing in a manner they have found to be more effective. If that is true, then the improved variation should be written into the documentation. This of course assumes that the experienced person can explain why the variation produces better results. If they cannot do so, this should elicit a further round of questioning.

The Value of Motivation

From my experience, the way to effective learning is through motivated learners. A motivated learner is one who has taken ownership of the learning process, and this requires that the learner understand the importance and value of what is to be learned. I do not believe that such an appreciation can be rammed down the learner's figurative throat. I believe the best way to motivate is by asking questions whereby the learner comes to understand the importance and value of the material. The posing of questions goes both ways such that the learners must feel free to ask questions to the extent that they reach the point where they have satisfied themselves that what is being learned matters, and they understand why it is as it is.

There are numerous modes whereby training for thinking can be delivered. In-

person, classroom type settings can work assuming the instructor understands that the environment must foster bi-directional questions and answers. The instructor must also understand that an answer of “I don’t know” can be acceptable. Electronic forms of instruction can also be effective assuming the interaction of some sort is possible, and that questions provided should invoke reflection, not regurgitation. An obvious form of training is that which often occurs in the laboratory or manufacturing floor, provided by an experienced person to an inexperienced one. Once more, the person providing the training needs to understand the importance of two-way questions and answers. By fostering such questioning, genuine understanding can develop, and compliance will flow naturally from understanding, as motivation will be internal to that trainee. My experience has been that if training is done with compliance as the primary goal, the trainee will resort to answering hard technical questions with “Because that’s the way we do things”, not with “It is done that way because (technical explanation)”.

Closing Remarks

It is my fervent belief developed over many years of exposure to different types of organizations that the best way to achieve compliance, and more importantly high quality products, is via the organization promoting an environment first and foremost of learning. Compliance will then follow naturally. A more “dictatorial” environment may work well for a while, but sooner or later conditions change and if its people have forgotten how to ask questions along the way, adaptability is lost, and the organizational compliance will eventually decrease substantially, or at least fail to reach its maximum potential.

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