

Why Training is More Than a ✓ in the Box

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It's Monday morning, and sitting in your inbox is an email invitation for this year's annual GMP refresher. "Oh Joy," you exclaim, "I can hardly wait!" Please pardon the sarcasm, but many life sciences managers don't feel all warm and fuzzy about compliance training. In fact, most will revert to delay tactics on account of the production schedule or demanding workloads and ask when the make-up sessions are being scheduled.

Let's face it. Compliance required training and other company sponsored training programs can be dry, boring and quite often described as "death by power-point" training. So no wonder folks want to get the training over with and mark it complete. When attendance lags, trainers lament about lack of management support, and management struggles with quantifying the return on their investment other than mandatory training that stays within the law.

The alternative is to deliver training that engages employees, provides meaning to job functions and is directly tied to performance outcomes. "Good" training is training that is effective. And effective training is managed within an efficient and controlled system. "As with any other technological system, the art of employee training should clearly be based upon the science of systematic control." (1)

System and Process: One and the Same?

A system, as *Webster's Dictionary* defines it, is "an assemblage or combination of things or parts forming a complex or

unitary whole." Systems can be controlled or allowed to be left in an uncontrolled status. In a controlled system, information is perceived and changes are effected in response to that information. But then what is a process?

A process is a sequential grouping of interrelated tasks directed at producing one particular outcome such as closing a knowledge, skill and/or performance gap. The elements of a process typically include its inputs, value added steps and outputs.

What Makes Training a System?

The answer depends on the reader's viewpoint. Do you consider training as an event where the trainer tells the novice the information or shows a new hire how to perform a task? Or, is there more to training, such as including the effectiveness of the interaction?

Then, how does a trainer coordinate all the pieces and ensure that they are incorporated into the training? They accomplish it by contemplating the whole picture from start to finish. Systems thinking, made popular by Peter Senge, is a conceptual framework for seeing how the parts all fit together. (2) In this case, it is how the inputs, training design and delivery, and the outputs can be managed whether for one session, one employee or for a series of courses for an entire organization.

So how do novice employees get trained in a consistent and reproducible manner ensuring their learning needs are met in an effective and efficient time frame? By

following a controlled process that organizes all the "pieces."

The Training Pieces

The training process also has its inputs, steps and outputs. Training begins with the people, the goals/objectives to be mastered, the information and the tools to be used. Then, the trainer performs a series of actions with the inputs before, during and after training to produce the outputs or the results. [Author's Note: See Table 1 on Training Inputs, Process and Outputs, which is modified from Jacobs, RL. and Jones, ML. (3)]

Trainers schooled in the principles of instructional design recognize this description as ADDIE (assess, design, develop, implement and evaluate). ADDIE represents a piece of the process albeit an important part; it is a sub-process. Likewise, the current use of Donald Kirkpatrick's, PhD, Four Levels of Evaluation is also a sub-process. (4) However, training as a system is more than the design, delivery and evaluation of training. The documentation requirements alone can warrant a separate subsystem. With the use of today's learning management systems (LMS), linkages to the other organizational systems are crucial. At the onset is the integral connection to Human Resources Information Systems (HRIS) for the accuracy and completeness of employee profiles.

The Training System vs. LMS

Reporting compliance training results is a key metric for the management review

Table 1 – Training Inputs, Process and Outputs

Training Inputs	Value Added Steps	Training Outputs
Novice Employee	Trainer's actions to prepare	<i>Training Performance</i> —meeting the learning/performance objectives
Seasoned Employees		
SMEs and Qualified Trainers		
Physical Objects and Tools	Trainer's actions to deliver	Task Performance—as identified by SOP or other established standard
Training Locations Including Work Stations		

quality system. But, having a validated LMS does not automatically guarantee that the training system is in control. Before the data is entered into the database, it follows a series of processes and manual human decisions within the training system or the training processes, if you will. The LMS is not the be-all to end-all. It is only the tool by which we store, sort, decide and report on who is trained and who still needs what additional training.

The training system organizes all the elements, sub-processes and linkages to other systems into a logical flow so that process variability is controlled. Training, like any other system, has its own policy and set of SOPs that need to be followed to consistently produce effective and efficient training outcomes; it is not just printouts of employee training history.

When the training system is in control, someone is responsible for every process and is held accountable by their management. There is also assurance that employees are adequately trained in GMPs and can perform their assigned procedures independently. This is achieved by developing and implementing a systems approach for training so that all the elements come together in a logical process flow. The key elements include: (5)

- ✓ Creation of a training policy
- ✓ GMP and compliance curricula
- ✓ SOP/procedural training
- ✓ Use of qualified trainers
- ✓ Employee qualification process
- ✓ Training documentation process
- ✓ Training effectiveness measures

Once these elements are defined and sequentially placed, the system must connect with quality systems for proper system linkages.

Cross functional Quality Subsystems

While all quality systems are necessary to ensure a state of control, there are three subsystems that stand out as being vitally cross functional in their design:

- ✓ Change control (document control) can be considered as the heart of an

Organization Factors that Influences a Training System

- ✓ Business priorities and competing systems goals
- ✓ Nature of ongoing change efforts and process improvement initiatives
- ✓ Perception of the value of training among management, 1st line supervisors and employees
- ✓ Alignment between job expectations and consequences of using SMEs as trainers
- ✓ Willingness of functions to manage and comply with the training system during peak production demands

organization. Processes and procedures are defined, validated and controlled within this system.

- ✓ CAPA/deviation management is the pulse. This system indicates the organization's "health" or compliance performance results.
- ✓ Training is the "lifeblood" that fuels and sustains the organization. Of the three, training is perhaps the most cross functional system.

Since more than half of identified training requirements are procedures, it is crucial that the training system be designed to interface with change control to ensure employees are in fact current with the ever-changing SOPs. An often overlooked connection is the linkage to CAPA. Once the corrective action has been appropriately selected and approved, the training system captures the training requirement and incorporates it as an input into the existing process.

Another important quality subsystem to consider is internal auditing. An effective training system undergoes a periodic evaluation, but the system review needs to be an independent verification performed by non-training staff. It can easily be included into the scope of QA's auditing program, like any other audited system. The systems view for training ensures these vital connections are present and the exact handoffs are well defined.

Proactive Organizations Have an Effective Training System

Best performing companies or highly regarded companies place a value on training, but it is more than mandating an X number of training hours. Yet, that is how some managers define their training program. Study the compliance training program of proactive companies. It is more than the basic GMP guideline for new hires and one annual GMP refresher course. These organizations develop their ongoing GMP training into additional GMP curricula for key compliance positions and include at least a second refresher requirement that allows for employee choice, so that it relates to their job function as is usually a current topic or emerging regulatory trend.

Link Training to Performance Outcomes

Completing identified training requirements by the due date is a minimum performance metric for compliance reporting. But what about the effectiveness of the training that is being delivered? Why are we delivering all this training in the first place? Proactive companies realize that managing their talent pool is more than providing required training.

They share the business goals with their employees, identify the key processes that are responsible for producing the outcomes of value and provide the necessary tools including training and development to ensure that their employees

are provided with the best possible resources to succeed as expected.

In a perfect organization, systems run flawlessly and are unimpeded by the outcomes of other systems. With training being so highly interfaced throughout an organization, this system is constantly being influenced by other organizational systems in which it functions within. [Author's Note: See sidebar entitled, "Organizational Factors that Influences a Training System," previous page.]

Quick Fix Solutions

Companies with an uncontrolled training system fail "to develop formal systematic approaches to GMP training and [fail] to install systems of written documentation." (1) Shortcuts in training become prevalent and give the appearance that training is just one big documentation exercise; a ✓ in the box. The following is a typical scenario that happens when a lot of new hires are brought on board all at once. Unable to slow down the production schedule and not having an excess of available trainers, many new hires find themselves in an office with their training plan in one hand and the SOP binder in the other. The need to supervise them becomes a huge compliance task. "So why not multi-task by reducing their exposure to processes and at the same time complete their training requirements? And then let them follow Joe and Jane around for a few weeks?" While it might seem like the perfect solution, this is not training. It is a waste of time and energy. It creates false "training" expectations for everyone and is certainly not an effective training system.

As a result, we find ourselves as participants in "event-driven" training where the general perception for the learning goal is to "get 'er done" or "just-in-time" training to close out an audit observation by the due date. When you skip through the difficult parts of the training process, especially the identification of the learning/performance need or the why as it relates to the business goals, the training becomes meaningless after the event and makes post-training

follow up nearly impossible to measure.

Today's Training Conundrums

The current perception of training sits in the middle of many debates as to its effectiveness, relevancy and value to an organization. This is most unfortunate. Informally, ask professionals from the life sciences arena why this is happening and you will receive a range of responses from lack of management support, to insufficient and boring training. Who's to blame? More importantly, who is going to clarify these perceptions when each is attributing the root cause to the other?

Like any good dilemma, you assess the risks, leverage small, but significant change by applying systems thinking. Start with the business need. What's driving the need for training or the need for performance improvement? Then close the gap using the system approach for training. If you have to redesign your current processes, then do it. The end result will be a more robust and supported training system. In the end, isn't that worth it?

Summary

"The system view helps us to distinguish between the means and ends of our actions." (3) Integrating the key system elements and the miscellaneous training pieces into one holistic process improves the efficiency of training. The ultimate outcome of the training system is to develop employees' expertise in both the technical functions of an organization, as well as the GMP principles beyond the tasks they perform; thus, ensuring the overall effectiveness of training.

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About the Author

Vivian Bringslimark provides human performance consulting services for improving people strategies with HPIS Consulting. In her current role, she partners with clients to analyze root causes of human performance gaps and implement appropriate solutions that align with stated business outcomes to bring about more long term and predictable performance resulting in yearly goal achievement and operational excellence. She is on the Board of Directors for GMP Training at the Education Association, Inc. as Chief Communications Officer. Prior to HPIS Consulting, Vivian worked for PAREXEL Consulting as a Senior Consultant re-engineering quality systems and developing organizational effectiveness solutions. Vivian began her pharmaceutical career at Ciba-Geigy in manufacturing and has worked for Watson Laboratories. She is certified in Covey's "7 Habits of Highly Effective People," "What Matters Most," and "Building Trust" courses to expand her role to include leadership and organizational development activities.