

SOP Training is Now “On-Line” But Are We Any More Compliant?



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Note: The views expressed in this article are those of the author and do not necessarily represent those of the employer, GxP Lifeline, its editor or MasterControl Inc.

Well, I'm told we are now more compliant with ensuring that only the most current SOP version is used for training. And yes, our Learning Management System provides us with curricula updates and “percent complete” and “percent overdue” notifications. LMSes and eDoc systems have given us efficient mechanisms to document that employees have completed their training curricula. But do they understand their procedures enough to perform them correctly back on the job? Just look at our human error deviations and training-related CAPAs.

Are the numbers declining? According to an excerpt from the PDA's Pharmaceutical Sci-Tech Discussion Group, there is “almost a 100% correlation between the percentage of read and understood SOPs and the number of compliance issues the company has.” (1) Has efficiency become the new metric for training and compliance? Using technology to read SOPs doesn't guarantee learning transfer.

It's still “Read and Understand” SOPs!

Whether we access our SOPs through an eDoc system or the LMS portal, we are still only reading them. To call this eLearning is a bit of a stretch especially when compared to the design of today's eLearning courses. Nonetheless, some new hires are still being provided with a long list of required SOPs and trained on where to find them in the LMS. “Oh,” I'm told, “but we've made it easier for them to manage their SOP list. They're online now!”

My response: access is only one part of completing the requirements. A new hire needs to have optimal training experiences with a qualified trainer using a structured and deliberately planned approach to completing his/her assigned curricula. Yet, we ask our least experienced employees to “read and understand” a massive list of department SOPs with little to no prior experience and wonder why the learning curve is so lengthy!

So what's wrong with “R & U Training” for SOP revisions?

Reading an SOP electronically or via print is fine if the employee simply needs to know what the SOP revision is about. A clear statement as to the reason(s) for change is most helpful. But for the employee who must perform the procedure, the risk factor for an error to occur goes up significantly. According to the same excerpt, “25% of lab personnel signed that they had read and understood a procedure change but, three months later had no idea that the change occurred.” (2)

Oh sure, our procedures require that we include a knowledge check and it's usually five multiple choice questions because it is quicker and easier than providing a short answer test. They pass, earn their check mark, and move on to the next SOP that needs to be completed. In spite of that, knowledge checks are fast losing their true purpose. Employees focus more on searching for the key word within the SOP to satisfy the “test” than they do actually reading the procedure or the revision. It's become a game to get those check marks in the least amount time needed and be done with those annoying email reminders from the LMS.

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Whose needs are we meeting, anyway?

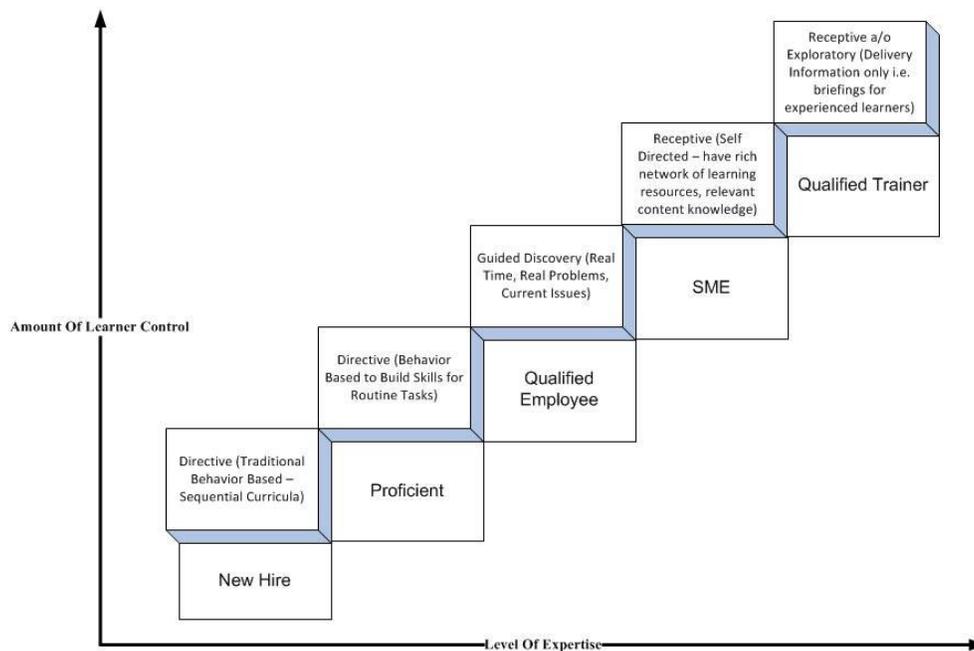
From a learning group perspective, we can sort our employees into general learning groups based on longevity with the company and/or prior experiences. We usually see the following classifications:

- Novice (New Hire)
- Apprentice (Proficient)
- Journeyman (Qualified Employee)
- Expert (SME)
- Master (SME as Qualified Trainer).

In her book “Building Expertise,” Ruth Colvin Clark summarizes the best delivery method to use for meeting the learning needs of employees. (3) (See Figure 1.) On the horizontal axis are the employee classifications. Along the vertical axis is the amount of learner control an experienced employee is given. A new hire typically lacks the knowledge and skill required to perform the task immediately. Thus the method is to provide the directive approach to ensure safe working conditions, instill confidence, and increase satisfaction with the overall training experiences. The more knowledge one gains, the less need there is to control how the employee learns.

So, a qualified and seasoned employee can handle less rigid supervision of his/her training requirements. Reading SOPs online may be appropriate for this group of learners. But new hires and those working towards proficiency status still need some level of trainer support. Nonetheless, our LMS may not be sophisticated enough to flag the difference between Online SOP revision training and required OJT- qualification. Theoretically, a new hire could be flagged for the revised SOP long before he has completed his OJT and qualification demonstration unless the database has “Due Date Assignments” or pre-requisite requirements. SOP revision training a la R & U (read and understand) for him/her would truly be ineffective and, quite honestly, wasted time.

Figure 1



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And then it happens ... a repeat deviation!

And so it goes, another deviation has occurred and the investigation begins. “What do you mean the knowledge did not transfer? We gave them a ‘test’ and they passed! Oh, is it a new hire? We can explain that, it’s the learning curve to get up to speed. Is it a seasoned employee? Hmm, maybe it’s a complacency problem and s/he needs a ‘pep talk’ session?” Could we have provided a scenario for application back to the job? Maybe. Would we have provided a challenge situation where they would have to demonstrate the knowledge in use? Sure, but the LMS isn’t configured to allow us to do this. And we have no budget to upgrade our software to include this new type of activity. We know in our hearts that we should create more effective ways to measure learning. But who has time to develop these kinds of questions? In the efficiency vs. effectiveness contest, efficiency wins hands down again.

So what’s missing?

What’s missing is the Q&A follow up. What’s also missing is the debriefing where moments of reflection and discussion are provided to make meaning from the content for the employee. In these debriefing sessions, employees are challenged with “Back to Your Job Application” exercises to ensure that when they are back on the job, they can put to use what they learned **and experienced** from training. The more skill-oriented the SOP is, the more practice-type of activities need to be included to master the revised changes. This also applies to major SOP revisions where the changes are significant enough to warrant a classroom session.

Rather than lecture what the changes are and spend valuable classroom time discussing what is already available, have them read the SOP revision in advance AND then schedule a classroom session for the debriefing and practice activities. This is a great use of reading SOPs online, provided that the opportunity to meet in person either virtually or face to face is also required. The pre-work is all done before attending the classroom session. This is when the tracking features of the LMS are helpful.

Given the need to produce more with fewer resources and shrinking budgets in increasingly record time, it’s tempting to eliminate or significantly reduce classroom sessions. However, the alternative to move all SOP training online, including SOP revisions, isn’t the most effective answer either. A blended approach of training delivery techniques needs to be deployed when appropriate to maximize the employee’s learning transfer, increase compliance and decrease human error deviations and CAPAs. This means we can still leverage today’s technology. Whether it be online, virtual/face to face classroom, or self-based CBT, we need to make it **effective** eLearning, not just reading SOPs online.

(1) “Recent Sci-Tech Discussion: Training from a GMP Perspective”, PDA Letter, April, 2009. Pp. 43 – 45.

(2) Ibid.

(3) Clark, RC. Building Expertise: Cognitive Methods for Training and Performance Improvement. 3rd Ed, San Francisco: John Wiley & Sons, 2008.

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