CASE STUDY

International Vaccines Manufacturer

Renovated Training Program Increases Compliance and Helps Restore License

Challenge

This international vaccines manufacturer had several site-wide instances in which employees did not follow written procedures, especially with regard to quality control. Because of an inadequate training program on Operational Procedures, its manufacturing license was revoked.

Solution

Clarkston Consulting worked with the client to overhaul the existing training program as part of a multifaceted effort to restore the manufacturer's license to produce vaccines. The new program consisted of creating reusable training modules that could be presented by process instead of individual procedures; training activities, walk-throughs, pictures, job-aids and/or process flows in each module; classes trained by experts in the relevant process to create an interactive learning environment; and an assessment process that included answering questions in the standard operating procedure (SOP) in class and during on-the-job assessments.

Benefits

With Clarkston's help, the manufacturer was able to have the license restored just six months after it was revoked, one-fourth the time it would have taken the client on its own. After reviewing the new training program, inspectors recognized it as a model program encouraging compliance in the following ways:

- The program raised participant accountability, with increased knowledge about the entire manufacturing process and an assessment at the end of each class.
- The training allowed for alterations in an efficient yet accurate manner with re-training any time an SOP changed.
- Overall, it increased program sustainability, with action plans and processes set up for the program to be maintained, managed, and improved upon for future drug production.

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Introduction

This international vaccines manufacturer trained employees by having them read a standard operating procedure (SOP) and sign off that they understood its contents. Under a training program with no assessment process, it was possible for an employee never to read the SOP, yet sign off as if he or she had both read and understood the procedure. When SOPs were read, it was possible for employees to do so in no particular order, with no regard to the relationships between separate SOPs. By having employees "read and understand" with no other training, only one learning style was engaged. The site had no real proof that employees understood the procedures or the relationship between them.

In August 2004, during a routine inspection by the site's national controlling regulatory agency, contamination was discovered in one of the production lots. Among other discoveries, it was determined that the existing training program had failed to sufficiently prepare employees to work in the regulated environment. The company lost their hold on the market for the year and stock prices immediately dropped 5%. Over the next month, a series of communications and follow-up inspections at the site resulted in a warning letter citing "failure to follow written procedures." Several changes were attempted unsuccessfully resulting in a citation, which among other things, referred to site-wide instances of training failure and the revocation of the site's license to manufacture.

Although the company was taking action, stock prices continued to fall and the plant was no closer to production readiness. Time was of the essence and Clarkston Consulting was engaged in a multifaceted effort to restore the license and implement a sound training program to get this company's products back on the market.

Business Challenge

The manufacturing site faced a seemingly simple business challenge—to ensure their employees followed written procedures. The timeframe was tight, however, and the challenge more complicated than it appeared. Within four months of Clarkston's arrival on-site, 80% of the existing procedures had to be modified or updated (more than 300), and 100 SOPs had to be created increasing total documentation by 20%. All employees also had to be trained on existing, revised, and new procedures, such that they could follow them on the facility floor. Above all, the site's training department desired a sustainable and repeatable program that would not cease to be effective after the restoration of the manufacturing license.

Clarkston team members worked with the site's training personnel to identify the areas of the training program that needed to be addressed. Training content, instructor, format, assessment, and management processes were all part of the improvement plan. Each focused area needed a solution tested and implemented within four months of Clarkston's arrival on-site, a process that would normally have taken the site up to two years.

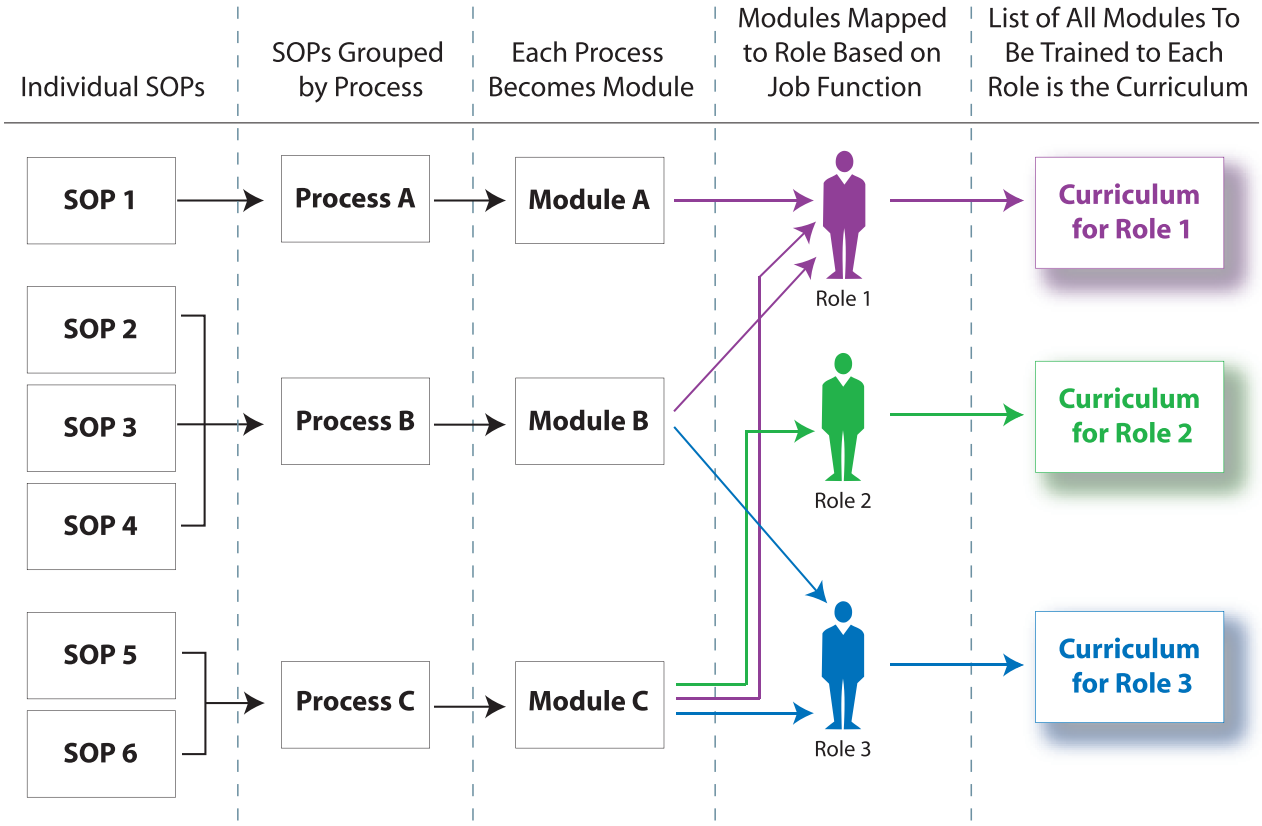
Business Solution

Clarkston and the vaccine manufacturer completely renovated the site's training program by creating process-based training of gathered SOPs taught by process experts in an environment that was conducive to many learning styles. Training was completed with an assessment process that included a plan for participants that needed extra training. The entire program was managed with a few simple tracking tools.

SOPs, historically distributed in no specific order, were grouped together in logical sets to increase understanding of the overall department and site-wide processes and the required hand-offs. Each manufacturing area already had a list of functions it performed and a list of associated SOPs. Therefore, the decision was made to turn each process into a training module, and each associated SOP would be presented as a logical part of that module.

Clarkston developed a presentation template for the training modules that could be modified to include a department's specific processes and associated SOPs, while maintaining the structure to deliver a consistent message. The template started with introduction slides about the purpose of the module; the agenda; and a process flow of how the entire department functioned. Highlighted within the process flow were the specific topics that were going to be addressed in class. This process flow helped partici-

Figure 1. Applying the Process-Based Training Approach.



pants relate the day's classes to other trainings and all the processes performed by the department. This encouraged understanding of what happened before, during, and after an operator was involved.

Following the process flow, each specific procedure was explained in detail using digital pictures of the process, and hands-on activities such as process walk-throughs. Participants were then asked to read the procedure themselves and the instructor was present to answer inquiries when necessary. After the participants had heard the procedure, seen it, read it and in some cases, tried it, they were given an assessment.

The assessment was comprised of open-ended and multiple-choice questions, which was a major change in the training program and involved a new documentation standard for the entire site. Each department was required to add five to ten questions to the end of each SOP. The questions became a part of the controlled document and the answers were maintained by site training. The departments then specified a "pass limit" of their choice as long as it was higher than 80%, per the SOP on SOPs maintained by the site.

The different components of the training modules and assessments were intentionally created to engage multiple learning styles. Historically, training only worked effectively for learners who could read something once and retain all of the information. With the new modules many types of learners were engaged. Visual learners could gain understanding through digital pictures or process flows. People who required hands-on training would benefit from walking through the operation or participating in training activities. There was even structured time to ask questions of the instructor.

After creation, each module underwent a review process. A peer review was first, and then the training department would follow. Finally, a quality officer would sign a cover page that stated, "I can confirm that the content of this training module accurately reflects the details represented

Figure 2. Engaging Multimple Learning Styles with Different Components of Training (Adapted from Colin Rose, *Accelerated Learning*, 1987.)

Learning Style	Training Component that Targets Specific Learning Style
 **Auditory** *"Hear"*	• Verbal instructions from trainer • Interactive sessions with dialogue about process and hand-offs • Question and Answer sessions with subject matter experts
 **Visual** *"See"*	• Presentations with process flows, diagrams, and pictures • Hard copy of the relevant SOPs used as references and read through in class • Demonstrations of the processes
 **Kinesthetic/Tactile** *"Do"*	• Participatory games and learning activities • Process walk-throughs • Assessments at the end of class

in the SOPs listed above." To review following versions of the same module, the same process was put in place and it was noted, "The SOPs listed above have changed since the training module was created and trained. Update and retrain the modules as defined above."

It was pertinent that the modules were not only created and reviewed thoroughly, but also modules needed to be trained by subject matter experts (SMEs). A SME could add his or her own real-world experience to the module, as well as provide real-time responses as participants raised questions. It was the case that some SMEs had never lead training courses before. Clarkston, therefore, conducted several Train-the-Trainer workshops to prepare the SMEs. During these workshops, the SMEs were given the basic facilitation skills and adult learning principles required to effectively train a class.

Several tools and templates were developed to help sustain the new training program. A curriculum template was created so departments could turn their department's SOPs into processes, processes into modules, and modules into curriculum by role. Next, an attendance tracking tool and an electronic folder management system was developed. To ensure consistency in training documentation, templates were also created for all modules, assessments, and training aids. Then Clarkston conducted a Course Developer's Workshop to help the site learn how to use each of the templates.

Business Benefits

The overhauled program addressed all of the risk areas of the initial program by:

- Increasing participant accountability
- Allowing for efficient change with each SOP change
- Utilizing management tools to create sustainable compliance

The fully functioning training program, along with other positive site-wide changes, helped to reinstate inspectors' confidence in the site, and the manufacturing

license was restored within four months of Clarkston's arrival on-site.

Participant accountability rose in the classroom and on the facility floor. Because the training now engaged several learning styles and was expert-led, participants continuously exhibit their knowledge and demonstrate their ability to apply their learning by passing their assessments. On the facility floor, accountability has risen due to participants' greater understanding of the entire manufacturing process. This is beneficial in the integrated environment of the regulated industry. Employees understand the effects of their actions on the entire process. They also know whom to contact when an issue arises and how important it is to contact that person in a timely fashion.

Training documentation management is now flexible, efficient, and effective. If a procedure changes, than the module for that procedure also changes. It is then retrained for all relevant personnel including quality control. Also, because SOPs are trained in modules grouped by process, when one SOP in that group is trained, the entire module is re-trained. This provides a refresher on each procedure in the module and allows discussion on any possible effects the change of one SOP has had on others in the group.

There were several tools developed for the site that continue to ensure success of the new training program. From attendance tracking tools to course development training. Each trainer on-site can develop modules as new SOPs are released and update modules as SOPs are changed. With proper use of the attendance tools, they can also be assured that all personnel are trained on relevant changes.

With the site's license restored on schedule, the national controlling regulatory agency inspectors released a statement showing they were "…pleased that [the site had] taken steps to address issues at their facility…." Less than two months after that statement was released, the manufacturer's vaccine reentered the US market.

The training renovation and implementation made a direct impact to the vaccine manufacturer during remediation. An elated Director of Site Training stated to Clarkston "What [Clarkston Consulting] did in six months saved our facility two years." The Director of Site Training was asked to share the details of the new training program with other international manufacturing facilities to review for a global rollout.

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