BOOSTING THE VALUE OF GMP TRAINING

FOR MEDICAL DEVICE AND PHARMACEUTICAL COMPANIES

Ellen Leinfuss, Senior Vice President, Life Science
Dave Peterson, Director of GMP Education

How Life Science companies can benefit from Good Manufacturing Practice refresher and continuous training programs.

Compliance with Good Manufacturing Practices (GMPs) by Medical Device and Pharmaceutical companies requires a well-trained, qualified workforce.

GMP compliance is essential for the production of safe, effective and regulatory-compliant products, and a well-trained workforce leads to fewer errors, less waste and more efficient company performance.

Implementing appropriate training programs for ensuring that employees keep up to speed on GMP requirements can, however, pose a challenge for companies. Too often, organizations use the "shotgun approach", pumping out training with a "one-topic-fits-all" approach that fails to target the knowledge gaps of employees and, just as important, fails to target the needs of the company for a well-trained workforce.

Regulators around the globe focus heavily on GMPs, the foundation of product quality, patient safety and regulatory compliance. In the US, for example, the requirement for a well-trained, qualified workforce to meet GMP compliance needs is codified in regulations including the Code of Federal Regulations (21 CFR 211 and 820), which establishes the following as a basic element of regulatory compliance:

Each person engaged in the manufacture, processing, packing or holding of a drug product shall have education, training and experience, or any combination thereof, to enable that person to perform the assigned functions.

This article explains how Medical Device and Pharmaceutical firms can implement effective refresher and continuous learning GMP training programs that add value to their businesses. While focusing on training requirements in the US, the underlying advice contained in the article is relevant to companies operating in any country.

In the US, meeting legislative obligation for staff training requires companies to provide three types of training: initial qualification, periodic refresher training and continuous learning. In our experience, working with over 250 Life Science companies, including both large and emerging, we see that organizations can be challenged by all three requirements, but especially how to meet the Food and Drug Administration's (FDA's) expectations for refresher training and continuous learning. It is worth remembering the underlying goal of continuous quality and process improvement. Simply meeting the basic requirement for

As printed in Scrip Regulatory Affairs

training by "checking the box" or patching up deviations and errors will not achieve compliance – nor will it achieve the company's goals of product quality, employee productivity and business performance.

Periodic Refresher Training

The FDA's GMP regulations specifically require that: "Training shall be in the particular operations that the employee performs in cGMP as they relate to the employee's function." In other words, the training must be aligned to an individual's job requirements. The one-topic-fits-all approach that companies all too often use meets the letter of the regulation but fails the "relevance test."

Which Employees Need Training in Which Topics?

Many best-practice organizations have adopted two approaches to meeting refresher training goals. First, companies identify their internal compliance concerns and train employees on those topics of concern. Second, companies requalify their employees to ensure that employee knowledge and skills continue to meet current needs. As a first step to accurately identify topics for refresher training, consider the points of "compliance pain" in your organization. That pain can be identified using a number of resources and internal data including:

- **Deviations from processes.** The value of periodic audits of operations and employee performance is obvious to any company that has learned of those deviations from an FDA inspection, 483 or Warning Letter. Deviations that are observed during internal audits can be quickly addressed by the trainers by matching up relevant topics with employees responsible for the specific work. Similarly, an uptick in quality issues signals a company's need to backtrack the process until it can identify the failed procedure leading to the quality problems. Employees involved in that process can then be targeted for specific retraining.
- **Job function of each employee.** Too many training staff fulfill their retraining requirement with a one-size-fits-all approach that delivers the same training to everyone, regardless of job function. That approach is unnecessarily costly and time-consuming. For instance, manufacturing floor operators should be retrained on completing effective batch records (a common deviation noted in internal and FDA inspections) and principles of good documentation. Computer engineers in the same facility may need refresher training in the company's validation policies or process controls.
- **Process and equipment changes.** Competition in the marketplace demands frequent updating of equipment and processes for greater efficiency. Those changes are all subject to new compliance requirements and related training demands. Linking changes of equipment and processes with training in a robust Learning Management System (LMS) (ie: a software application for administering, documenting, tracking, reporting and delivering education courses or training programs) can prevent the problem of updating systems – but leave employees behind.

CASE STUDY:

To meet its GMP refresher training requirement, a west coast Biologics company provided everyone in the organization with the same two courses: "An Introduction to GMPs" and "Change Control." The company "checked the box," confident that it had met its refresher training requirement. Unfortunately, the company's response missed badly for usefulness and impact. Most employees found the training redundant and irrelevant because the training did not target their job functions or knowledge needs. Just as bad, the Training Department lost reputation and credibility – and the company lost an opportunity to improve knowledge, performance and employee confidence in corporate policies and programs.

Refresher training can also be used to requalify employees for their job functions. Typically, companies requalify employees annually or every two years in order to ensure employee proficiency with rapidly changing regulatory and operational changes. As an example, each employee in a GMP-related job role who has been previously "qualified" must requalify by completing a portion of the original qualification requirements. A chemistry lab analyst, for instance, might run a selected number of assays repeatedly to demonstrate consistency while a floor operator might demonstrate operations activities without loss of product or procedure deviation.

Regardless of the approach, or combination of approaches used to tackle refresher training needs, topics must be relevant to internal compliance concerns and the knowledge needs of employees if they are to gain acceptance and buy-in from managers and learners. Just as important, training has to engage the learner. Taking a creative approach to what is, in effect, a compliance requirement can go a long way to increasing the effectiveness and long-lasting benefits of refresher training.

What is "Continuous Learning?"

"Continuous learning" differs from refresher training in several important ways. Unlike refresher training, which should be specific to job function and identified knowledge gaps, continuous learning seeks to update and reinforce non-job-specific knowledge across specific groups or even the organization as a whole.

Training and education typically focus on corporate policies, Codes of Conduct, industry standards and evolving domestic and international regulations. Specific topics at the management level might include trends in FDA inspections and Warning Letters, new or revised FDA requirements, regulatory changes in the company's international markets, health and safety issues, and compliance requirements related to enforcement actions. At the operational level, continuous learning might include topics such as new automation technologies and their impact on product quality, the importance of validating processes and systems or new software system implementations.

Proficiency and Performance

Training is a compliance requirement but companies that go beyond "checking the box" gain multiple operational benefits. Increased learning proficiency results in fewer errors, less waste and more efficient company performance. But to be effective from a business perspective and achieve compliance, relevant training needs to reach the right audience. It should focus on what matters most to the company's operation and overall regulatory compliance. Training is most effective when it is role-based and provided just in time to the operational need. Equally important, training must be documented, preferably in an LMS that maintains real-time records

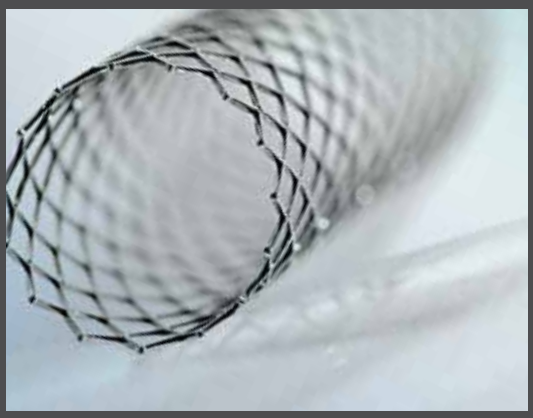
CASE STUDY:

A midwestern Pharmaceutical company identified a problem in their quality control laboratories: some lab technicians were not following Standard Operating Procedures (SOPs). So, the company linked refresher training with the need to improve SOP compliance, choosing an innovative, engaging approach to go beyond the typical "read and understand" methodology. The company selected 20 SOPs and framed the training program as a "contest" among lab groups to see which group could score the highest on a comprehensive exam.

Members of the winning team and their guests would go to dinner at the best restaurant in town. Competitive juices kicked in and the various lab teams took on "above and beyond" learning activities. Over the next several weeks, employees planned training sessions around brown-bag lunches and after-work meetings. Employees helped each other learn, and exam results confirmed the effectiveness of the program: all groups scored greater than 95%. (Management recognized that the company was the real winner in the competition, not just because of the high test scores but also because of the shared team spirit and camaraderie that developed in each team, and took everyone to dinner.)

of training requirements, scheduled training items and completions. The combination of good data and a practical underlying approach to refresher training and continuous learning will produce more than regulatory compliance: they will produce operational, cultural and performance benefits throughout the company, ultimately improving patient safety.

CASE STUDY:



An east-coast Medical Device company recognized the FDA's growing focus on inadequate reporting of adverse events and proactively audited its own compliance with reporting requirements. The audit revealed inconsistent reporting throughout the organization, leading the company to develop a new training program focused on heightening employee understanding of the reporting requirements and their importance to the company's compliance and responsibility to patients. The training was not tied to a specific job, nor was it designed to fulfill "retraining" requirements. Rather, it was designed to increase awareness among all employees of a critical compliance requirement and corporate commitment to patient safety.

About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council and the Duke Clinical Research Institute.