

Keeping Tabs on Training

It's not enough to train your staff. You have to keep training them — a good learning management system can help

In the FDA-regulated world, any compliance effort has to include a strong training component. Training also figures prominently in the certifications issued by the International Standards Organization (ISO), which are prized by companies that produce medical or pharmaceutical products and technology. The rigorous standards of the FDA and the ISO 9000 model focus particularly on documenting policies, procedures, and records related to a company's quality systems and subsystems. These can encompass anything from a plant's overall quality assurance operation to software applications, the machines that mill tablets, or guidelines on sterile areas.

Expediting and easing the regulatory compliance effort were among the driving reasons that Guidant Corporation decided to automate its training system and integrate it with other corporate assets.

With nine facilities in the United States, Puerto Rico, and Ireland, Guidant is one of the world's largest manufacturers of medical devices including pacemakers and the stents used in angioplasty. As such, Guidant closely monitors emerging regulations in

several countries and has a staff devoted entirely to compliance tasks. Guidant has now moved to automated tools to track, store, and deliver training to more than 11,000 personnel. The change means that Guidant's compliance staff can quickly show FDA auditors, simply by sitting them in front of a PC and retrieving the desired history or audit trail, that specific divisions or individuals are trained.

The Challenges of Paper

Before it moved to an online training database, Guidant maintained a cumbersome paper-based system for both training records and the courses or standard operating procedure (SOP) documents that instruct employees in various tasks. When procedures were revised — something that happens at Guidant as often as 300 times a month — managers had to spend time making sure that affected employees had scheduled mandatory retraining on the revision, completed the retraining, and certified they had done so — on paper. Rows of binders packed with years of training histories and SOPs had to be locked in cabinets to satisfy auditors' concerns about the security and accuracy of training records.

In 1999, these challenges led Guidant to implement a learning management system (LMS) at several of its facilities. The LMS is an enterprise-scale software application that manages training content and records, schedules online and classroom training for students, and allows employees in various locations to access learning material online. Numerous LMS systems are available, but

Guidant chose one made by Plateau Systems, a provider with experience at other highly regulated clients including pharmaceutical plants, nuclear reactors, and the U.S. Air Force.

Moving to an LMS required migrating 1.4 million legacy training files to the new database, a major undertaking. Guidant also had to acclimate thousands of employees and managers to a new way of receiving and fulfilling their training requirements — a fundamental change in our business culture, and one of the biggest challenges we faced as we shifted to a paperless system.

After a few months spent importing data and educating the staff, the learning system went online, with excellent results. Every job category at the company now has a cluster of training qualifications associated with it, whether the position describes a technician who must learn about preventing contamination, or a manager who must develop "soft skills." As training deadlines approach, employees are alerted automatically by emails, which persist until training is completed. When employees change jobs, their training profile is easily updated. If instructors want to schedule a traditional classroom or on-the-job training session, they do so using the LMS's calendar.

This has allowed supervisors to focus on other work, and has largely eliminated the time lags that Guidant experienced in carrying out training. Administrators can get a holistic look at the training gaps within a particular division. Using the LMS in tandem with personal on-the-job

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assessments, managers can gauge manufacturing workers' skill levels and certify them for assembly work. All completed training is stored in the LMS as a series of unique, time-stamped events in a secure archive that the compliance staff was taught how to query.

Integrating with Other Systems

Groups of procedural documents are also linked to the qualifications in each employee's job profile, and when these documents are revised — for example, when a manufacturing instruction is changed to reflect a tooling modification — the LMS detects the revision and automatically notifies any affected employees that they must now retrain on the document. This feature is appealing to FDA and ISO inspectors, who are particularly concerned with "change management."

These seamless interfaces are possible because we have connected the learning database to other enterprise systems at our company. Because the LMS is integrated with our PeopleSoft human resources system, it is able to "see" employees' statuses and job categories. Integrating the LMS with Guidant's document management systems — which are repositories for thousands of SOPs, policies, and procedures — allows the training system to associate required content with specific employee groups, and then to the universe of employees for each SOP. At our Cardiac Rhythm Management plant in St. Paul, MN, where Guidant manufactures pacemakers, the LMS database is integrated with the shop-floor security system. If a worker's training is out-of-date, he or she is denied access to the tasks performed at that work station.

Validating the LMS

Integrations among systems like this must be initially validated and then monitored to make sure the interfaces function properly. For example, one of our document management systems moved to a new numbering sequence, so the LMS had to be adjusted to recognize the renamed SOPs. And like any enterprise software asset in a regulated environment, the LMS must be validated every time there is a business or interface change.

Government and ISO auditors aren't present during the validation process itself, which can take weeks, but they usually ask to see documentation of completed validation for the software systems they look at. At a recent conference on good manufacturing practices (GMPs) in Athens, GA, FDA staff identified "lack of process and computer validation" as a frequent GMP violation (along with "inadequate employee training"). Guidant has successfully

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validated its LMS twice since implementing it and continually monitors the system to ensure that it is running as validated.

In addition to asking for validation records, FDA and ISO inspectors routinely ask to see records of completed training related to specific production lines. For example, in the past two years Guidant's Houston facility launched a product that administers radiation therapy during the placement of a stent in coronary surgery. Because it was a new initiative, and because FDA closely scrutinizes any radiation product, auditors wanted to see training records for employees working on that product line. Guidant compliance staff simply went to a PC with the inspector and queried the LMS.

New Rules for Online Documents

We are counting on the LMS to help us as FDA begins to enforce its new guidelines

for electronic documents, 21 CFR Part 11. For facilities that have shifted from paper to online records, the regulations require controls guaranteeing that such documents remain accurate, authentic, auditable, and secure from fraud. Part 11 suggests password controls for employees, restricting how an electronic document can be changed, and tracking documents when they are revised. These are all features that Guidant already has on its LMS for training-related documents, so we feel well prepared for this compliance task as well.

In the past year, after experiencing success with the LMS at several locations, Guidant expanded it throughout the company, establishing a true enterprise-wide asset. Among other benefits, assembling one unified training database for the entire company has allowed employees' records to follow them if they transfer between departments or locations. The company now has 9,200 employees and 2,200 contractors on the LMS.

In the future, it's possible that FDA's compliance standards for medical devices will be closely aligned with the ISO regime. Such a move would ease the burden on many regulated companies that have devoted time and resources to complying with both bodies, which often overlap. Even so, Guidant will still have to satisfy multiple standards in Britain, Japan, India, and elsewhere, all of them with an ardent interest in records and training. Regulation is a constant in our business, but adopting an online system for recording and delivering training has lightened our compliance workload considerably. **BPI**