

Regulatory Compliance Training Who Needs It?

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Whether they are forward thinking and offer ongoing training in regulatory compliance or are prodded into it by failure-to-comply citations, pharmaceutical companies must ensure that their employees know **how federal regulations affect their jobs** and must know how to keep them trained.

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Understanding regulatory compliance is one thing; putting this understanding to work is quite another. Pharmaceutical manufacturers, ever under the watchful eye of federal inspectors and always keeping their fingers on the pulse of profitability, are pressed to keep their employees sharp and up to speed when it comes to understanding and implementing the demands of federal regulations. Thus employee training is a crucial investment for companies that are competing in an arena that calls for efficient and regulation-compliant processes.

Areas of training

“Training is an ongoing requirement because the concept of good practice should be flexible and develop over time,” said Gordon Richman, vice-president of strategic compliance consulting and general counsel at EduQuest (Hyattstown, MD, tel. 301.874.6031, Info@EduQuest.net), which provides regulatory compliance consulting and training services. Richman identified three areas of training for all industry employees.

Relevant training. Regulatory compliance training ensures that workers in the industry are adequately trained in the area in which they work. This type of training is especially important for personnel working in supporting roles, even if they are not directly involved in manufacturing. For example, employees in the IT department who are developing process control systems or manufacturing resource planning systems should be trained in GMP compliance and must understand what the regulatory requirements are that relate to their jobs and the systems they are developing. Applying this rule generally, each employee in each area of the company should receive detailed training about FDA requirements that directly affect or even have peripheral influence on their function in the organization. As Richman sees it, the optimum result is that “each employee will understand the nature and context of his or her job and how it affects the nature and context of the business the company is in.”

“If people going into the industry don’t see the big picture, they don’t understand [their role],” said Joyce Redmond, president of QualiPharm Consulting (Wayne, PA, tel. 610.964.9484). “Oftentimes they’ll go into regulatory compliance training or GMP training, and they may be in the lab and they’ll ask, ‘What does manufacturing have to do with what I do?’” Redmond maintains that a good understanding of how their particular job relates to the overall manufacturing process enables employees to help their company comply with all federal regulations.

FDA-specific training. Ideally, everyone in a company will have a general awareness and understanding of FDA's enforcement powers, the procedures the agency is interested in reviewing, and the reason behind its regulations. "Some very senior-level executives in the pharmaceutical industry are surprised to find out that they are subject to potential criminal prosecution by failing to meet FDA requirements," Richman stated. He emphasized that it is critically important for every employee to understand the nature of the business they are in, the level of regulation that applies to that business, and the consequences of being noncompliant.

Each company is held accountable for having the documents they are required to by law, Redmond pointed out, but the government fails to provide the detail that is needed to carry out that task. Thus written standard operating procedures (SOPs) must be in place to document procedures and establish consistency, which is the basic standard that FDA holds companies to. In the most fundamental terms, FDA seeks to confirm that "you have the document, you know what the document says, and you follow it," Redmond said. Lacking SOPs or failing to operate in accordance with them is a common reason the agency issues FDA-483 Inspectional Observations warnings. Project management, a system for planning and implementing a project so that it is done better, quicker, and faster, helps employees understand SOPs and "define the key steps to SOP processes: plan, prioritize, execute, evaluate, report," Redmond explained.

Inspectional preparedness training. FDA investigators are law enforcement officers who gather evidence that can be used to take action against a company. Therefore employees who will be involved in an FDA inspection must be trained so they understand the scope of the agency's inspection authority. They should know what FDA will look for, how to handle questions and requests for documents, and understand FDA's mindset as it applies to inspections. IT personnel, for example, are developing systems for manufacturing and therefore are frequently asked to respond to queries during FDA inspections. They are questioned about the development and control of systems, system maintenance and validation, and are asked broader questions about the company's practices for system development, implementation, change control, and company practices that go beyond individual systems. Providing acceptable answers is a lot to expect of an individual or department, who in essence is being asked to speak for the company about compliance practices and the degree to which the company meets regulations.

If that isn't enough, employees who are not directly involved in day-to-day manufacturing design but who play supporting roles also can be pulled into FDA inspections. Oftentimes they "don't know what they're dealing with, they don't understand the situation, and they don't understand how to appropriately respond," Richman cautioned. "It has created some very big problems for some companies, and it's something that can be substantially avoided by proper training. Smart companies recognize that the more people understand about the regulatory requirements, the more likely they are to do their job in a way that will meet them."

A proactive attitude

Unfortunately, one incentive that prods some companies to

train their personnel more thoroughly is failure—undergoing a major system problem or a problem with GMP that leads to a recall, for example, or being found out of compliance by FDA. Routinely recognizing the value of training in the three areas previously described and proactively rather than reactively seeking regular training for their employees puts smart companies ahead of the game and may save them considerable time and money in the long run.

According to Redmond, all new employees should be trained in documentation practices. "It helps the new person learn what is appropriate to document, what's not, how to handle electronic records and signatures, and Part 11 compliance." Redmond thinks all employees in the pharma industry should be trained in 21 *CFR* Part 11 because it applies to everyone. She maintains that companies should provide all employees with overview training so they understand what each compliance regulation is and how it applies to their work. For example, if employees work in toxicology, they would be trained in good laboratory practices, and if they work in clinical, they are trained in good clinical practices.

Getting trained

In-house. To a large degree, companies themselves offer internal training about regulatory compliance through company universities. Most companies require their employees to follow overview training with in-depth classes in which the same material is discussed but in greater detail and with an emphasis on current problems and trends in regulatory compliance.

Outside experts. Many companies conduct internal training by bringing in outside experts. This training may either be ongoing or be spurred by significant developments such as new regulatory requirements, new FDA guidelines, or a bad inspection that triggers a round of GMP update training. Consultant companies such as Richman's train employees in areas such as regulatory compliance, data management, audits and pre-approval inspections, computer validation, adverse-event reporting, change control, process deviations and failure investigations, and GxP requirements.

EduQuest offers training in general FDA enforcement and compliance, inspectional awareness, and understanding the reasoning behind 21 *CFR* Part 11 and FDA's expectations regarding the validation of computerized systems. In addition, the company was hired by FDA to train the agency's investigators, headquarters compliance officers, and field analysts on auditing computerized systems and Part 11 and also offers this same training to the industry. Trainees learn how "to think about the parallel situation in the hard-copy or paper world from a compliance perspective. Oftentimes having that discussion helps people better understand how those same sort of compliance concepts have been applied in the electronic world," Richman remarked. His company teaches people to "take their well-known and understood longstanding concepts of control and compliance and translate them into the electronic environment."

Training institutes. Universities and independent training institutes offer a variety of classes for regulatory compliance training, as do organizations such as the Parenteral Drug Association and the International Society for Pharmacoepidemiology

(ISPE), two large societies that sponsor training and have institutes associated with them. PDA's institute, headquartered in Baltimore, Maryland, offers courses such as "Preparing for FDA PAIs, CGMPs, and Postmarket Inspections" and "CGMP Trainer Certification." ISPE offers individual learning modules and an extensive course listing for mastering regulatory compliance. Temple University's (Philadelphia, PA) QA/RA graduate program includes "classes taught by industry experts who have experience in legal, regulatory, quality, and compliance activities in a variety of companies. The curriculum emphasizes laws, regulations, quality principles, and practices" (1). The school also offers a four-credit research project associated with numerous aspects of quality assurance or regulatory affairs.

The Pharmaceutical Education and Research Institute (Arlington, VA) is a not-for-profit organization that offers training in regulatory compliance. It has open courses, in-house training, and distance education, some with the specific purpose of interpreting FDA regulations; identifying regulatory, source documentation, and recordkeeping requirements; discussing current FDA inspection trends; and describing the roles and responsibilities of sponsors, monitors, investigators, and regulatory authorities.

The Pharmaceutical Training Institute (PTI, www.pti-international.com) conducts classes in various US cities. It offers classes such as "Strategies for Ensuring FDA Compliance" and "Conducting Internal Audits and Preapproval Inspec-

tions." PTI identifies general areas of expertise such as quality assurance and GMPs, identifies job functions in these areas, and then offers core and elective courses to match these areas of expertise. Students may work toward an official certificate of completion. The organization also offers consulting and on-site training.

Conclusion

Rapidly changing technology and the compliance requirements that change with it demand effective and thorough employee training. Operating at below-standard levels of compliance is at best risky and at worst, disastrous. Education is a simple tool for ensuring that a company's reputation and revenue are not jeopardized. To secure its survival and success, a pharmaceutical manufacturing company must be willing to make an ongoing investment in education.

As Richman put it, "Smart companies recognize that the more people understand the nature and context of their role in the organization and what it is the organization ultimately is going to be held to do properly, the more likely they're going to be successful in meeting those requirements."

Reference

1. Temple University Web site, <http://www.temple.edu>, accessed 15 October 2002. **PT**