

# If Training Is So Easy, Why Isn't Everyone in Compliance?

**Vivian Bringslimark**

**Training programs do not have to be complex to be successful. There are basic elements, however, that all must have to meet FDA requirements and ensure that employees have the knowledge and skills to maintain high quality standards.**



the fact they can produce volumes of signed records showing their employees have read the SOPs.<sup>1</sup>

Why are these records insufficient for FDA compliance? Because the pertinent question for training is

not, "Can you prove that your employees have read the SOPs?" What the FDA wants to know is whether you can prove your employees understand the procedures and can perform them in accordance with the SOPs. To be able to confidently answer "yes," manufacturers must have training programs that are carefully designed, effectively delivered, regularly evaluated, and frequently updated — in addition to being well-documented. Such programs do not have to be overly complex or burdensome to be successful. In fact, complicated and tedious



**Vivian Bringslimark**

*is a quality systems consultant with KMI/Parexel, 195 West Street,*

*Waltham, MA 02451, 781.434.4852, fax 203.270.6519, vbringslimark@belmont.kminc.com.*

**W**hat constitutes good training for employees engaged in pharmaceutical manufacturing? Many pharmaceutical companies think they know the answer: "We give our employees copies of the applicable SOPs to read, and they sign a form stating that they understand them." But reading a document is not the same as receiving training on a process or procedure.

In recent years, FDA has cited a growing number of pharmaceutical companies for deficiencies in their training programs — despite

training can impede compliance just as much as an underdeveloped program.

FDA regulations covering training for employees involved in pharmaceutical and medical device manufacturing (such as 21 CFR 211) are very broad and subject to interpretation. Although FDA does not provide detailed guidelines for doing so, the effectiveness of your training program should be validated by a formal evaluation program. Each company is responsible for establishing its own monitoring procedures to show that employees not only attended training courses but that specific messages were received and understood.

While FDA compliance is critical for pharmaceutical companies, it is not the most important reason to have effective employee training programs. Every manufacturer should be concerned about training because it is an essential component of quality. In the demanding environment of pharmaceutical manufacturing, companies cannot maintain high-quality production without high-quality training. Just as every manufacturing process must be thoroughly tested and proven to deliver consistent results to maintain product quality, effective training programs are essential to ensure that employees have the knowledge and skills they need to perform their jobs.

## AN EFFECTIVE TRAINING SYSTEM

Despite the lack of specifics in the regulations, there are a number of common elements that should be present in any effective training program

- cGMP training for new employees
- an ongoing cGMP curriculum that includes regular updates and refresher courses
- a formal program to qualify instructors
- a structured on-the-job training program
- regular assessment of knowledge transfer
- a training documentation process
- a policy document describing the training program and the supporting SOPs.

Each of these elements plays an important role in the process of giving employees the training they need to do their jobs safely and correctly and also provide the necessary documentation to demonstrate that the training was performed properly.

**cGMP Training for New Employees.** Many new employees do not have experience in the

pharmaceutical industry, so it is important to begin their training with an overview of cGMP basics and why these practices are vital to the welfare of the employee, the company, and the patients who will ultimately use the company's products. The course should include a discussion of the regulations (such as an introduction to Subparts A through K of 21 CFR 211) and the role of SOPs in maintaining quality in the pharmaceutical manufacturing environment. Although this course is especially important for those new to the industry, it should be mandatory for all new employees regardless of their previous experience. This training should occur as soon as possible after an employee joins the company — typically within the first week of employment — and should include a testing component to ensure that new employees understand the material.

**Ongoing cGMP Curriculum.** According to 21 CFR 211.25,

Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.<sup>2</sup>

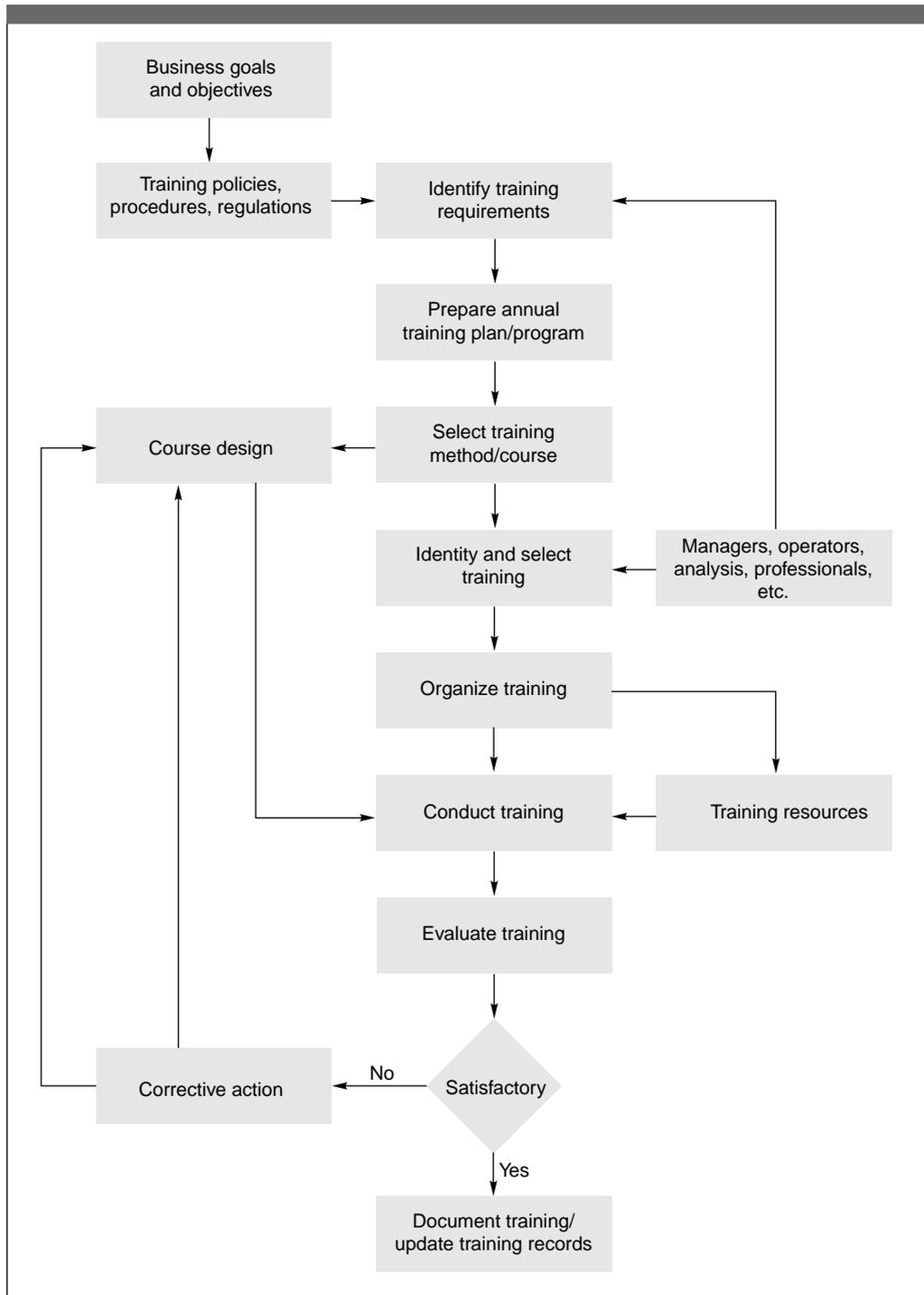
The regulation does not state how frequent the training should be, but a company's training program documentation should define the frequency for each category of employee and should also include evaluation results that demonstrate continuing knowledge of cGMP standards. Keep in mind that a refresher course must be more than a cGMP video shown to all employees once a year. While an ongoing cGMP education program should focus on regulations, it can be made more effective — and more interesting — by including relevant current events from inside or outside the company, such as customer complaints, product recalls, warning letters, or concerns that have been raised by site management. Such issues clearly demonstrate how regulations relate to everyday operations at the facility, and they provide an incentive for employees to apply what they've learned in the classroom to their jobs on the manufacturing floor or in the lab.

Assessments of ongoing training can take the form of evaluation checklists distributed at the end of the sessions or actual tests. In addition to meeting the requirements of the regulations, feedback from cGMP course evaluations can help refine future sessions and evaluate overall site

quality. The results also give the training manager and the training group an opportunity to demonstrate the value of training as a quality tool.

**Instructor Qualification.** Trainer selection and qualification has come under close scrutiny in recent years. Regulators want to know how trainers

are selected and how a company knows an individual has the knowledge and skills to effectively teach and evaluate others. Employees who have subject-matter expertise or extensive experience with a particular task may have the right knowledge but lack the skills needed to convey that knowledge to others. Trainers don't need to have a degree in education or formal training in course



**Figure 1. Schematic of a training quality system**

## Suggested Reading

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design to be effective teachers, but they should be expected to meet certain minimum criteria. In their book *Structured On-the-Job Training: Unleashing Employee Expertise in the Workplace*,<sup>3</sup> Jacobs and Jones suggest the following criteria:

- task knowledge and skills
- participation in specialized training or education programs
- willingness to share expertise
- respect from peers
- interpersonal skills
- literacy skills
- concern for the organization
- job requirements that do not interfere with availability or scheduling of training.

The selection criteria should be part of the training program documentation along with any supporting statements for candidate selection (for example, nominated by supervisor or responded to call for volunteers). All candidates should be assessed for their subject matter and educational skills, as well as knowledge of the site's training and qualifications procedures. Any shortcoming should be addressed with validated "train-the-trainer" or similar courses. Also, be careful about "grandfathering" current trainers. Without a formal assessment of their skills, there is no information to document their qualifications. Remember: an effective training program documents the qualifications and performance of both the trainers and the employees being trained.

Another vital component of instructor qualification is ensuring that all trainers maintain their skills and continually update their knowledge. How often do the trainers receive refresher courses in training procedures? How often are they evaluated for effectiveness? Are they learning additional skills or training techniques? A company must be able provide definitive — and adequate — answers to these questions to maintain an effective training program.

**Structured On-the-Job Training.** Traditionally, on-the-job training consisted of having new employees watch experienced employees do their jobs. The quality of this "training" was governed by the abilities of the person being followed on any given day; the indication of its success was whether the trainees made mistakes in the future. In a regulated environment, such informal training is clearly inadequate. Because the

regulations state that training "shall be conducted by qualified individuals," structured on-the-job training, or SOJT, is crucial. Jacobs and Jones define SOJT as "the planned process of developing task-level expertise by having an experienced employee train a novice employee at or near the actual work setting."<sup>3</sup> This type of training is also known as performance-based training or procedural training. It requires advanced planning, approved training materials, documentation, and formal evaluation of the skills acquired. This approach also necessitates trainers who are qualified to train new employees and to evaluate their ability to perform the procedures with minimal supervision. This type of one-on-one training and evaluation should be taught in train-the-trainer sessions tailored to individual trainers and tasks.

**Assessing Knowledge Transfer.** The essential element of any effective training program is the ability to document its effectiveness — not just to prove that the training took place, but to prove that the trainee learned the intended lesson. While most pharmaceutical companies already do this on an informal basis, the qualification process cannot be validated unless it is formally documented. How is that done? Using an approved SOP, a qualified observer or trainer should observe the employee performing the procedure, compare the performance to the SOP, and record the results on a qualification or competency assessment sheet. The results should be communicated to the employee, his or her supervisor, and to the trainer responsible for the original training, indicating whether the prescribed level of competency has been attained. The process of how the competency assessment sheets are approved, distributed, and evaluated also should be defined in a qualification SOP as part of the overall training system.

**Training Documentation.** "If it isn't documented, then it is only rumored to have happened." While this expression may be a cliché, it succinctly summarizes the importance of documentation for an effective training system. FDA regulations in 21 CFR Part 211.25 do not specifically require documented procedures and records for training, but without documentation there is no proof of effective training. Each step of the training process should be covered by an SOP and documented thoroughly and consistently. For every process and procedure — both for trainers

and trainees — you should be able to document how it is to be performed, taught, tested, and monitored over time. In general, you should have two types of training records: those relating to a particular individual's training and those relating to specific critical processes.

Equally important to keeping comprehensive records is the ability to access them quickly and conveniently. While a centralized, computerized system is probably the best way to maintain consistent and accessible training documentation, decentralized or paper-based systems can be just as effective if they are organized and kept up to date. Change control is also important to maintaining a validated training system.

To maintain the integrity of the records after your training system procedures and documentation have been established and approved, you need a review and approval process for additions, deletions, and changes to the documentation and the SOPs. Also, training records should be reviewed periodically to identify gaps and evaluate the timeliness of training; adjustments should be made as necessary.

An often unforeseen aspect of implementing a thoroughly documented training system is its impact on veteran trainers and employees whose training occurred before the system was restructured. It is an unfortunate fact that most of their training will have to be redelivered and formally documented to have a fully compliant training system. Once this initial round of requalification is completed, however, there should be no need to repeat it.

**Establishing Effective Training System SOPs.** The evaluation of your existing training program should include a comprehensive review and update of the training SOPs. An effective, compliant training program would typically incorporate the following key SOPs:

- policy statement or SOP for cGMP training and refresher course schedules
- SOP on how to deliver training on SOPs
- SOP for the qualification/testing process
- SOP for qualifying trainers
- SOP for the training requirements of all applicable positions
- SOP for training documentation
- SOP for approval of courses that are not dictated by SOPs or policy statements
- SOP for entering data into the database (if

## Task List for Establishing a Quality Training System

1. Establish and maintain training program policies and procedures.
2. Identify jobs that require particular skills.
3. Document the training requirements for specific jobs.
4. Produce and maintain training plan documents.
5. Implement only the training defined in training plans.
6. Monitor the effectiveness of training.
7. Maintain records of training.
8. Maintain skill- and activity-based records of training.
9. Review training records periodically to identify retraining needs.
10. Make training records available to onsite managers.
11. Identify equipment used for training purposes.

applicable).

Remember that a quality training program does not need to be elaborate or expensive — it just needs to be thorough, consistent, and well documented. Creating a validated training system will take less time than responding to a warning letter from the FDA, and it will cost less than a quality lapse on the manufacturing floor.

## IMPLEMENTING A TRAINING SYSTEM

To see how your company's current training program measures up, examine all previous gap analysis reports, review the existing SOPs for training, and examine the training documents. Talk with your current trainers and internal auditors to get their input. It can also be very instructive to observe a training program in the classroom and on the shop floor. If you discover shortcomings, put together a plan to bring the program into compliance.

**Identifying Training Needs.** The regulations in 21 CFR 211 require training “in the particular operations that the employee performs and in current good manufacturing practices...as they relate to the employee's function.”<sup>2</sup> Training should not be carried out just because a course is available but to meet specific needs that have been identified. Training requirements may arise from job specifications; process specifications; plans for new products or technologies; new regulations; and analysis of nonconformances, customer complaints, or other problems. For each of these needs, training requirements should be specified for both the individual performing the

process and the process itself, covering such factors as academic qualifications, prior experience, training requirements, and even personal characteristics. Both new training and refresher training needs should be spelled out, as should the method of evaluating the effectiveness of the training.

**Planning for Training.** Once the training requirements have been specified, training plans should be developed. An effective training program may require several plans covering different types and levels of training — from company-wide or division training plans to managerial and professional training to subject matter and manual skills training. Training plans should identify the persons responsible for coordinating the training, the type of training, the organization that will deliver the training, course materials, examination arrangements, the venue, the date, and the attendees. The training plan should include all employees that could affect the quality of products, including management, purchasing, production, validation, auditing, packaging, and (of course) quality control.

**Evaluating Your Progress.** If you want to evaluate your progress, don't wait for a quality lapse or FDA inspection to occur. Put yourself to the test

by raising the kind of training issues you might expect to hear from an FDA inspector: Show me the training requirements for a new employee and the records for a recently hired employee. How frequently do your veteran employees take refresher courses and what are they taught? Show me results of a recent on-the-job training session that demonstrate what the employee learned. Show me your training SOPs. Who is on the distribution list for your training reports and how frequently is it distributed? How did you validate your training database?

When you can answer these types of questions with confidence and produce the requested documentation quickly and completely, you'll know that you have an effective and compliant training system — and well-trained employees.

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195 West Street	The Quays
Waltham, MA 02451-1163	101-105 Oxford Road
USA	Uxbridge
Tel: +1 781 487 9900	Middlesex UB8 1LZ
Fax: +1 781 487 9926	UNITED KINGDOM
	Tel: +44 1895 238000