Defining Your GMP Training Program with a Training Procedure

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FDA and quality auditors expect pharmaceutical manufacturing companies to have standard operating procedures (SOPs) defining their GMP training programs, but it is up to each company to determine what should be included its SOP. Here are information sources to consider and specific topics to include when writing a training program SOP.

Having a standard operating procedure (SOP) that defines your training program is not a specific requirement of the drug CGMP regulations (21 CFR 211.25). However, a training SOP is an expectation of the agency and quality auditors because it is both feasible and valuable: The leading companies in our industry each have one, and it adds to the control of each company's operations, products, and decisions. From a quality and business perspective, a procedure that defines and describes your GMP training activities is a simple yet effective way to communicate and standardize what is expected.

It seems logical, then, to describe what should be considered in a document defining a GMP training program. If your company does not have a training procedure, you can use these as "points to consider"; if your company does have one in place, you can use these as a checklist in evaluating it.

SOURCES FOR CURRENT EXPECTATIONS

What specifically should be included in your GMP training program SOP? Where can you find a list of what regulators want to see in such a document? Unfortunately, there isn't one easy place to look: There is no FDA "guidance to industry" on training.

First, look at the GMP regulations that apply to your company. They might include the regulations of one country or several countries, depending on where your products are marketed. You'll see words and phrases in FDA's CGMP requirements on training that will require definition in your company's procedure, such as "training shall be conducted by *qualified* individuals," and "on a *continuing* basis" (emphasis added). In your procedure, you define what those words mean to your company (consistent with other expectations mentioned below).

Next, look for other applicable regulations that require training. For example, FDA's Electronic Records and Signatures regulation (21 CFR 11) requires that companies using electronic signatures provide training to their personnel on the regulation and associated procedures.

Review recent warning letters and 483s issued by the agency. Warning letters, available online (www.fda.gov), and "observations of noncompliance" show what other companies lack. Consider those issues as you prepare a procedure. Pay special attention to the warning letters because they have been reviewed more thoroughly. The *Gold Sheet* listed "training" as an item in 10 of the 71 warning letters issued in 1999 (1).

Read through the training-related comments in the preamble to the 1979 version of the GMPs

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(items 100 to 111). They give FDA's "original intent" about what the agency expects in a GMP training program and why.

Look at the GMP regulations of other countries and regions — Canada and the European Union, for example — even if your company is not required to comply with them. You'll find that those perspectives can help give you a richer understanding of what training should include. For example, in the Canadian GMPs, a strong rationale for training includes the observation that "without the proper staff with the right attitude and the right training, it is almost impossible to fabricate, package, label, test, or store good quality drugs" (2).

Read through a classic article on GMP training such as "A Systematic Approach to GMP Training," by Ron Tetzlaff, formerly with FDA (3). Some of the terms used are slightly different from what training professionals use today, but the article describes clearly what your program should include.

POINTS TO INCLUDE IN A TRAINING SOP

What should be included in your company's training SOP? Here are some points to consider. The information sources listed above provide additional details that you may include.

Scope of the procedure. Define what personnel or sites are covered by the training procedure. For example, the procedure might have a corporate-wide scope, or it might affect only one site or business unit.

Types of training covered by the procedure. GMPs call for training personnel in the application and interpretation of GMP regulations and in the tasks they perform. Some companies have one procedure that covers both types of training; others have two or more SOPs.

Responsibilities for the training program. The SOP should define what organizational unit(s) is (are) responsible for oversight of training efforts, design and delivery of the training events, and auditing to be sure a training program is working. Responsibilities are frequently split among units. For example, some companies include GMP training as part of the quality assurance (QA) unit and SOP and skill training as part of the individual operations area. Other companies include GMP and skills training as part of the human resources (HR) organization. Use caution; some HR groups are not sensitive enough to the special compliance issues that are part of GMP training: It is not just another "soft skill" topic, a "nice-to-know" course, or one that a generalist can teach.

Who is to be trained. In this part of your procedure, identify the general audiences for training. This includes operations, maintenance, lab, and technical staff; it also includes management (read 21 CFR 211.25b), contract, temporary, and consulting personnel. As I work with drug and biopharmaceutical managers, I encourage them to give some GMP training to everyone. Because GMPs are product-critical, everyone in an organization needs to have some "GMP literacy." As you consider audiences for training, do not forget senior- and executive-level management who make GMP-related decisions.

Temporary (temps) and contract personnel present a particular training challenge. Organizations like using them for flexibility and to keep head counts low. That doesn't excuse a company from the GMP SOP training requirements. One company that made extensive use of temps was told by local FDA investigators that FDA would review temp and contractor training in future inspections.

When training is conducted. GMPs require that training be ongoing. Most companies conduct formal GMP training or reinforcement training at least annually; some do it twice a year; a few do it quarterly. Training on specific GMP-related skills (such as conducting root-cause analysis) and on new, revised, and unchanged procedures should be considered here as well. (In an upcoming article, I will discuss frequency of procedure training.) Be realistic as you set training intervals so you can actually accomplish what is defined.

Quality unit involvement. The quality control (QC) or "quality assurance" (QA) unit should approve various elements of your training program. QA review and approval of GMP-related training courses are particularly important. QA approval should indicate that the courses are complete and accurate, covering topics and using examples that are relevant and meaningful to the learners. The quality unit also should review and approve GMP-training curricula for job functions or positions.

Although the points listed above are consistently adopted as industry practice, the approval of SOP training varies considerably. It is easy to say that QA should review the training outline for each course (for each procedure), but

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what real value does QA add if it is asked to approve 1,000–1,500 SOP courses? What does the typical QA representative know about teaching a cleaning procedure for a ribbon blender? In some situations, QA "approval" is just a rubber stamp, an act that looks good but gives a false sense of assurance. An alternative is for QA to approve the "templates" or standard outlines for training (to be discussed in a future article) and place a high emphasis on the review and approval of instructor qualifications.

Learning plans and curricula. A learning plan or curriculum for a position lists the instructions that person needs and the recommended sequence and time points for each event. Some companies have integrated learning plans that cover more than GMP topics, such as worker health and safety, organizational development, and so on. The list of procedures, protocols, and methods used is also part of a person's learning plan. Learning plans should be developed for everyone in a GMP organization, including all levels of management. The quality unit should review and approve the learning plan for each job function. Learning plans become the "specifications" for training. Periodically, they need to be compared against the training records for each person to ensure that the prescribed training is taking place.

Development process. Many companies use a standardized approach to developing training courses and events, which is called instructional systems design (ISD). The ISD model includes analysis, design, development, implementation, and evaluation (sometimes referred to as ADDIE) (4). To ensure course integrity and consistency, some companies require that such an approach be used.

Maintenance of training materials. FDA and regulatory agency expectations regarding GMP and regulatory compliance change over time. An SOP should include a provision for periodic review and updating of training courses and events. All changes should be approved by the quality unit before being implemented. The plan also should consider the impact of new content on those who have already taken the course; alternatives to retaking the full course may be adequate.

Retention of training materials. An official copy of instructional materials (such as course outline, worksheets, and instructor's notes) should be retained. Your procedure should define where such materials are filed. Regulatory investigators rarely ask to see course outlines; such materials are more valuable as a record of what was actually taught. In deciding how long to keep them, you could do a complex calculation (for example, the expiration date plus one year of the last lot made by people who were trained using that material), but a more practical solution is to keep the materials (and approvals) of the course currently being used along with the version previous to it.

Qualification of instructors. GMPs require that instructors be qualified; in your training SOP, you have a chance to define what that means. One way is to establish minimum instructor requirements, such as successful completion of basic and advanced GMP training, and communication skills such as successful completion of a presentation skills workshop. Then for each course, define what additional knowledge or skills the instructor needs. For example, an instructor of a course in basic GMP and quality auditing should have experience as an auditor.

Sometimes it is difficult to find good trainers who also have solid experience or knowledge in a particular technical area. For example, I've seen experts in computer validation who are competent in developing and executing protocols but are noticeably uncomfortable leading a class. That is an excellent opportunity for co-teaching: an experienced instructor helping to lead the formal sections of the course and the expert serving as a resource to relate experiences and answer questions. If a co-teaching approach is used, both people should be qualified as a team, and that should be provided for in your training SOP. The quality unit should review and approve potential instructors.

Scheduling and administration of training events are time-consuming tasks essential to the success of a training department. Different approaches used by companies include an assignment approach ("you will attend on this date and time") or providing learners (or their supervisors) with a set of dates they can select from. Some training management systems and networked meeting scheduling tools help with this task. The method(s) used and responsibilities should be defined in the SOP.

Documentation of participation in training events. Several elements figure into documenting when someone completes a training course. For leader-led sessions, minimum information is a sign-in sheet with the person's name, signature, name and number of the course, date of the session, and the instructor's name and signature. The participant's signature attests to his or her attending the complete session; the instructor's signature attests that the program was given and that the people listed did attend.

Many companies enter the attendance list into a training management system (for example, Plateau, from Plateau Systems, Ltd., Fairfax, VA; or Training Tracker, Interpharm Press, Englewood, CO). Your SOP should define how this is done, including verifying the transcription, retaining the sign-in sheets, and controlling the system.

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Some e-learning courseware automatically feeds completion and testing information into a training management system. If such software is used, it also should be described in the procedure. If testing scores or pass–fail assessments are collected, it is useful to include them in the training management system.

Attendance in outside training and educational events (such as conferences and technical meetings) also should be documented because it contributes to a person's "education, training, and experience." Copies of certificates, continuing educational units (CEUs), and program outlines or mailers are useful records to retain. Some electronic training management systems have provisions for documenting outside events.

Your procedure should define where such information is kept (preferably not as part of the person's confidential personnel files) and how long it should be retained (typically several years beyond the last date of the individual's employment). Your training procedure also should consider keeping records on temporary and contract personnel who must meet GMP training expectations. Training management systems often are tied into a company's personnel and payroll database, which does not include temporary or contract people.

Learner assessments. Your company's use of testing or assessment is described in this part of the training procedure, including the types of assessment used (such as pen and paper, "orals," computer-based, or performance-based). A particularly important element is determining what constitutes passing and what happens when an employee does not pass a test. You do not want to create the awkward situation of a person independently performing a GMP task on which he or she has been assessed and failed. Consideration also must be given to other legal issues of testing on the job if it in any way affects a person's salary or position.

Program evaluation. Virtually all drug companies use participant feedback forms to collect subjective information from the attendees of at least some of their training events. Your SOP would state when feedback forms are appropriate and how the data are to be collected and summarized for the instructor and various members of management.

Reports to management. Management at all levels should be kept informed about training activities. Summary data can include the number of people attending programs, percentages of those who have completed particular courses, people who are significantly behind in meeting their training plans, and assessment scores. If people are not getting trained in a timely way, management may find that production demands are impinging on time available for training.

KEEP IT PRACTICAL

Your training procedure needs to be complete, but don't burden it with unnecessary and impractical details. You want the procedure to define and standardize your GMP-related training activities so you can enable your personnel — at all levels — to make decisions and take actions that contribute to products that are safe, identified, of the correct strength and purity, and of high quality.

REFERENCES
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