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## A Comprehensive Approach to Compliance Training in a Pharmaceutical Manufacturing Facility

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*The Road to Performance Excellence*

# A Comprehensive Approach to Compliance Training in a Pharmaceutical Manufacturing Facility

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## Introduction

Pharmaceutical companies today are challenged to produce quality products, contain costs, improve efficiency, and speed new product introductions. Ensuring that personnel have the skills and knowledge necessary to perform their jobs safely and efficiently is critical to meeting these challenges. Industry regulations indicate that the most important and potentially most hazardous factor in the manufacture of medicines is the human operator (Sharp, p. 37). Success in developing critical skills and knowledge is related to a training effort that is an integral part of GMP principles of quality assurance such as change control, validation, and documentation.

The Code of Federal Regulations 211.25 under Personal Qualification mandates that:

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. Training shall be in the particular operations that the employee performs and in current good manufacturing practices (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. 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.

(b) Each person responsible for supervising the manufacture, processing, packing, or holding of a drug product shall have the education, training, and experience, or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess.

(c) There shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug product.

According to John W. Levchuk, then of the FDA, "The FDA has not published a guideline establishing acceptable procedures for personnel training, nor is a guideline being planned." Neither has the FDA specified strict training requirements ("Training for GMPs," *Journal of Parenteral Science and Technology*, Vol. 45, 1991). In the absence of firm guidelines for training, many in the industry have interpreted FDA commentary and audit results as supporting a competency-based approach to training, with validated and reliable training programs that produce measurable performance outcomes. Some FDA investigators have cited facilities for lacking competency-based approach. Work responsibilities and tasks are specified in standard operating

procedures, guidelines, batch records, employee directives and protocol.

Training must ensure that all employees know of the existence of these documents, how to access them, and how they are used to direct work. Further, they must demonstrate that they have read and understand these documents and can perform work as directed by them. Managers are beginning to see training as a critical component in achieving improved performance and compliance with regulations, but may wonder how exactly to proceed (Model).

The following article discusses a comprehensive approach to training in a pharmaceutical manufacturing facility through developing a training plan. The key elements of a successful training effort are identified and discussed in a recommended order of development to provide those responsible for training with guidelines to direct their efforts.

## Decide to Develop a Training Plan

Many organizations have a sense of what they want their training to look like. Yet few have a well-defined, written training plan to help them get there. A training plan is a roadmap that guides and integrates the training process throughout the facility. This plan helps ensure a facility accomplishes its goals consistently, according to its standards of quality, production, cost, and safety. The plan should carry the full weight and authority of other corporate directives with the highest levels of management support for training as an essential component in the manufacture of safe and effective healthcare products.

The first step, then, is to decide to develop a training plan that will do the following:

- define line management accountability
- define training roles, responsibilities
- include quality oversight of training
- set out a systematic approach to training
- describe the implementation schedule
- delineate pathways for personnel qualification
- define other key terms and elements related to training at a site

Each department should also develop its own training plan, including the training needed to qualify personnel for all job functions. This departmental plan should provide a schedule of training and retraining to ensure the availability of a sufficient number of qualified personnel to perform all job functions at all times.

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## Formulate a Training Philosophy

Once the decision is made to develop a training plan, those involved need to formulate a training philosophy. Most organizations have developed philosophies around production, quality, cost, safety, and other aspects of their operation. Ask an employee what the company's philosophy is on meeting production quotas, and he or she will probably sum it up in a few words. But how many organizations have developed a training philosophy? The answer is very few.

A training philosophy that acknowledges training as a critical component in achieving corporate business objectives is a key element in establishing the credibility of training in an organization. It tells employees, suppliers, customers, and other stakeholders that an organization is committed to ensuring its people have the skills and knowledge needed to compete in an increasingly competitive environment. A training philosophy should be articulated not only to meet regulatory requirements but because properly trained personnel contribute to the quality of the operation and financial success of the company.

## Develop a Training Mission Statement and SOP

The training philosophy provides the basis for the training mission statement. The mission statement identifies the overall goals of organizational training. It emphasizes the importance of establishing personnel standards of performance and positions training as critical to quality outcomes. Representatives from every department should participate in drafting a company training mission statement to ensure it reflects their interests.

Next is the development of a corporate training policy, specifying the approach to take in implementing the training process. Once this is done, each department should develop its own mission statement and training SOP.

Once the training philosophy, mission statement, policy and SOP are developed, they need to be communicated to all stakeholders to solicit feedback and support. The communication should focus on the direction the company is taking and the role stakeholders will play in ensuring training is carried out effectively in the organization. A clearly worded philosophy, mission statement, and SOP set the groundwork for building a plan that integrates training into all areas of personnel development.

## Identify Personnel Involved in Training

The training plan must define terms and identify roles and responsibilities for designing, developing, implementing, evaluating, and recording training activities. Our experience has shown that training is most effective when training administration is a corporate function, setting direction with full departmental support; when senior operators and supervisors serve as subject matter experts and trainers; and when training programs are developed by personnel with backgrounds in instructional system design.

Roles and responsibilities should be defined in the plan as follows. Depending upon the size of the facility, some of the roles can be combined.

### *Training and Development Manager (TDM)*

Since the goal of training is to ensure that personnel are capable of performing their jobs to produce consistent, quality products, the training function must support all other functions and be supported by them. The TDM must have lines of communication with all other functions including quality, safety, production, information systems, laboratory, and so on. Although many organizations agree on this in principle, the practice is likely to be different.

The TDM should direct, monitor, and build support for the training effort throughout the organization. The position should meet regularly with site management to review the training plan of action, progress to date, and ensure the training effort supports current business and compliance goals. He/she will also direct Training Coordinators (TCs) and assist in communicating and developing training plans and outcome assessments for the departments to ensure they are implemented effectively.

This function should extend to departmental training to ensure that systems exist in each department to meet specific training requirements. The TDM should develop guidelines to be followed by each department for complying with the corporate training policy. Guidelines will identify instructional developers, trainers and subject matter experts (SMEs), as well as persons responsible for scheduling and recording participation in training.

The TDM should be responsible for at least the following:

- Developing, maintaining, and administering the facility training plan.
- With Training Coordinators, identifying training needs for each department to support site business objectives and compliance efforts.
- With Training Coordinators, developing training plans and schedules to meet organizational training needs.
- With Site Management, reviewing training plans and schedules to ensure support for training from all involved areas, including QA, Operations, and IS.
- With Training Coordinators, establishing assessments to measure training effectiveness.
- Directing and monitoring Training Coordinators in executing training plans.
- Managing the training recordkeeping system.

### *Training Coordinators (TCs)*

Training Coordinators report to the TM. They are responsible for communicating with departmental management and Instructional Designers (IDs) to identify and develop training programs that support the plans set out by the TM with site management approval. They are also responsible for building support within the departments for executing training plans.

Training Coordinators are responsible for at least the following:

- Consulting with department management to identify training needs.
- Communicating departmental training needs and progress of training to the TM.
- Developing departmental training plans and specifying

training programs as directed by the TM and department management.

Directing IDs in developing training programs, evaluations, and assessments.

#### *Instructional Designers (IDs)*

The IDs develop training programs as directed by the TC. IDs serve as a liaison between the TC, TDM, departmental supervisors, and Subject Matter Experts (SMEs).

IDs are responsible for at least the following:

Working with departmental management to identify appropriate SMEs for training projects.

As directed by TC, developing competency-based training programs according to established principles of Instructional Systems Design.

With the TC, developing evaluations and assessment measures.

With the TC, developing Train-the-Trainer programs for Department Trainers (DTs).

#### *Department Trainers (DTs)*

The Department Trainers should be selected for their skill and interest in training and their ability to perform their jobs.

In their role as Department Trainers, they are responsible for at least the following:

- Working with IDs to design and develop training programs.
- Training new hires and incumbents on job-specific skills and regulatory issues.

### **Establish a Training Program Design Model**

Employees need job-specific training in environment, safety, and GMP regulations along with training in technical skills and SOPS. The training plan should ensure a systematic approach to competency-based training for all programs and materials.

#### *Training Program Design Model*

Effective competency-based training is the result of applying a systematic process to training program design. This process involves following certain well-defined steps to develop a training program that meets both the trainee's and the organization's needs.

The most reliable method of training and qualifying people in the safe and effective performance of work is using an instructional system design model. One instructional system design model, the Training Program Design Model (TPDM) developed by Gallup and Griffin, is shown in Figure 1.

#### *Validating the Training Process*

Training is considered valid when it accurately reflects the competencies required to do a job and when trainees can demonstrate those competencies as a result of the training. The way to ensure this is to follow an instructional design module that ties the task analysis to training program objectives, materials, and evaluations.

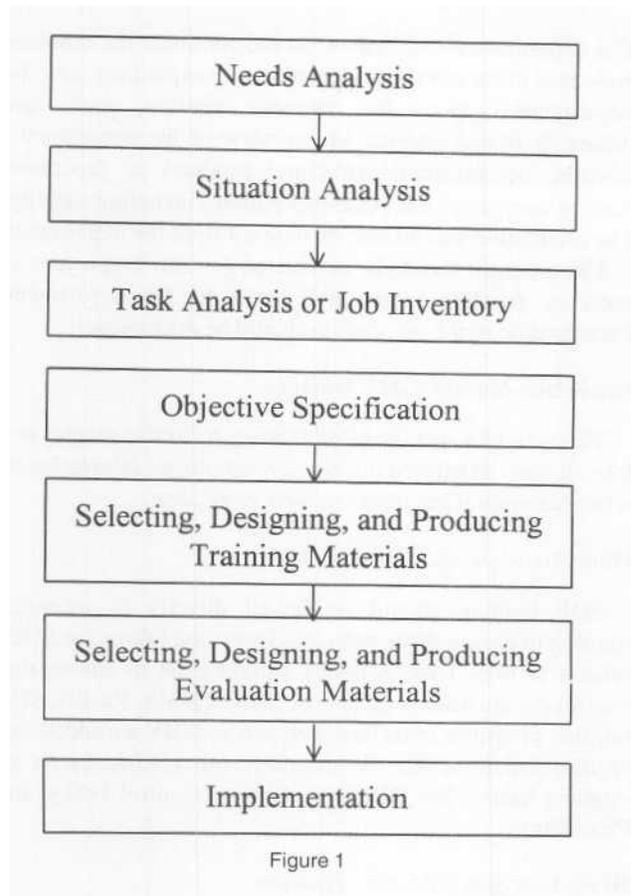


Figure 1

A complete discussion of competency-based training program design will appear in the next issue of this journal.

### **Develop and Conduct Technical Training Programs**

To ensure workers understand and are able to perform competently at their jobs, the following training programs are recommended for employees of healthcare manufacturing facilities.

#### *New Employee Orientation Program*

The new employee orientation program is an organization's first opportunity to introduce employees to its mission, goals, and values, including an overview of the GMPs, and SOPS that apply to the facility. It should stress the history and rationale for GMPs, especially documentation, and the necessity for SOPS. New employees should participate in an orientation to the company as soon as possible upon hiring. The orientation may include a tour of the facility and other general training applicable to all new hires.

An orientation program for each department should be developed and implemented. The program should cover at least the following topics:

- Department overview and tour
- Department mission
- Organization and structure
- Products and processes
- Personnel policies
- Safety requirements

The departmental orientation should reinforce the message presented in the company orientation by explaining how the department supports the corporate mission, goals, and values. It should provide an overview of the department's mission, organizational structure, products or processes, rules of operation, and personnel policies including training. The orientation should also include a tour of the department.

The program should be conducted for new employees as soon as possible after they report to the department. Participation in the orientation should be documented.

#### *Work-Area-Specific GMP Training*

This provides specific GMP training related to employees' jobs. It may be offered during new-employee orientation or when the employees report to their work area.

#### *Work-Area-Specific SOP Training*

SOP training should be linked directly to technical training to ensure that employees know and follow the SOPs related to their jobs. A policy should exist to ensure that employees are trained on new or revised SOPs. Finally, SOP training programs must be developed as SOPs are added and revised and reviewed for accuracy and consistency on an ongoing basis. (See Develop a Change Control Policy and Procedure.)

#### *Work-Area-Specific Safety Training*

Employees must know the safety, environmental, and industrial hygiene requirements of the facility and the specific safety requirements in their work areas or jobs. Certain safety training is mandated by Occupational Safety and Health Administration (OSHA) and must be conducted for a facility to be in compliance, and should be part of competency-based technical skill training.

#### *Current Good Manufacturing Practices (cGMPs)*

Each department should conduct ongoing cGMP awareness training to ensure employees follow cGMP regulations. It should explain how specific work area changes might affect procedures related to cGMPs. The cGMP training program should include objective evaluations. It should be conducted with a degree of frequency that demonstrates the importance of a GMP quality system and supports compliance with GMP regulations.

#### *Department and Job-Specific Technical Skill Training*

Competency-based technical skill training provides employees with the knowledge and skills needed to perform their jobs. It should ensure that employees are qualified to do their jobs and that knowledge and skills are upgraded as needed.

These programs should have structured lesson plans, pre- and post-tests, measurable performance objectives, and evaluation instruments to measure knowledge and skills (competencies).

These programs should be presented by a qualified trainer and include both classroom and on-the-job training.

### *Develop and Conduct Supervisor/Management Training Programs*

New supervisors, managers, and team leaders need the knowledge and technical skills to lead and train the personnel under their direction. Periodic training in management and technical skills helps maintain the credibility and effectiveness of managers and supervisors.

### **Establish Personnel Qualification Pathways**

Good business practice, as well as 21 CFR 211.25, mandates that each employee possess the education, training, and experience to enable him or her to perform assigned functions in a safe and effective manner. The training plan must contain a policy allowing personnel to demonstrate their qualifications. This should cover training and supervisory personnel, as well as those involved directly with operations.

A qualification pathway should include the steps necessary to qualify and re-qualify employees in job functions; it should also include related SOPs, GMPs, and safety training. The steps to personnel qualification should identify all training courses and qualifying exercises necessary to complete the pathway and trainer qualification requirements. Qualifying operators means ensuring that they produce quality outcomes; therefore these evaluations must include demonstrating competence.

### **Establish Failure Response**

This element of the training plan should describe a procedure for dealing with personnel who do not pass qualifying evaluations. It should list steps for isolating the cause of the failure and differentiate between discrepancies in training program design and inappropriate candidates for the job. It should include a protocol for dealing with test failure.

### **Develop a Change Control Policy and Procedure**

A change control policy helps ensure personnel are prepared to carry out new and revised policies and procedures effectively. An effective change control policy should include directions for regular reviews and revision of training materials and training procedures as well as scheduling training for new and incumbent employees on all pertinent SOP'S. The plan must also include a procedure for responding to developments in operations, processes, and documentation.

### **Develop an Implementation Schedule**

The plan must include a schedule to ensure that training begins at initial employment and is ongoing. The schedule should include time frames for completing job qualification training, and address training required for changes in process and new or increased performance expectations.

## Design Recordkeeping System

The plan should describe the approved approach to maintaining training records for all personnel. Details of the recordkeeping system must include:

- 1) Training requirements for each job or function including: GMP, SOP, Safety, Environmental, and Job Skills
- 2) Training activity and results for each worker (employee as well as contract workers)
- 3) Ongoing training requirements for all personnel including dates by which training should be completed

- 4) An approved approach for maintaining and easily retrieving records for all personnel

## Summary

A healthcare manufacturer seeking to ensure that dollars invested in training return value in performance improvements will want to consider each of these elements and develop a written training plan. Companies who have created a training plan to meet their business objectives are already reaping benefits of reduced turnover and increased productivity.



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