



AMERICAN JOURNAL OF PHARMTECH RESEARCH

Journal home page: <http://www.ajptr.com/>

Training- A Key Factor to Deliver Quality and Regulatory Compliance in Pharmaceutical Industry

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ABSTRACT

Training is the attainment of knowledge, skills, and competencies as an outcome of the teaching of vocational or practical skills and knowledge that relate to specific useful competencies. Training in a regulated environment is a continuous process that should be adaptable from a single business unit to an entire organization. Training entails providing, developing, and reconfirming knowledge, skills and core competencies to meet business requirements. This paper will create a framework by which specific requirements for setting up and maintaining an effective and complaint training program are explained by providing overview of vital training topics.

Keywords: Personnel Training, Personnel Qualification, Compliance.

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Received 18 March 2015, Accepted 26 March 2015

Please cite this article as: Moin A *et al.*, Training- A Key Factor to Deliver Quality and Regulatory Compliance in Pharmaceutical Industry. American Journal of PharmTech Research 2015.

INTRODUCTION

Training is the attainment of information, skills, and competencies as an outcome of the teaching of vocational or practical skills and knowledge that relate to specific useful competencies. Training has precise goals of improving one's performance. The adoption of quality management practices has long been associated with an increase in the provision of employee training. The originators of quality exercise in manufacturing highlighted the importance of employee development, education and training for the development of quality performance and firms seeking to implement quality management have steadily found it necessary to improve their effort. Firms chasing a quality strategy have found it necessary to capitalize in human capital enhancing activities in productivity and customer satisfaction¹. Employees require some training in order to manage the enlargement of their work role following the delegation of responsibilities for quality. They also require some training in non-technical skills to be able to participate in quality improvement activities. Training for quality management requires the development of specific skills to support quality management practices. The success of the quality strategies adopted by the firm and the effectiveness of the quality management system adopted within the firm, are reliant upon the supply of appropriately skilled labour². Some studies have suggested that employee training directly enhances firm performance by raising the general level of abilities. As workforces become greatly motivated and more highly skilled, so their task performance improves and organizational effectiveness is directly enhanced. Employee training may, in this view, can be seen as discrete or stand-alone management practice, one that directly enhances the human capital of the firm and so directly leads to performance improvements³. In a complex and highly regulated environment like pharmaceutical industry, understanding the components of a compliant training program may prove overwhelming and at times insurmountable. This paper will describe employee's and regulatory expectations and create a framework by which specific requirements for setting up and maintaining an effective and complaint training program are explained by providing overview of vital training modes. FDA's mandate for training requirements are codified in 21 CFR 211.25 (a-c), current Good Manufacturing Practices (cGMP) in manufacturing, processing, packing, or holding of drugs and finished pharmaceuticals and 21 CFR 820.25, quality management system regulation as follows:

21 CFR 211.25 – Personnel Qualifications^{4,5}

- a) Each person engaged in 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'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.

Subpart B – Quality System Requirements

21 CFR 820.25- Personnel⁶

- a) General. Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assurance that all activities required by this part are correctly performed.
- b) Training. Each Manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented.
 1. As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific job.
 2. Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.

Regulatory requirements and guidance relating to training to Active Pharmaceutical Ingredients manufacturers, Q7A Good Manufacturing Practice Guidance for active pharmaceutical ingredients, follows:

Personnel

A. Personnel Qualifications⁷

- There should be adequate number of personnel qualified by appropriate education, training, and/or experience to perform and supervise the manufacture of intermediates and APIs.
- The responsibilities of all personnel engaged in the manufacture of intermediates and APIs should be specified in writing.
- Training should be regularly conducted by qualified individuals and should cover particular operations that the employee performs and Good Manufacturing Practices (GMP) as it

relates to the employee's functions. Records of training should be retained. Training should be periodically assessed.



Figure 1: Training process

Training in a regulated environment is a continuous process (as shown in figure 1) that should be adaptable from a single business unit to an entire organization. Training entails providing, developing, and reconfirming knowledge, skills and core competencies to meet business requirements. A formalized training program provide the tools and resources for ensuring employees are qualified and fully trained in the particular operations they perform.

Training- Pharmaceutical Industry Expectations

A company generally spends a lot of money and time on training their employees. They don't do it for fun although training should be fun. They do it in the hope that it achieves the following objectives

- Information is imparted to the employee.
- Employees become more knowledgeable.
- Employees understand what GMP is and its relevance.
- Employees understand why they have to follow GMP.
- Employees know specific requirements of GMP.

- This extra knowledge is used and applied to their particular jobs.
- Employees can perform required procedures.
- Employees understand more about the products handled.
- Employees understand why they do what they do.
- Employees understand the risks of getting it wrong.
- Employees get better at their jobs.
- Fewer mistakes are made.
- Less waste.
- Fewer complaints and recalls.
- Their profits go up.
- It satisfies legal requirements.
- The employee performs better

Training-Regulatory Expectations

Inspectors from Regulatory Authorities have a duty to check that a company complies with the legal GMP requirements and to assess their level of compliance and potential risks to patients.

When reviewing a company training system they expect to see that:

- The company follows legal GMP requirements.
- The company trains and educates their employees in GMP when recruited to the company.
- The company provides hygiene training for those Involved in manufacture and packaging.
- The company provides on going continuing training.
- Employees are trained in new requirements and expectations.
- People know how to perform their specific tasks.
- The company can prove that they have done the training.
- The company maintains the training records as evidence.

Training-Employee Expectations

It is a statement of fact that every employee does not necessarily need the same training, but all employees need training relevant to their job when they initially join the company and on an ongoing basis.

Every employee will have the following expectations from any Induction training programme:

- To learn the structure of the organization
- To appreciate the intentions and purpose of the organization
- To know who to go to for help and advice on various issues

- To realize their exact role within the organization
- To understand terms and conditions of employment
- To be informed of health and safety expectations
- To know what is expected from them on a day to day basis
- To be given specific help and guidance on how to perform their duties
- To understand their responsibilities
- To know the boundaries within which they work
- To understand how their performance will be assessed and by whom
- To understand any rules that they must follow, e.g. GMP, and why

If the employee's job can impact in any way on the quality of the pharmaceutical products, then even the above basic induction training is necessary, which is all part of the requirements of a quality System. For those more directly involved in the pharmaceutical operations their expectations from the company will be to be kept up to date with new GMP requirements and expectations. Ongoing GMP training is a must as procedures change, and a Quality System requires a pharmaceutical company to continually improve⁸. Part and parcel to designing a compliant and effective training program is crafting standard operating procedures that will define the scope, approach, implementation, and documentation requirements necessary for creating employee learning plans, courseware, conducting training, and documenting training activities in compliance with current good manufacturing regulations. The training SOPs will govern the various responsibilities for administering and carrying out the training program and should be updated at a minimum of every two years. The following are modes to address in the training program. These will serve as guideposts for ensuring employees are adequately trained to perform their respective job functions.

Modes of Training¹

Induction training

It is expected that pharmaceutical, biotech, and device companies typically identify core new hire training that employees must complete prior to starting their jobs. Induction training typically entails basic safety, cGMP, company orientation, department specific requirements, and new employee set up procedures.

Self-Study

A method of training that allows the trainee to complete a course of study and demonstrate competence without having a trainer present. This method of training is used primarily by employees trained on SOPs or by new employees when they read the company procedures.

Classroom training

The trainings which are arranged in classroom for a group of employees. Classroom trainings are conducted based on training calendars. Heads of respective department will identify trainees and topics and schedule them. These trainings are normally delivered by qualified trainers. In order to assess the understanding of the trainees, written evaluation is done after completion of the training. Questionnaires are prepared based on level and approved. Trainees are evaluated by asking them to answer questionnaires for which acceptance criteria is already set. Training feedback is also taken by the trainees by using approved feedback forms. Feedback is taken to evaluate the trainer's efficiency and understanding of the training.

Retraining

Retraining is typically identified based upon feedback from periodic management reviews, trends, or corrective and preventive action commitment of a deviation or an incident. For retraining due to an event, the company must set a deadline by which retraining is completed. This is a common area by regulations during inspections: the "reportedly trained" employee. If an employee cannot demonstrate mastery of their particular job, the regulatory inspections would likely consider this employee as lacking adequate training as a primary cause.

On the job training

Training imparted to an employee by demonstrating the actual activity/task. Like Classroom trainings on the job trainings are also conducted as per the calendars. Training topics are identified based on QMS trends/Skill development/department requirements. Criticality of the process and Critical control points are focused more to identify critical activities that needs demonstration to impart training. Head of the department or subject matter experts will deliver on the job trainings.

Refresher trainings

Trainings which are organized at periodic intervals to fulfil all the applicable training requirements of the employees which are identified and approved by the department heads.

Event Trainings

Any training is intended to fulfil the training requirements arising out of events related to QMS or cGMP are referred to as event triggered trainings or event trainings. An employee shall be subjected to event triggered/ need based training under the following circumstances but not limited to:

- An approved change control
- Change in regulatory requirements
- Market complaints
- Corrective and preventive actions
- Audit observations
- Out of specifications
- Deviations
- Introduction of new product/equipment/process
- Revision of SOP or introduction of new SOP
- Other training needs which arise from quality systems review (need based training)

External Trainings

External trainings are the ones that are conducted internally or externally with the help of trainers from other training organizations. These are also called as third party trainings. External trainings are organized based on the need.

Contract employee trainings

Just like permanent employees contract employees also need fundamental understanding of their respective operations. They are trained on the topics such as but not limited to good manufacturing practices, entry and exit procedures, dos and don'ts in the premises, personal health and hygienic practices, and good grooming practices.

GxP Trainings

A category of trainings which elaborates and explains the regulations/ regulatory guidelines prescribed by the regulatory bodies. This includes the GxP trainings such as GMP, GDP, GLP, GEP etc.^{9, 10}

These trainings are conducted once in a year.

- GMP- Good Manufacturing Practices
- GDP- Good Documentation Practices
- GEP- Good Engineering Practices
- GCP- Good Clinical Practices
- GLP- Good Laboratory Practices
- GPP- Good Pharmacovigilance Practices

Safety Training

Training imparted to employee about basic safety procedures and policies.

Qualification¹¹

Certain critical operations in the manufacturing of pharmaceutical products need thorough understanding of tasks and some amount of assurance that he or she will perform it as intended. Qualification is performed for the key tasks identified. Employees require qualification are identified and trained on relevant procedures and are evaluated for the same. After evaluation of the understanding of the employee is subjected to qualification. Employee under qualification is asked to perform the activity under supervision of subject matter experts who also evaluates the performances over standard procedure. Based on the observations employee is qualified. Qualification process is shown in figure 2.¹²

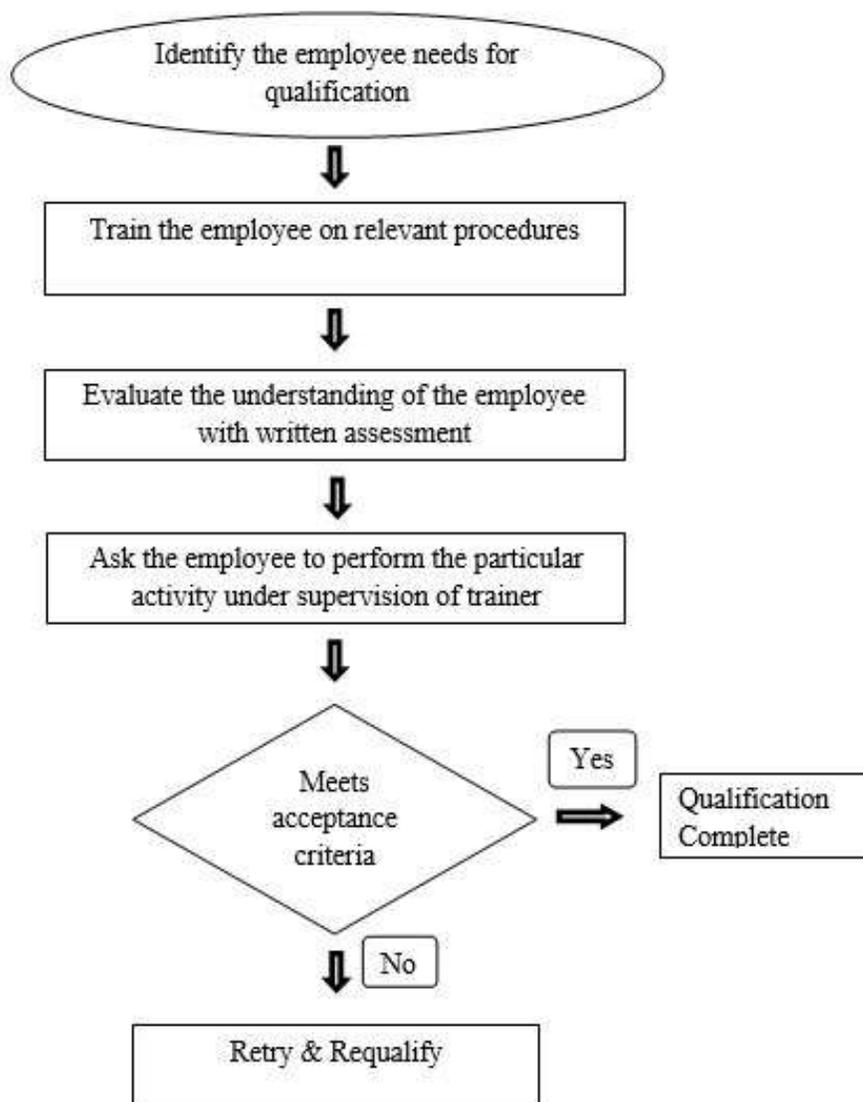


Figure 2: Qualification process

Few examples include

- Gowning Qualification

- Environmental Monitoring Qualification
- Analyst Qualification
- Line Clearance Qualification
- Qualification For Sampling Of Raw Materials
- Batch Record Review Qualification

Assessment of Training

Trainings are evaluated for the following reasons:

- To identify weakness in programme or approach
- To Improve future training course
- To Identify barriers to training

Written assessment may consist following type of questions

- Multiple choice question
- Practical assessments for specific tasks
- One to one observations
- True or false statements
- Closed questions
- True or false statements
- Closed questions (numbered assessments)
- Open structured questions (yes/no with comments)

Documentation¹³

In conducting a rapid review of FDA warning letters, one can understand that the agency is cracking down on companies that cannot demonstrate training occurred, in part due to lack of proper documentation. This is a serious matter since failure to train is a chief cause of non-compliance according to the FDA. Training must be sufficiently documented to reflect attendance and the specific materials that were utilized and presented during the training session. To demonstrate compliance in terms of documentation, trainees must sign a training record upon completing training sessions, including SOP competency tests (where applicable). Associated training documents should be filed into the electronic and physical training program files. In addition to well-documented training program, it is essential to assure that training records and complete and accurate as per the company's training program SOPs.

CONCLUSION

Training plays vital role in organization development by achieving objectives of the employees as well as objectives of the organization. By training we can enhance the skill of the employees and it helps to reduce the cost and time of the organization. The safety and precautions strategy in the organization can be possible with the aid of training. Training need arises due to advancement in technology, need for refining performance or as part of professional development. Above mentioned training modes may establish a compliant training program which is essential for meeting business and compliance goals, and satisfying consumers with products of consistent quality. Training must be sufficiently documented.

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