

Research Article

Personnel Training for Pharmaceutical Industry

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ABSTRACT

Many of the pharmaceutical industries failed to identify the importance and necessity of quality training programs for their employees which lead to lack of development in the skill levels of employees. They even failed to judge the training level of their employees before assigning them specific responsibilities. This will reduce the quality level of skills as well as final product of the company as in compliance with the various regulations to be followed. Self-efficacy is related to the transfer of learning, knowledge and skills to the employees and is therefore an indicator of training effectiveness. The importance and necessity of evaluation, documentation and assessment of all training programs designed and practised by the industry to meet the guidelines is mentioned. This article mentions about Effective SOP training, cGMP and on the job training where a trainer can judge and plan for retraining for the personnel if necessary. The trainers whom company appoints for training shall be skilful and experienced. It is also crucial to know that ‘why training program fail’ apart from proper guidance and training methods. This article highlights about these failures and how to overcome these obstacles through proper and effective training to yield good results. Thus there is a large scope for research in training field as training itself is a bigger tool to improve the standards of industry.

Keywords: Training Needs, Training Programs, Training Evaluation and Feedback.

INTRODUCTION

The pharmaceutical industry is facing a tremendous changes and challenges nowadays. It has been observed that lack of proficient, talented, capable employees has enforced organization to be innovative in formulating methods to maintain their priceless workforce. To survive in the highly competitive scenario, industry is precised to improve quality, increase productivity, cut down waste and cost and eliminate inefficiency. The modern pharmaceutical industry come of age with the introduction of guidelines laid down by several regulatory bodies that new pharmaceutical product proven to be safe and effective before they can be marketed and sold. The employees of pharma need to be trained in order to meet the challenges of pharma industry. Effective training programs always impart responsibility in all employees to perform their tasks with utmost care and commitment¹. In the healthcare manufacturing industry each employee needs job specific training in technical skills, SOPs, and awareness of the GMP. To satisfy this requirement, companies must adopt a systematic approach to training design, development, and implementation². Training helps the pharmaceutical industry to meet the compliance, consumer safety, product quality and to their development. But many of the pharmaceutical industries failed to identify the importance and necessity of quality training programs for their employees which lead to lack of development in the skill levels of employees as well as final product of the company as in compliance with the various regulations to be followed^{3,4}. Regulatory Agencies around the world has drawn certain Guidelines for Good

Manufacturing Practices (GMP) which highlights the importance of proper training with relevant documentations to be conducted by Pharmaceutical Industries. However, the Guidelines of Regulatory Agencies does not reveal how training process has to be followed and conducted, they give few specific details as to how the training is to be performed; they do not say how it should be done⁵. The FDA has not published a guideline establishing acceptable procedures for personnel training, nor is a guideline being planned. Unfortunately, this lack of guidance may cause some industries to think that training is a simple process. However, for training to be an effective and efficient tool which contributes to performance, so it must be done properly⁶. As per FDA 483 observations, training isn't done well, isn't timely or effective, isn't always meaningful. Individuals working in a GMP environment should be trained on concepts of GMP⁷. Recent warning letters and 483s issued by the agency and “observations of noncompliance” show what companies lack. The Gold Sheet listed “training” as an item in 10 of the 71 warning letters issued. Also while reviewing FDA inspectional observations; the warning letter for training was received at the frequency rate 46. Human errors are also significant factors in almost every quality problem, equipment shutdown or accident in industrial and manufacturing facilities. Thus, this article describes why GMP Training is important and how it can be implemented and evaluated to meet GMP requirements.

DISCUSSION

The effective training module will give scope to learn and understand about the importance of training for personnel in each department to curb the human errors caused by lack of proper training system.

Procedural Overview

Training need identification

Preparation and maintenance of training planner

Training Design/Plan/Model- *Training Requirements, Identify/Select Trainers*

Training programs

Validation of training

Effective implementation of training program

Assessment/Evaluation of training and feedback

Retraining

Periodic review of training program

Training records/ documentation and retention

Training Needs Identification

The first step in training is identification of training needs. Respective HODs shall identify their own training needs periodically. HODs shall identify training needs of personnel working with them based on a Skill Gap Analysis.

Formula: Desired Capabilities minus Existing Capabilities = Training Needs

Department manager /designee including immediate superior shall identify the training need matrix for all employees. It shall be drawn based on following situations but not limited to:

Area of operation /function of the employee/specific skill needs

Responsibility of the employee

Annual employee appraisal process

Discrepancy arising out of internal or regulatory inspections

Change in regulatory guidelines

A new product /equipment/customer introduction to the facility

Feedback from various levels in the organization

Unusual incidents / occurrences

Wherever necessary, other qualitative methods of training need identification shall also be applied with prior authorization from top management team. The qualitative methods could be the use of interviews, questionnaires. This exercise of training need identification shall be jointly done by the department head with a representative of training/personnel department and concerned employee. Training need matrix for the training of personnel on SOP's, technical/non- technical/GXP shall be prepared by the individual manager/designee and approved by respective department heads.

Preparation of Training Planner

Each department shall have a job description and individual training plan for its employees so that the employees obtain the qualitative knowledge, skill and attitude supported with adequate experience necessary to perform the assigned job effectively. The annual training planner shall be prepared and updated by quality assurance department.

Training shall be executed based on the various levels as described below, but not limited to

Level I Operator

Level II Technical Trainees/ non-technical trainees

Level III Analysts/ Senior Analysts

Level IV Team Leaders /Asst Managers/Deputy Managers/Manager/Sr. Manager

Level V Department Heads

Training Design/Plan

When designing a training course, the training Plan identifies the topics to be covered and a training method, such as a presentation, case study, demonstration and other activities that convey information to the trainee.

Selecting the Trainer/s

The selection of trainers is a critical factor for the success of a training program. A satisfactory performance does not qualify a person as a trainer because other skills are needed. Selection criteria are based on individual experience on relevant subject, familiarity with departmental procedure and level of competence in GMP/cGMP at workplace. Trainer shall be identified by concern department head and Quality Assurance department head. Certificate for qualified trainer shall be jointly issued by department head and Quality Assurance department head. Trainer shall be subsequently evaluated by reviewing the Feedback Form on trainer and training program. Trainers must have complete knowledge of the subject, good communication skills, strong desire to meet trainee's needs with a great desire to train. For each training course it is recommended that minimum trainer requirements are established, each trainer attends train the trainer's course. The trainer's qualification has to be documented.

*Training Programs**Training of New Recruits – Orientation and Induction**Phase I – A General Orientation*

This should be given to all new recruits. An Orientation of Staff document is initiated and training shall be given with a view to facilitate entry into the organisation and to acquaint with the systems and procedures as applicable. Phase I training should be carried out during the employee's first day in the company.

Phase II – A Specific Orientation

This training is aimed at new recruits in each area, department or section whose activities take them into production areas or into control laboratories including maintenance and cleaning staff, and for other personnel whose activities could impact on product quality. A brief previous experience shall be filled for the documentation purpose. The induction training shall be carried out in accordance with the schedule specified in Training program during Induction. The details of departmental training imparted shall be recorded by the training coordinator in the Departmental Induction Training Record. Phase II training should also be considered for personnel if they are transferred from one department to another department.

*Work-Specific Area Training**cGMP Training*

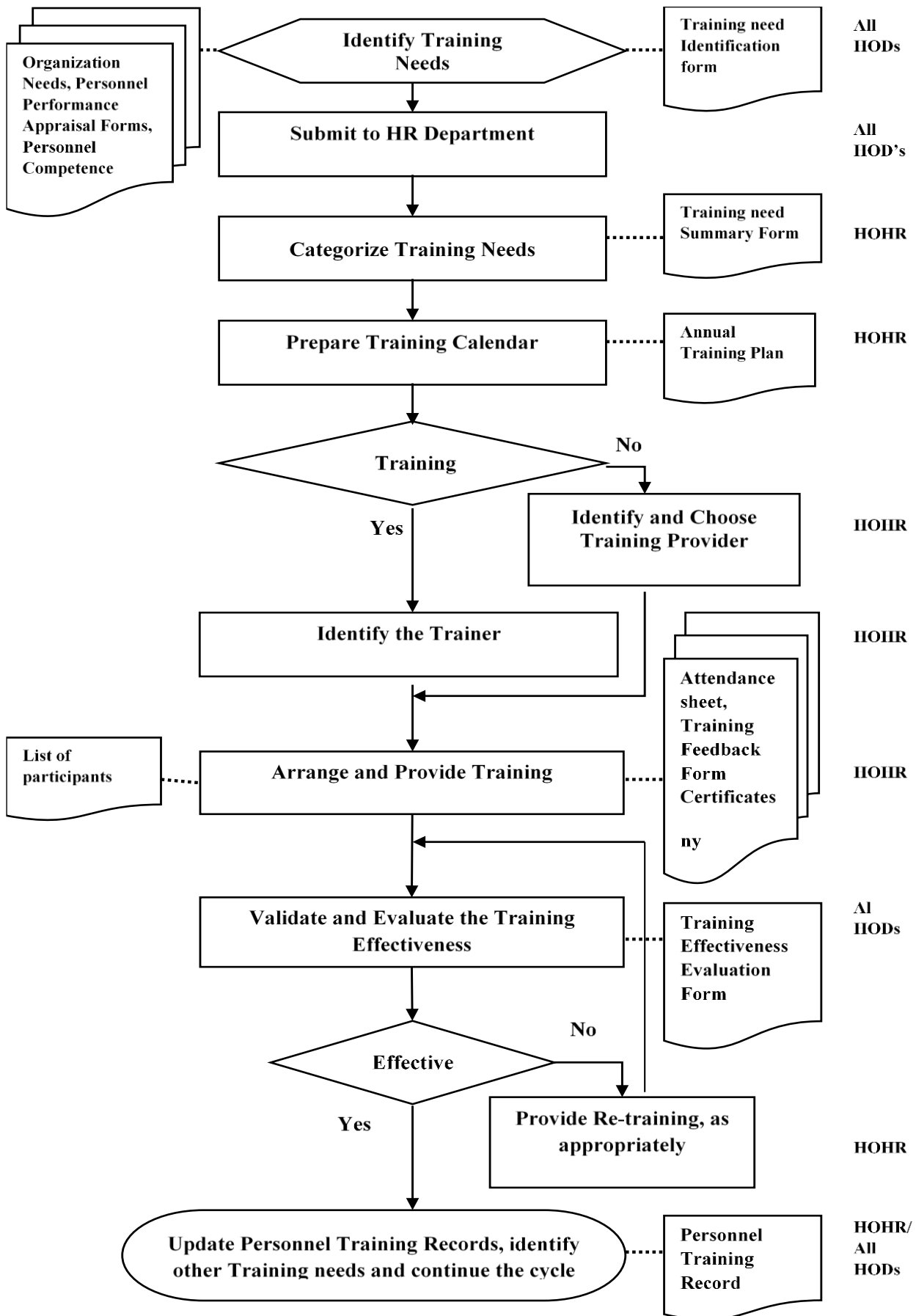


Figure 1: Flowchart for Effective Training

This training must cover topics related to cGMP of regulatory agencies and current industry practices. Training material to be used for cGMP training shall be approved by head Quality Assurance Department Head-Operations. All employees shall undergo GMP training upon joining during induction and thereafter once in a year. After training, the evaluation is done by giving GMP questionnaires.

On-The-Job Training (OJT)

Department head/sectional in charge shall be responsible for conducting OJT and department head/ head quality assurance department shall be responsible for evaluating training performance. On the job training shall be given as per the SOP's to the employees in their respective areas of operation according to the protocols of individual departments. During this period employee shall be trained for usage of equipment, various unit operations, safety norms to be followed, Quality Assurance procedures, general rules and SOP's, validation and calibration procedures, cGMP, preventive maintenance as applicable.

SOP Training

The new employees shall also be trained to applicable and/or necessary standard operating procedures /modules, required to perform their job as per their Job Responsibilities, before they execute the responsibility independently. The concerned department head shall ensure that the employee will not perform his/her work until he gets complete training as per his/her Job Description. Training either new or experienced personnel on new SOPs, can be conducted as follows.

Table 1: Self-Assessment Form

S. No	Questions	Yes	No	Comments
1.	Did I participate in training program today?			
2.	Was the training program effective today?			
3.	Am I learning in the best way?			
4.	Did I understand and remember the contents of training program?			
5.	Do I need to do revision myself?			
6.	Did I understand what are my strength and weakness?			
7.	Did I understand what my targets are?			
8.	Did I understand whether my work is good?			
9.	Do I need to do better to understand my responsibilities?			
10.	Am I satisfied with the training program?			

The supervisor will provide the current copy of the SOP related to the task and allocate time for reading. The supervisor will review the SOP with the trainee and will answer any questions regarding the documents.

The supervisor will show the trainee how to do the task. The trainee will perform the procedure by himself/herself under supervision. The supervisor will review the work in such a way that positive performance will be reinforced. A checklist to evaluate the performance of the trainee can be very helpful.

The trainee will perform the procedure without supervision. When the supervisor is satisfied with the trainee's performance, the supervisor and the trainee will sign the training record. Such training will be recorded and maintained in SOP Training Record

Safety and Hygiene Training

The safety department identifies those who need to have safety training, which may be given individually or to a group of employees in the same or related occupations. The topics approached will be defined according to the existing risks and complexities. These should cover: The knowledge of mechanisms of exposure to the specific risk agent, including toxic chemicals, biohazards and sensitive machineries. The appropriate use of personal protection items, how to proceed in an emergency. A Training Certificate shall be issued to successful employee. Only successful employee shall be allowed to perform his assigned duties and responsibilities independently.

Job-Change Training

Job change training may be organized and accomplished in these ways. Review the employee's training record, Review the training requirements for the new job position, prepare a training plan for the employee based on the analysis of the employee training record v/s the training requirements for the new job; consider the orientation to the department in case of movement to another department.

Training to Contract/ Temporary Employees

This type of training presents a special challenge for most manufacturers because, by their very nature, temporary and contract workers are transient. Temporary employees and contractors whose work takes them into production areas or quality control laboratories and those whose work can impact the quality of the product must be trained. They should be educated and trained robustly to get desired results without any deviations. Training records for these personnel also require special attention and shall be filled.

Managers Training and Supervisors Training

Managers need to be trained in their responsibilities under cGMPs and good laboratory practice (GLPs). It is the responsibility of the supervisor to provide clear direction, to lead by example, to set high standards of performance, to provide feedback (mostly positive), and to ensure adequate resources (especially time).

Trainer's Training

On-the-job and SOP trainers shall be recognized as experts in the area or in the tasks that they perform. They shall also understand the best ways to teach tasks and procedures. Group trainers shall have "presentation skills" to use

various training media, methods and know how to respond to questions and difficult situations.

Crisis Management Training

Signature
Reviewed by
Training Feedback

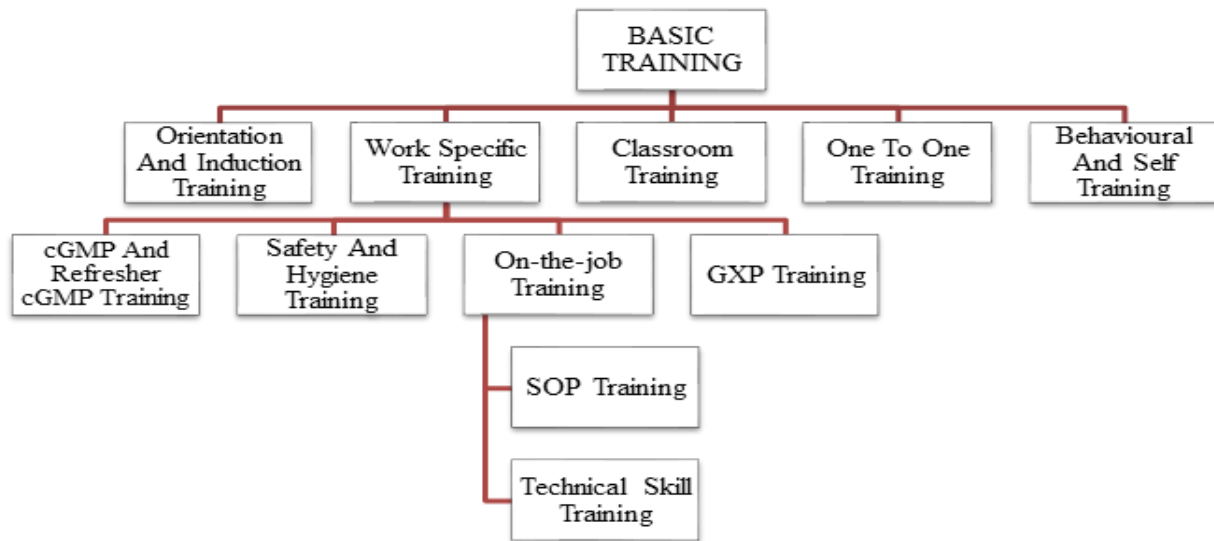


Figure 2: Training Programs - Basic Training

Pharmaceutical companies are highly exposed to critical situations. Manufacturing of drugs and handling of other problems sometimes leads to serious results. However, managing and overcoming of all these require specialization in handling critical issues. Critical management skills can be enhanced and brought into practice by highest level of training. This can help the organization to meet all the possibilities of possible serious crisis in the company. It is given either by an expert or through some training institutions.

Validation of Training

Validation provides assurance that your training program is meeting expected standards. Validation is the certification process that assures trainees have achieved the skills and knowledge training was intended to provide. At the conclusion of a training program, employees should have the skills to move on to the next step in their education or to progress in their job. The system of training shall be audited during self-inspection/internal audits and wherever necessary reviewed during product quality reviews.

Assessment and Evaluation of Training

There are several assessment methods to evaluate knowledge, skills and attitudes, Oral examination, written examination (using paper or computer systems), Simulations (actual or virtual using computers), Performance-based assessment. "Self-assessments" are used frequently in self-study and computer-based courses to give the trainee a chance to evaluate how much they have learned. Self-assessment can be recorded with a form which can be documented for further evaluation. Evaluation should be appropriately graded to ensure that the objectives set for the training are met and they form a basis for the review and next training activity.

Name

Designation

Department

A training program can be evaluated on the basis of feedback collected from the attendees regarding the training pattern, trainers, topics, facilities provided, materials provided etc. Combination of questionnaire and feedback form will lead to know and understand the quality of a training program as well as the trainer himself for a better evaluation.

Retraining

Remedial training is given when there is evidence that the original training was not adequate, resulting in a person who cannot correctly, safely, effectively or efficiently perform the task. Remedial training is frequently used incorrectly as corrective actions for deviations or failures.

Periodic Review of Training

The top management team shall review the training program with personnel department periodically. Also department head shall review the Individual Training Plan with the employees periodically to ensure that the plan has been completed for satisfactory performance of the functions employees expected to perform.

Training Records, Documentation and Retention

Training records provide the evidence that the training was carried out. Quality assurance should audit training records periodically. User department will be responsible for preparation of training planner, verify the training records of the entire employee as per their job description, keeping and maintaining a copy of training planner. The training records shall be archived as specified in the document management SOP's. The department heads shall ensure updates of training records.

SUMMARY AND CONCLUSION

Training as a subject in this article has various dimensions. The prime factor which this article emphasis is how training programs can effectively manage the workforce to the best of their ability and how useful it can be in the success of pharmaceutical industry. Globally training

programs are taken as effective and developmental practice to ensure that the all employees are trained to

1. Mahbuba S. Impact of Training in Pharmaceutical Industry: An Assessment on Square Pharmaceuticals



Figure 3: Training Programs – Technical Training

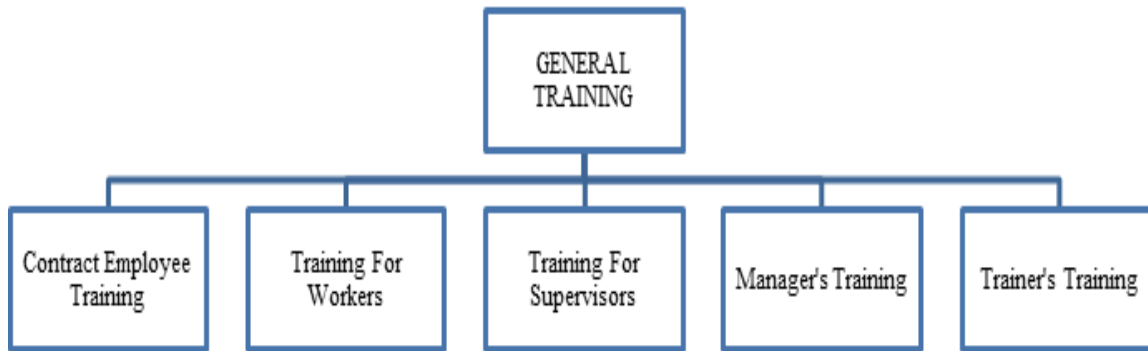


Figure 4: Training Programs - General Training



Figure 5: Training Programs - Advanced Training



Figure 6: Health and Safety Caution Signage

perform their job responsibility and to meet any challenges thrown at them.

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