# PHARMACEUTICAL TRAINING GUIDELINE

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INTRODUCTION

A good training system provides the process for ensuring all employees receive adequate, relevant, and documented training to enable them to perform their assigned functions safely and in compliance with applicable guidelines/regulations. This guideline will outline practical training approaches to evaluate, establish and/or provide training for FDA regulated industries. An evaluation should be made to verify all local or corporate standards are met concerning the program and outline provided. Here are some key points for quality pharmaceutical training:

- Companies should organize their activities along functional lines with each department training its own members.
- There are two basic needs for training in pharmaceutical companies:
  - Extend quality training to all departments.
  - Perform specific departmental training in each functional area.
- Quality is EVERYONE’s responsibility! Quality training should be, and is required by cGMPs, across the company.

Incorporate quality-related concepts into all management training, and provide quality tools for other functional areas. As the focus of this guideline is on pharmaceutical operations training, examples of the types of managerial quality related training, and other functional area tools are found in Juran’s Quality Control Handbook.

BASICS FOR A SUCCESSFUL TRAINING PROGRAM

A quality training program should start at the top of an organization and flow directly to the bottom of the organization. It can be effective to create a training task force, or individual with support from upper management, who coordinates training and is responsible for its implementation.

- Planning should be based upon:
  - Who is to be trained?
  - What are the training topics or subject matter?
  - From where will training materials come?
  - How will training leaders be secured?
  - Where to conduct training?
  - What is the cost of training?
  - What is the duration of training?
  - What are the schedules and priorities?

Site or Corporate Training

- Large companies may coordinate training and training programs from a corporate level or leave it to the local sites.
  - Problems may arise if site to site training programs are significantly different.
  - Corporate guided training may be necessary for items that need to remain the same between different sites.
- At a minimum, companies should:
  - Coordinate training programs (verify that each site is adequate)
  - Provide training for upper management
  - Provide adequate training budgets
  - Assist in the development of training materials
What are your training needs?

- Analysis should be conducted by the training task force
- How do you determine your needs:
  - Ask the department managers
  - Evaluate internal findings
  - Review FDA or customer audits
  - Evaluate corporate wide findings

- One potential way to evaluate training needs is to develop a training matrix
  - List potential training topics or categories
  - Identify the various personnel requiring the training

Example:

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<th>QA</th>
<th>Packaging</th>
<th>Management</th>
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**TRAINING FOR DIFFERENT LEVELS OF PERSONNEL**

**Upper Management**

- Any quality training program should include the top managerial levels
- Should be a broad coverage of all quality activities of the company
- Establish a link between business goals and quality
- Focus on results – not techniques
- Evaluate separation of training between upper management and the rest of the company
  - Upper management may have unique situations that should be discussed in closed sessions
- Some suggested topics:
  - The job of upper management
  - Annual quality improvement initiatives
  - Training for quality
  - Motivation for quality
  - Quality initiatives around the world (future quality issues)
- Upper management usually prefer outside trainers rather than personnel from their site/company
**Middle and Lower Management**

- Evaluate offering a single training program or designing unique categories for each section.
- Most managers are results oriented but also have departmental responsibilities
- A major portion of the training should focus or be based upon quality improvement
- Some suggestions:
  - Quality mission
  - Supplier relations
  - Manufacturing
  - Product development
  - Inspection and testing
  - Field Issues – complaints or recalls
  - Motivation for quality
  - Future quality issues
  - Quality tools

**General Employees**

- Course outlines may be broken down per specific function with general sections covering all areas
- Have course handouts on the topics covered
- Provide “tools” for them to use in their daily work lives (these must be approved and controlled)
  - Handouts, laminated cards with quick reference material, booklets
- Some suggested quality introduction topics:
  - What is quality?
  - Evaluation of quality tools (i.e. Pareto diagrams and control charts)
  - Evaluation of “customer” needs
  - Future projects and/or products
  - Field issues
  - FDA initiatives or issues
  - Suppliers to discuss their operations
  - Representatives from other sites
- To keep the pace going at an acceptable rate, it may be necessary to bring in outside trainers

**Other Employees**

- Evaluate all personnel who “work” at your facility
- Don’t forget about:
  - Temporary workers
  - Consultants
  - Contractors
  - Janitorial services
- These “workers” should have the required training conducted dependent upon their required function
TRAINING TYPES

The following are different types of delivery methods for training. The type to be used should be determined when reviewing the training needs.

New Employee Orientation

- Performed within the first few days of hiring
- Requires a qualified instructor
- Follows classroom type training
- May be held off-site or in a separate area
- Often involves tests during or after training

New Employee Training Program Outline

Although some areas, such as the Facility Overview, do not contain specific activities to be performed, other areas, such as GMP, require understanding for job performance. Therefore, the completion of the new employee training should be documented and maintained. The following are some areas that benefit new employees (this is not an all-inclusive list and will depend on the company structure/purpose):

- Facility Overview
  - General layout of the facility
  - Flow of materials and people
  - Controlled access areas
  - Departmental organization

- Product Overview
  - Controlled drugs
  - Dosage forms

- GMP
  - Applicable regulations
  - Introduction to the FDA

- Documentation
  - Requirements
  - Logs
  - Forms
  - Rules for corrections

- General Operating Procedures
  - General SOPs in the specific areas

- Contamination Control
  - Handling toxic compounds
  - Handling infectious compounds
  - Gowning

- Safety
  - Alarms
  - Evacuation/emergency procedures (i.e. fire, flood, weather, earthquake)
  - Material Safety Data Sheets (MSDS)
• Operational Requirements
  ➢ Aseptic
  ➢ Controlled environment
  ➢ Hardhats
  ➢ Lab coats
  ➢ Personal Protective Equipment (PPE)

• Materials Handling
  ➢ Reconciliation
  ➢ Rejected material
  ➢ Quarantined material

• Equipment
  ➢ Operation
  ➢ Safety
  ➢ Calibration
  ➢ Validation

**Full Effect Training**

• This is a concept by which key employees are “processed” through all job functions in the facility

• Gives the employee a full understanding of the unique operations of each function

• Requires a qualified individual with strong knowledge of each area

• Usually given during new employee orientation as a “tour”

• Suggestions:
  ➢ Receiving/Warehousing
  ➢ Sampling
  ➢ Laboratory
  ➢ Formulation
  ➢ Manufacturing
  ➢ Packaging
  ➢ Labeling
  ➢ QA
  ➢ Marketing overview

• Usually there are no tests after this type of training

**Read and Understand**

• Employee reads the document (often a procedure) and signs training documentation stating they read and understand the document

• Usually there are no tests on the document

**Computer Based Training (CBT)**

• Often PowerPoint presentations, or contained in a learning, education and development system (LEADS)

• Can have tests any time during or after training
Classroom Training

- May be held off-site or in a separate area
- Requires a qualified instructor
- Can incorporate the following:
  - Video tapes
  - Computerized systems
  - Speakers
  - Manuals or booklets
  - Tours
- Methods for training can incorporate the following:
  - Application of instructions or training subjects with company problems or issues
  - Role playing
  - Case examples
- Often involves tests during or after training

Classroom Training Recommendations

- People must have sufficient space to sit properly
- Use comfortable chairs
- Use tables – each person will need about 2 – 4 feet of table space
- Control the room temperature
  - Not everyone will be happy with the temperature
  - Best rule is to keep the room temperature slightly cooler and notify everyone to bring along a jacket or sweater
- Have proper audio/visual equipment setup prior to the start of training
  - Have backups
    - Overheads
    - Spare light bulbs
- Provide handouts with an area for notes, if it will be helpful after the class
- Ask that people turn off pagers and cell phones
  - Provide for a means of obtaining phone messages
  - Provide for a means of accessing company email
- Provide food or drinks for breaks and lunch

On-the-job Training (OJT)

- OJT may be one of the most effective forms of training
- Usually performed by a qualified subject matter expert (SME) or qualified supervision
- Caution should be taken that product is not manufactured or tested by an unskilled individual who is performing OJT
• If possible, create a training area for OJT
  ➢ Small area with representative equipment to be used for training only
    ▪ Laboratory
    ▪ Manufacturing

• Usually involves a comprehensive test to verify understanding and competence on the task

• Usually the last step in employee qualification

**Self-training**

• Employee usually takes the initiative and pursues additional training

• Should be encouraged by the company

• Is often integral to the employee development part of the performance review program

• May include:
  ➢ Membership in professional societies
  ➢ Training outside the company to increase understanding or knowledge on a job-related topic
  ➢ Visits to other companies
  ➢ Publications
    ▪ Magazines
    ▪ Manuals/booklets
    ▪ Books

• There are usually no tests

**TRAINING PROGRAM ESSENTIALS**

**The Budget for Training**

• Plan for training annually
• All employees should be included in training
• Determine in-house training and external training needs
• Estimate the cost of preparing and/or buying training materials
• Estimate the cost of bringing speakers in-house
  ➢ Travel
  ➢ Lodging
  ➢ Food
  ➢ Time
• Estimate the cost of sending personnel to conferences or classes

**Procedures**

An SOP should be established documenting how training will be developed, reviewed and approved, delivered, documented, and maintained. This SOP should also include how and when employees are qualified and re-qualified.
**Training Documentation and Access**

Any documentation signed (either electronically or by hand) needs to contain a statement informing the employee to check with their supervisor if they have any questions prior to signing the document, and that by signing they are verifying that they have read and understood the document.

Training documentation can range from files maintained in the work area to training completed, recorded, and stored in LEADS. Regardless of how training completion is documented, it should be readily accessible for FDA audits, etc. Also, it should be easy to quickly identify if individuals are qualified for the tasks and positions they are performing.

**Instructors**

Employees previously trained on topics can be a SME and can perform training. Training documentation should list the qualified instructors for each course and should be verified to be accurate during reviews.

**Qualification**

Qualification training most often includes a checklist for the training required for qualification for a task or position. The qualification checklist must be pre-approved by Quality. The checklist contains some of each type of training.

After completion of the read and understand, classroom and CBT training the remainder of the training required for qualification is usually OJT training while in the work area, and is supervised. Testing by the trainee during qualification should not be performed on incoming raw material, in process samples, or finished product. This type of training often involves an instructor performing a task while the trainee observes, then the trainee performing the task with the instructor assisting, and finally the trainee performing the task unassisted while being observed by the instructor. Approval to perform the task unassisted without supervision is given after proper completion of the tasks is documented.

**Training/Qualification Reviews**

Training associated with procedures should be reviewed at the same time as the procedure. Training not associated with procedures should be reviewed at least every 2 or 3 years to ensure accuracy, compliance, and appropriate instructors. Qualifications should also be reviewed every 2 or 3 years to ensure the appropriate training is associated with the functions.

**Training Feedback**

The following are some ways of obtaining feedback from attendees regarding the training, speakers, topics, presentations, surroundings, food, etc.

- Newsletter questionnaire
  - Allows people to think on the subject matter prior to answering the questions
  - Can use this form of information gathering to inquire as to changes implemented as a result of the training
- Evaluation form at the end of training
  - This is probably the best method – collect the evaluation forms prior to attendees leaving the training area
- Combination of the above two applications
Was training effective?

- This is an important FDA concern!
- Determines the attendees grasp of the subject matter
- Can use this data to evaluate the effectiveness of the trainers
- Usually performed via some form of written test or close observation by a trained employee (preferably someone in a management role)
- Document effectiveness evaluation
- Have pass and fail criteria which are reasonable

WHY PROGRAMS FAIL

A comprehensive training process is critical to ensuring employees are adequately trained to perform their tasks and job functions, that training documentation is accurate and easily accessible, and qualification to perform a task or function is quickly identified.

The following are common reasons training programs fail, and suggestions for resolution:

- Lack of participation
  - Upper management
  - Middle management

  Resolution tip: Involve these individuals in training. Make it their responsibility for success.

- Resistance
  - People see training as a waste of time - time that could be better spent “making money by getting product out the door”

  Resolution tip: Present information regarding waste or lost time due to investigations, etc. Review customer complaints or customer needs. Have external speakers’ present information.

- Poor facilities and environment
  - Too noisy or repeated interruptions
  - Presentation material or audio/visual not prepared properly

  Resolution tip: Prepare ahead of time. Make sure everything works and there are backup plans in the event of a problem. Practice the training session to see how it works. Hold training off-site.

- Complex presentation material
  - Language is too “high-level” for the audience
  - Material involves calculations or perceived knowledge in the subject

  Resolution tip: Careful preparation of material. Use various aids as needed. Practice the training session on a trial audience.

- Poor trainers
  - Lack of experience or knowledge
  - Speaking ability
  - Nervous

  Resolution tip: Screen your trainers (someone who is very knowledgeable in a subject may not be a good presenter).
• Lack of application
  ➢ No perceived relationship between subject matter and workers job duties

  **Resolution tip:** Use issues currently applicable in operations as part of the training. Have attendees participate in problem resolution training.

• Varied audience knowledge
  ➢ Personnel with vast subject matter knowledge are included with new hires

  **Resolution tip:** Hold separate training sessions for the various levels of management and for the levels of experience.