

Good Manufacturing Practices

(PHAR 533)

Fifth Grade – Spring Semester

Faculty of Pharmacy

Pharmacy Department

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Lecture 3

Organization and Personnel

Dr. Louna Altrjman

Louna.altrjman@tiu.edu.iq

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Outlines

- Personnel Responsibilities
- Personnel Training
- Components of an effective GMP training
 - 1- Job description
 - 2- Curricula
 - 3- Training Plans
 - 4- Training Activities
 - 5- Assessments and Evaluations
 - 6- Records
- Examples of Citings Issued by the FDA



Learning Outcomes

At the end of this chapter, you will be able to:

1. Explain the GMP requirements related to personnel responsibilities.
2. Identify and discuss the key components of an effective GMP training system.
3. Differentiate between corporate, site, and functional training requirements.
4. Analyze real FDA citation examples related to personnel and training deficiencies.

Personnel Responsibilities

1. Personnel engaged in the manufacturing processes shall **wear clean clothing and protective apparel** appropriate for the duties they perform, such as head, face, hand, and arm coverings, to protect drug products from contamination.
2. Personnel shall **practice good sanitation and health habits.**



Personnel Responsibilities

3. Only personnel **authorized** by supervisory personnel shall enter those areas of the buildings and facilities designated as **limited-access areas**.
4. All personnel shall be instructed to **report** to the supervisor any health conditions that may have an adverse effect on drug products that affect the safety or quality of drug products, to **exclude them** from direct contact with components.



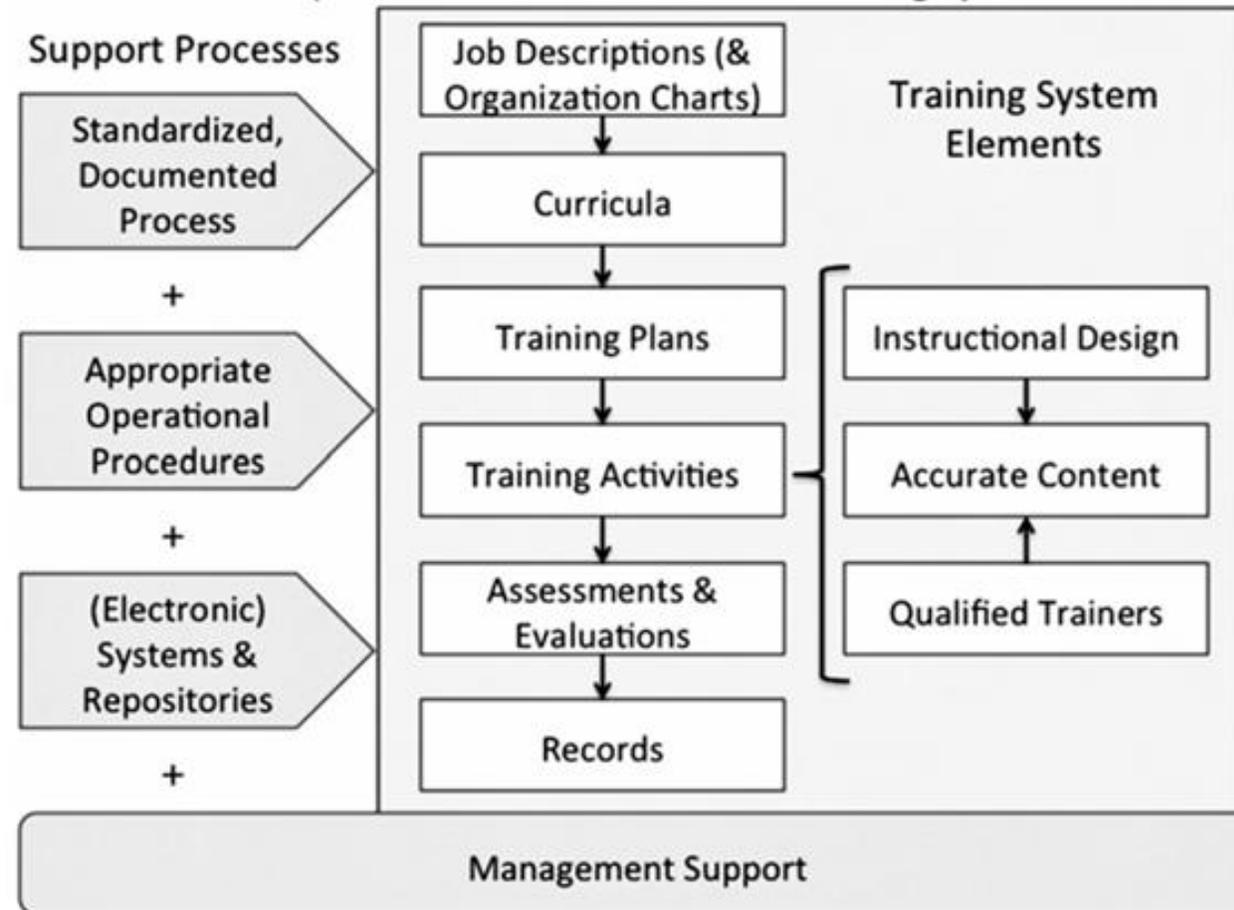


Personnel Training

Under a quality system, managers are expected to establish training programs that include the following:

1. Evaluation of **training needs**
2. Provision of training to **satisfy these needs**
3. Evaluation of the **effectiveness of training**
4. **Documentation** of training and/or re-training

Components of an Effective GMP Training





Components of an Effective GMP Training

1- Job description: (who is responsible for performing which roles)

A JD should exist for each position in the company and define the **role, tasks, the required background of education and experience**, along with describing the **level of performance** required.

JDs also allow us to assess an individual's knowledge, skills, and experience against defined criteria, which helps avoid placing someone into a position they're not prepared to perform.

	Sections	Details
1	Job Title	Educational Assistant
2	Location	Chicago, IL (On-site)
3	Role Summary	The Educational Assistant will support teachers in classroom management, assist with lesson planning, and help students with educational activities. This role is essential in fostering a positive learning environment.
4	Key Responsibilities	<ul style="list-style-type: none">- Assist in preparing teaching materials and classroom setups.- Support students with tasks, projects, and homework.- Monitor students' progress and report concerns to teachers.- Help maintain classroom discipline and assist in behavior management.- Assist in organizing educational events and activities.- Provide one-on-one support to students with special needs.- Maintain and organize student records.- Communicate with parents about student progress when necessary.
5	Required Qualifications	Associate's degree or equivalent, previous experience in an educational setting preferred.
6	Compensation & Benefits	\$28,000 - \$32,000 annually, Health insurance, Paid time off, Professional development opportunities.



Components of an Effective GMP Training

2- Curricula: (what training is needed)

Training requirements for specific tasks and roles should be relatively standard and expressed as role-based curricula for all personnel, including senior management and contract personnel (including temporary employees, contractors, and consultants).



Components of an Effective GMP Training

2- Curricula:

Curricula should define at least three different sets of training requirements:

1. **Corporate requirements** are those **global items** required for anyone working for the company.
2. **Site requirements** encompass those items required for everyone working at a **specific plant site**, including plant-specific safety policies and Environmental Health & Safety training, local HR/IT/legal requirements.
3. **Functional area requirements** are the **task-specific procedures** and other task-related training needed for personnel to perform specific job-related tasks correctly. (Requalification should be considered for tasks where technique or behavior is critical and for tasks that are difficult or not performed frequently.)



Components of an Effective GMP Training

3- Training Plans: (when it's appropriate and how to provide training)

Training plans should address at least three areas:

1. Onboarding
2. Job skill training
3. Ongoing/continued training (annual basis)



Components of an Effective GMP Training

4- Training Activities: (delivery of the training)

The **quality of the training activity** directly affects **training effectiveness**, but it actually results from the combined outputs of three different process elements:

1. Instructional Design
2. Accurate Content
3. Qualified Trainers



Components of an Effective GMP Training

5- Assessments and Evaluations: (ensure accomplishment of our desired outcomes)

It's important to use the right assessment type to get an accurate picture of the trainee's capability (assessments are not one-size-fits-all).

1. For **hands-on, task-oriented training**, a performance assessment checklist is a robust training assessment technique.
2. For **knowledge-based training**, the most common assessment approach is a knowledge assessment (i.e., quiz) that demonstrates the trainee's level of understanding of the topic/content.



Components of an Effective GMP Training

6- Records: (demonstrate the effectiveness)

1. **Job descriptions** and assigned duties
2. **Personnel CVs**, demonstrating education, background, and prior work experience
3. **Training curricula and plans**
4. Records of **training activities** (including topics covered, date of training, identification of the trainer, attendee signature sheets for instructor-led training, and records of assessments administered to trainees)
5. Records of **trainer** qualification and traceability to topics/sessions taught



Examples on Citings Issued by the FDA

1. “The Director of Quality Systems requires a Bachelor’s degree in Science /Technical/ or Engineering disciplines. The person holding the position has a Business Administration degree.”
2. “You did not train contract employees in cGMP or in job-specific procedures.”
3. “Temporary employees are given cGMP training by the temporary agency that employs them; they do not receive any additional training at this company, such as job-specific training.”
4. “The QA Manager has not received cGMP training since 2009.”
5. “The individual responsible for providing training to the Microbiological Laboratory personnel is a Chemist with a limited background in Microbiology.”

References

Bunn, G. P. (Ed.). (2015). *Good manufacturing practices for pharmaceuticals* (7th ed.). John Wiley & Sons.

