

Auditing a Personnel & Training System

Title Auditing a Personnel & Training System					
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Audit Training Manual: 03

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Organization

The company or site should have an organization chart and/or clearly defined reporting structure. There should be no gaps or unexplained overlaps in the responsibilities of personnel concerned with the application of GMPs. There should be a Quality unit/Quality Assurance Unit (QA) that is independent from production, up to an appropriate level in the organization. The level of separation of QA from Production is determined by the company's organization and size.

Personnel Responsibilities

Personnel must assume responsibility for producing a quality product and should understand the impact of their activities on the product and, ultimately, the patient. All personnel are responsible for following company and site policies, procedures, practices, company standards, and quality requirements and regulations. These responsibilities include, but are not limited to:

- Following established dress codes within the work area
- Maintaining good hygiene and health that will not compromise a pharmaceutical product
- Completing documentation correctly
- Advising management of problem situations
- Understanding and following SOPs for specific job functions
- Undergoing training when necessary
- Refraining from eating, smoking, drinking, or chewing within a production area
- Assuring that there is adequate supervision for all activities related to drug production
- Incorporating regulatory requirements into their particular job function
- Preventing contamination of drug products
- Avoiding direct contact with exposed product as well as with any part of the equipment that comes in contact with the product
- Protecting product quality

Personnel Qualifications

Personnel working at a pharmaceutical company are expected to be qualified in the operations that are assigned to them. This qualification can be achieved through training which focuses on job tasks (job skills training) and regulatory requirements, experience, and education or a combination of the three. Employees are considered qualified when they can demonstrate satisfactory proficiency in job performance.

Training

To create qualified employees, companies need to have an effective GMP training system in place. Training should be:

- Competency based
- Conducted by a qualified trainer
- Evaluated for effectiveness
- Focused on particular job skills and regulatory requirements
- Documented
- Joint responsibility between the trainer, trainee and management.

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performance. This training should also be documented.

Certification/Assessment of Training Efficacy

All personnel should have training evaluated, possibly in conjunction with a certification program. Certification could include successfully completing an approved curriculum of courses pertinent to the certification, successfully passing a comprehensive knowledge test, and demonstrating competency through a performance measure.

Training Documentation

When auditing, one of your responsibilities is to determine how training attendance is tracked. All training attendance must be documented and tracked, either electronically or manually. Training documentation may be kept in an electronic format as part of a validated learning management system, or a paper based system. If an electronic system is used, it should be validated as required by the regulations.

The tracking system should be established to identify both those personnel who have attended the training and those who were absent from the training. There should be a process in place to ensure that those absent during scheduled training receive the training at a later date.

Training documentation includes:

- An overall SOP for management of the training system
- Training SOPs, guidelines
- Attendance records/sheets containing name of trainee, date, title and/or brief summary of training, type of training, identification of trainee (e.g. company ID #, distinct password, etc.), name of trainer if appropriate
- Training materials
- Individual training records which list all of the employee's training
- Training plan

A training management SOP should define:

- Roles and responsibilities of all parties involved in training
- Who should be trained
- What training is mandatory and required
- What method is used for the training, if appropriate
- When and how often the training should be given
- Who maintains training records
- What constitutes qualification

SOPs or Training Plans may be generated by the individual departments, specifying which tasks the employee is to be trained on, or there may be a general site training SOP.

All training records should be complete, accurate and current. Training records should be in-place and easily retrievable. At a minimum, the record should contain the name of the trainee, topic discussed, trainer and the date of the training. The Training Records should document, not only training performed at the job site but also external sessions, such as conferences, educational courses, and/or training performed by a vendor.

A Training Summary should be a history of all the training the employee has received. This can be electronically maintained in a validated tracking system or manually maintained. The Training Summary should be in agreement with the job description and/or training plan for the respective position.

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Training materials

Reviewing training materials is also part of your audit. Training materials should follow principles of instructional design. They should have objectives based on a training needs analysis and, if appropriate, contain an assessment for training effectiveness. They should also be up-dated and maintained, using a change control procedure. Functional areas and/or Quality should approve them.

Delivery of training

The training format and methodology should be determined by the content of the materials, and the audience. Training may be instructor led, self study, computer based, instructor led with video supplements, a facilitated discussion, or other methods. Whichever method is chosen, it should meet the same requirements, i.e., reviewed and approved by management, documented, evaluated for effectiveness.

Personnel Requiring Training

All personnel, both full and part-time, whose job functions are impacted by GMP and regulatory requirements, should receive regulatory training, job skills and ongoing training.

Contract personnel should be trained to perform the services they are contracted for and have knowledge of GMP if working in a GMP area. Qualification of contractors should be documented and kept on file.

Visitors or untrained personnel should not be taken into restricted areas. These areas include research and development facilities, document archive areas, production, storage and quality control areas. If this is unavoidable, they should be given sufficient information in advance regarding hygiene, safety, protective clothing, GMPs and other restrictions. They should be closely supervised following the sites written procedure for visitors.

Audit strategy

A suggested strategy is to

- 1) Select employees with differing times of service and different job functions.
- 2) Review their training records for completion of all training requirements.
- 3) Observe them while they perform their duties.
- 4) Ensure that personnel are following procedures.

Summary

Personnel must follow regulatory requirements as well as company policies, guidelines, and procedures. They are responsible for practicing good hygiene and remaining in good health as a safeguard to protecting the quality of the drug product. To achieve this they must be qualified as a result of training, education and experience to perform their job functions. One way to assure this is to provide necessary training.

Training is a process, not an event. It is similar to other processes in that it needs to be controlled, documented, and focused. To determine if training is adequate and compliant, SOPs, job descriptions in conjunction with training qualification plans, training records/histories, and training materials need to be reviewed. To determine if training is effective, employees using the trained skills and knowledge should be observed.