Regulatory Basis:
FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

General Discussion
This document discusses considerations for site GMP Training systems including training on regulations, GMP concepts, GMP tasks and knowledge necessary to perform those tasks.

GMP sites must comply with GMP requirements for training by defining the knowledge, skills and attributes colleagues must have to competently perform GMP tasks and other activities. This may be accomplished through education, training, experience or a combination thereof.

Introduction to the GMP Training System should be part of any colleague's orientation to the site and should be the structure upon which all the GMP training needs of the colleague are met. This document will cover the various aspects of the system including job function curriculum, training record system, GMP orientation, SOP training, GMP concept training, structured on-the-job training, and training effectiveness assessments.

Scope
This document applies to all colleagues including temporary and part-time, performing job functions potentially impacting medicinal product integrity at production sites, laboratory sites, and logistics centers.

I. Training System

☐ Procedures and practices for managing and administrating GMP training including, but not limited to, planning, designing, executing, recording, and tracking training.

☐ **Components**
i. *Job Function Curriculum (JFC)* – A list of all training (including SOPs, OJT and other topics) that must be completed and kept current for each person in that job function. Each of the items on the JFC are required to be completed as specified, unless there is a documented exemption for an item based on a combination of their previous education, training or experience. The JFC must include achievable targets that, once completed, allow the person to work on a GMP task without direct supervision

ii. *On-the-Job Training* (OJT)– the one-to-one process of providing and mastering knowledge and skills to perform a specific task within a job. Training should include specific criteria to be met to show that competence has been achieved in the task.

    ii.   The use of part time trainers should also continue to evolve. These colleagues should be representative of the types of training that is occurring at the site to ensure that their expertise is being utilized properly.

    iii.   Training materials such as job function curriculums and OJT materials need to be continually assessed for accuracy and updated to ensure they meet the current approved requirements at the site.

III.   Defining and Determining Training Method

- **Communication** – to provide general and/or basic knowledge of a GMP topic, issue or document that is useful for the audience but site leadership has determined is not critical to perform the current job function. This may include general revisions to SOPs such as grammatical errors.

- **Knowledge** – information the audience needs to know as they routinely perform or oversee some or all of the tasks or activities described in the SOP.

- **Skill/Performance** – the audience is directly involved in performing an activity or fulfilling the responsibility defined in the SOP and there are performance expectations of how well they can perform the task.

    i.   Training includes a witnessed and documented activity that a colleague can perform the functions relating to a particular activity/skill (as defined in an SOP) that they have direct responsibility for performing.

- **Training Method Decision Model** (see appendix #2) to decide what type of training should be implemented, you should consider the audience and their job function as it relates to the subject. If the training information is general and will not directly change the colleague's job performance, then communication may be adequate. This will inform colleagues of the information but not require any assessment of the training effectiveness. On the other hand, if the information, such as changes to an SOP, will directly impact the colleagues job performance, then knowledge or skill training may be required to ensure that colleagues understand and can apply this new information as well as perform the task as per the requirements.

IV.   Defining and Developing Trainers

- **Identifying Trainers** – trainers should be identified based on their education, training and experience relative to the subject and demonstrated competence in:
  - i.   Assessing and defining training objectives
  - ii.   Effectively performing the appropriate training methodology for the audience and application

Appendix 1

Training System Owner

Definition	Responsibilities	Skills/Competencies
Designated individual responsible for overseeing, designing, and implementing the site GMP Training System. Must be knowledgeable of and have experience in applied GMPs, as well as training concepts and practices.	• Develops, implements and maintains the GMP Training System • Ensures completion and maintenance of GMP Training Documents and Records • Maintains current knowledge of regulatory requirement in relation to training • Understands and works with other departments to ensure that the GMP Training System is linked properly with other quality systems (eg. Document Control, Deviations, etc.) • Maintains a list of all qualified trainers and ensures that these people are given the opportunity to stay qualified • Develops and maintains site strategy and plan for training and qualification activities • Monitor system and implement continuous improvements • Presents/explains the site GMP training system to auditors/inspectors /visitors.	• Strategic Planning • Communication Skills • Analyzing needs • Decision making • Presentation skills • Coaching • Meeting leadership/facilitation • Process mapping • Adult learning theory

Full Time Trainer – Training is primary job function

Definition	Responsibilities	Skills/Competencies
An internal site trainer who is responsible for the development, preparation and effective delivery of training activities. Typically training is their primary job function	• Contribute to the site's strategy for training and qualification activities • Monitor training activities to ensure compliance with company, regulatory and legal requirements • Facilitates the identification, planning, actioning and evaluation of training needs for all employees • Is the reference or expert for all parts of the training process: analyzing needs, writing learning objectives,	• Analyzing needs • Writing learning objectives • Developing training modules • Delivering training • Presentation skills • Training coordination • Developing evaluations and assessments • Facilitation skills

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Appendix 3

Model for GMP Training System

Change job function in same department

Transfer to new area

Hire New Colleague

GMP Orientation must be performed before a new colleague is allowed to perform any GMP Task

If an individual is new to a department but not new to the company, then GMP Orientation training may not be necessary

GMP Orientation → Training Record

If an individual is new to a job function within the same area, the department orientation training may not be necessary

Department Orientation → Training Record

Job Function Curriculum Assigned/ Developed → Record filed

SOP Training → Training Record

Continuous Monitoring of Colleague Training History

On-the-Job Training → Training Record

GMP concept training should be performed as per the site policy. This can occur at any time during the colleagues initial training

GMP Concept Training → Training Record