

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.
- iii. *Training Record System* – process for creating, filing, retrieving, and archiving training records that tracks and reports the status of completed and required trainings. Training records or reports must be readily available to substantiate that all employees performing GMP Related functions have completed the training requirements.
- iv. *Training Effectiveness Assessments*
 1. Training Evaluation – instrument or methodology to gather feedback to improve the training process.
 - Level I-Survey questionnaire that measures training effectiveness relative to satisfaction
 2. Learning Assessment – instrument or methodology to assess how well the participants have met the defined learning objectives and or links to business results
 - Level II-measure trainee recall via written, verbal, computer based assessments, case studies, simulations or demonstrations
 - Level III-measures trainee performance via direct observation, feedback from others, performance attributes or parameters
 - Level IV-measures impact of training on business performance by evaluating business results, metrics or data.
- v. *GMP Orientation* – training designed to provide new employees to a specific area the fundamental knowledge necessary to work in this area. For example, regulations, industry history, health and hygiene, documentation practices, GMP values and other site specific information.
- vi. *GMP Concept Training* – training designed to refresh colleague’s understanding and application of cGMPs. The courses should be designed to promote learning and improve colleague’s focus on cGMPs, regardless of their specific job function.
- vii. *Standard Operating Procedure (SOP) Training* – training designed for all employees impacted by new or revised SOP’s. This training must be completed prior to the effective date of the SOP therefore ensuring that the employee has been completely versed on all changes affecting their

- i. Training topics and focus should be relative to the activities occurring at the site. For examples, GMP Concept Training topics should be chosen so that they are pertinent to site and area needs. Department management should be involved, so that they can ensure that training topics are pertinent to colleague's job functions, preventing deviation occurrences, past site regulatory observations or to address continual problems that occur in the area/site.
- 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.

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.	<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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, 	<ul style="list-style-type: none"> • Analyzing needs • Writing learning objectives • Developing training modules • Delivering training • Presentation skills • Training coordination • Developing evaluations and assessments • Facilitation skills

Appendix 3

Model for GMP Training System

