

- 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