

specific job function. Training should ensure that all employees understand the changes to their job function and the timing to which these changes are effective

- viii. *Communication of Training* – The site should notify effected employees of training far enough in advance for an employee to attend and also provide make up session(s) or alternative approach for those unable to attend.

## II. Implementation Model for GMP Training System:

- **Implementation** – The implementation phase should include the following steps:
  - i. An assessment of the job functions that have direct or indirect GMP impact,
  - ii. Determination of the knowledge and skill requirements to do tasks associated with the job, and
  - iii. Assessment of the risk to quality and business if those tasks are not completed competently.
  - iv. An SOP describing the training system,
  - v. Authorization of training materials by the site Quality and Production leadership as appropriate.
  - It may take time to build the system to its final state, so a planned, prioritized and documented phased approach to full implementation is recommended.
- **Measures and Monitoring** -The system should be monitored on a continuous basis to ensure that all training requirements are being met. This process may include:
  - i. A regular review of individuals' JFC to determine if all training is up to date. This will ensure that all colleagues are adequately trained to perform their job functions according to the current procedures in place.
  - ii. A review of training records to ensure that all colleagues attend the required GMP Concept training sessions. A similar monitoring system can be employed for procedural type training, such as SOPs and Batch Records. This ensures that each colleague is fully trained on all necessary information needed to perform their job function. The review of the records can be performed manually for a paper based system or by creating and running a report in Electronic Learning Management System
- **Continuous improvement** -As with any system, monitoring for gaps and improvements means assessing whether training is effective, appropriate and adequate. The GMP Training System is an evolving system that should be structured based on the current working environment and the needs of business and colleagues.