

applied to task such as batch record review, environmental monitoring techniques, internal audits and other job functions that require acquiring a new skill.

Typically there are five phases to a Structured OJT System:

1. Preparation of the Structured OJT Process
2. Introduction
3. Knowledge & Skills Training
4. Practice Sessions
5. Training Assessment.

Step 1 – Preparation

1. Trainer
 - a. Select a qualified trainer, who has expertise, training or a combination of these in the specific area/topic. This may be an individual who performs training as their job function or an SME who performs training secondary to their primary job function.
 - b. Evaluate /train this individual before identifying them as a SOJT trainer to ensure that the trainer has the appropriate skills and knowledge. For example, review of a documented resume or job profile that states experience in this type of training or attendance in a Train the trainer type program for this type of training would be sufficient.
2. Training Tools
 - a. Training Objectives should be determined before starting the training process. These are key learning points to be discussed during the SOJT. Recommended steps to define the learning objectives are:
 - i. Review all task steps in the SOP, Batch/Packaging Records and/or related documents.
 - ii. When selecting the steps that will be included the following criteria should be considered, not all may apply to every task that you are training on. Select those which are most applicable.
 - Criticality-Select steps that if done incorrectly, could affect the colleague safety, the product integrity, equipment integrity or the environment.
 - Complexity – Select the task with higher complexity
 - Difficulty – Select task with higher difficulty
 - Frequency –Select task done with lower frequency
 - iii. Establish the Learning Objectives based on the selected tasks.
 - b. Training Documents & Materials
 - i. If an SME is not identified as the OJT trainer, identify one the area to help develop and review material.
 - ii. Identify the required training documents.
 - SOPs & Batch/Packaging records are the preferred training tools when they are easily understood and clearly define the steps and outcomes for a process.