

Guidance 064 Structured On-the-Job Training System

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.

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- Emphasize any special safety or quality points that apply to the task

Skills Based Training

1. Trainer should ensure an appropriate learning environment for this part of the training.
 - If the area is too noisy it may be difficult for the trainee to hear your instructions.
 - If the area is very crowded, the trainee may not get a good view of all of your actions.
 - Prior to starting the demonstration, ask the trainee if they are comfortable with the environment.
 - Determine if you are speaking loudly enough and if the trainee can adequately see what you are doing.
2. The trainer should demonstrate the task in the workplace or simulation area.
 - Using the SOP, follow all the correct steps, showing & explaining how to perform the task.
 - Go through each step of the SOP with the trainee so that they can visually see each action that is performed.
 - Emphasize important steps & precautions (the identified critical tasks, learning objectives).
 - Include non-routine occurrences and the appropriate actions to take when they occur.
For example, when training operators for visual inspection of labels on vials the SOJT should not only include the process for inspecting correct labels but also what steps should be taken when operators find a improperly labeled vial.
3. Repeat the demonstration, moving a little faster each time.
4. This training should be documented

Step 4 – Practice

Practice

1. Allow the trainee adequate time to practice the task, under supervision, prior to having to demonstrate competence.
 - All practice sessions should occur under the supervision of an approved instructor.
 - Instructors need to be available during the practice session to offer support and guidance to the trainee while they are still learning the task. The amount guidance should be reduced as the trainee becomes more familiar and competent in the task.
 - A predetermined number of practice sessions may be set for certain tasks. The practice phase is not a one time process. The length of this phase depends upon the complexity of the task/job. Observe the performance for *correctness, sequence, quality and safety*.
2. Provide both positive and constructive feedback; recognize and encourage the good performance, provide coaching if the performance is not within the expectations (*offer in the form of specific suggestions*).
3. All practice sessions should be fully documented and records retained in the training history. The site could use their current training form to document these sessions or create some other type of documentation method as long as it is specified in the SOP.

Step 5 – Training Effectiveness Assessment

Appendix 1

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