

Structured On-the-Job Training System

Regulatory Basis:

FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

General Discussion

This document discusses considerations for a site Structured On-the-Job Training system including GMP tasks and knowledge necessary to perform those tasks.

Sites must comply with GMP training requirements for training by defining the knowledge, skills and attributes colleagues require to competently perform GMP tasks. This may be accomplished through education, training, experience or a combination there of.

On-the-Job training should be part of those colleagues' job function curriculum (JFC) who have a direct impact on product quality to ensure that colleagues can competently perform all job skills prior to working unsupervised.

Job skills refer to the acquired measurable behaviours that are required to perform a job.

Scope This document will cover the various aspects of a Structured On-the-Job Training (SOJT) system including determining when SOJT is appropriate, components of the system, components/steps in the system and the required documentation.

SOJT should be targeted to all job functions potentially impacting product integrity at production sites, laboratory sites, and logistics centers, including temporary and part-time employees. Assessing which specific job functions require this detailed approach to training can be done through a risk based approach.

Structured OJT can be defined as the one-to-one process of providing and mastering knowledge and skills to perform a specific task within a job; with the following characteristics:

- Occurs in the actual or simulated workplace;
- Uses a predetermined training sequence (structure for the training should be documented and approved prior to execution);
- Requires the active presence of a trainer and trainee;
- Uses materials and guides; and
- Employs a systems approach, with practice opportunity and demonstration of competence. Structured OJT provides employees with the knowledge and skills required to perform job functions in accordance with approved SOPs, and other instructional materials. OJT includes, but is not limited to technical skills training and sequential steps to perform tasks within predetermined criteria. For example, OJT practices can be 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

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- b. Specifications and review cycle times. Show examples of both, good and defective products.
4. Provide a Training Process Overview
 - a. Explain the Training Process (*Introduction, Theory, Demonstration, Practice and Evaluation*)
 - b. Explain Training Objectives
 - c. Explain Assessment Methodology and criteria
 - d. Hand out and explain training materials to be used

Step 3 – Knowledge and Skills Training

Knowledge Based Training

1. Train on the applicable SOP and other documentation (e.g. machine manuals, engineering drawings, etc.). The SOP training may also be concurrent with or subsequent to the demonstration step depending on the job task and the trainee's needs. Emphasize tasks identified as learning objectives during the training process. This training should be documented.
 - a. Equipment/Documents/Products
 - i. Tell the trainees the correct names of records, attachments, log sheets, equipment, equipment parts, tools, hardware, software, etc.
 - ii. Explain how they works, where are located, what they are called, and why they are important
 - iii. Explain safety precautions and/or special maintenance needs.
 - b. Materials
 - i. Tell the trainees the correct names of materials
 - ii. Explains Safety and/or Quality Precautions.
 - c. Tasks
 - i. Discuss the knowledge information from the training documents (SOPs, etc) such as: (choose that which are applicable to the task)
 - What tasks need to be accomplished
 - Why is the task important
 - Importance of doing it right
 - Consequences of doing it wrong
 - Which job function can perform this task
 - In what location or step in the process can the task be performed
 - At what time during the process can the task be performed
 - What materials are needed to accomplish the task
 - What is the impact to the product quality
 - 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.

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Documentation of Structured OJT Process Flow

It may be helpful to the process for creating, approving, utilizing, and updated SOJT materials formalized in an SOP or flowchart. This process flow may include detail about how the OJT process works and who is responsible for carrying out each step. All roles and responsibilities should be defined and documented to avoid confusion.

Appendix 1: Structured On the Job Training System