



Training Management Procedure Template

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1.0 PURPOSE

This procedure provides instructions for the creation and implementation of training activities. The implementation activities include the delivery, maintenance, evaluation and storage of training content.

To verify that the personnel involved in GxP activities are properly trained (certified) in all applicable works to be performed related to GxP.

This procedure brings the requirements for the identification, execution, documentation, and evaluation of the effectiveness of training activities.

To provide the mechanism to document the training history records of each trained person and register its signature in a signature log.

2.0 SCOPE

This procedure applies to all employees that perform any GxP function or responsibilities. These functions include any activity required to accomplish the tasks and duties assigned to the corresponding quality and operations departments.

It also applies to any other departments that provides or performs any GxP training (e.g. human resources department) or includes customer services.

Besides, the scope of this procedure cover three (3) different scenarios or groups of training, specifically for:

New Hires Resources -Training Group: This group of training considers the situation in which the resources that start working for the company for the first time must be trained with the necessary information to know and initiate its journey familiarizing with the company culture, its policies and expected requirements.

Existing Resources - Training Group: This group of training considers the scenario in which the existing personnel that will perform work for the first time must be trained with the specific information to know and execute any GxP tasks assigned. This group of training is divided into two (2) scenarios, either associated with a work order or not:

- a. **New Training:** This group considers the training requirements has never been taken and are necessary to perform any GxP task.
- b. **Re-Training:** This group considers the training requirements that have been taken before, but; maybe refreshed since the last time before performing any current GxP task that even it has been done before, but it needs to be confirmed and documented as re-training.

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3.0 ASSOCIATED DOCUMENTS

3.1 Internal Documents

The following Internal documents are referenced in this document:

Document Number	Document Title

3.2 External Documents

The following external documents are referenced in this document since it applies to the FDA regulated industries.

Doc Ref Number	Document Title
21, Part 820	Quality System Regulations, Good Manufacturing Practice for the Medical Devices (current revision)
Part 807	Establishment Registration And Device Listing For Manufacturers And Initial Importers Of Devices
Part 610	General Biological Products Standards
Part 606	Current Good Manufacturing Practice For Blood And Blood Components
Part 600	Biological Products: General
Part 320	Bioavailability And Bioequivalence Requirements
Part 314	Applications For FDA Approval To Market A New Drug
Part 225	Current Good Manufacturing Practice For Medicated Feeds
Part 212	Current Good Manufacturing Practice For Positron Emission Tomography Drugs
Part 211	Current Good Manufacturing Practice for Finished Pharmaceuticals
Part 210	Current Good Manufacturing Practice In Manufacturing, Processing, Packing, Or Holding Of Drugs; General
Part 111	Current Good Manufacturing Practice In Manufacturing, Packaging, Labelling, Or Holding Operations For Dietary Supplements
Part 110	Current Good Manufacturing Practice In Manufacturing, Packing Or Holding Human Food
Part 11	Electronic Records; Electronic Signatures
ISO 13485	Medical Devices Quality Management Systems Requirements for Regulatory Purposes (current revision)
MDD 93/42/EEC	Medical Device Directive (current revision)



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4.0 DEFINITIONS AND ACRONYMS

The following key terms, definitions, and acronyms apply to this document:

Word or Acronym	Definition
Competent –	When a person is qualified (either by experience, training or both) to carry out the task(s) he/she has been assigned.
Training Form –	The method in which trainees may document the completion of a task in a training form dedicated to this purpose through the use of the electronic signature.
Computer-Based Training (CBT) –	A method in which training is delivered via electronic format with trainee interaction. Trainees are not required to demonstrate the tasks or procedures, but rather demonstrate an understanding and competence of the material presented.
Control Document Training (CD) –	A method of training in which the trainee may complete the given assignment unassisted from a subject matter expert.
Curricula –	Related training items grouped according to the subject matter (e.g., department, position, task, product, job function, skill, etc.) that are assigned to a Training User Group or Training Role.
Instructor-Led Course (ILC) –	A method of training in which that is delivered by a subject matter expert to introduce or review a concept, theory or process. Trainees are not required to demonstrate the tasks or procedures, but rather demonstrate an understanding and competence of the material presented. ILC may be delivered one-on-one or with multiple trainees in attendance.
Learning Objective -	A description of a performance you want learners to be able to demonstrate before you consider them competent. The purpose of objectives is to tell the trainees what they will know or be able to do when they have finished the training course.
On-the-Job Training (OJT) –	A method of training that is delivered in a normal working situation, using the actual tools, equipment, documents or materials that will be used training is complete. OJT requires the trainee to demonstrate the tasks or skills in which training was covered.
Required Training –	Defines the minimally required training for the execution of a specific function or task for the associated Training User Group.
Trainer –	Individuals qualified by certification, education and/or experience along with subject matter expertise to facilitate on-the-job or instructor-led sessions.
Training –	The development of skills, knowledge and/or behaviors through instruction and/or practice.
Training Author –	Individuals qualified by certification, education and/or experience along with subject matter expertise to create training content and associated materials.
Training File –	A compilation of the associate's training records and can be maintained either electronically or manually.
Training Plan –	A compilation of all assigned training for a Training User Group
Training Record –	Documented proof that training was completed
Training User Group -	Defines an associate's task-specific function to the business as it relates to training requirements



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5.0 GENERAL REQUIREMENTS-

5.1 Types of Learning Methods

Training requirements shall be determined based on position responsibilities and assigned tasks. Training activities may be delivered in the following four (4) types of learning methods:

- a) *Instructor Led Course (ILC) - Classroom*
- b) *Computer Based Training (CBT)*
- c) *On-The-Job Training (OJT)*
- d) *Document Read (CD) - Self- Training.*

5.2 Types of Training Records Forms

Training records forms shall be used and documented based if is associated to a work order or not. There are two (2) types of training forms:

Original Trainings - Non-Work Order-Related Training Form – Use this type of training record originally when the user will document a training. The Non-work order related trainings are documented using the Training Record Form. Typically, the new hire training or existing resources training taken before start any work order. Refer to Appendix 1. Training Attendance Form

Confirmation Trainings - Work Order-Related Training Form – Use this type of training record to confirm that a particular user took a training. The work order related trainings are documented using the Training sheet located in the corresponding form to document it. Typically, the confirmation of training on existing resources training is defined as Work Order related since it is a refreshing training or confirming that the training material was reviewed since the last time the training was taken. Refer to Appendix 2. – Online Training Confirmation

6.0 TRAINING PRE-REQUISITES

The task procedure or test method procedure to be covered by the training must be completed, approved, effective and released.

The persons involved in this training procedure must complete all its instructions as per:

- a. Responsibilities Procedure.
- b. GDP Good Documentation Practices Procedure.

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7.0 TRAINING REQUIREMENTS TO PERFORM THE TASKS OR TESTING

Training the team is an integral part of ensuring its effectiveness. Training should be appropriately planned to address an operational and testing need with clear and measurable objectives.

The benefits in ensuring that all team members receive the correct training to perform their roles can apply across an entire project, e.g.:

- Trained personnel are more likely to be able to spot potential issues or defects earlier on in the testing life cycle.
- Trained staff are less likely to encounter problems in producing meaningful test cases and test scripts; therefore, minimizing the likelihood of tests having to be re-executed due to test case and test script problems.
- Trained personnel are less likely to encounter problems in determining how activities should be completed during testing cycles.
- The number of avoidable human errors generated across the entire range of testing activities should be minimized.
- Evidence of an effective testing process can give business increased confidence that the product received will be of a high standard and will be fit for its intended use.

All company members should participate, at a minimum, in an induction program, which explains how testing is expected to be performed on a project, as test strategies and supporting processes can vary significantly from one project to the next. Test team members should participate in the induction program even if they have undertaken a testing role before the new project.

Regardless of where testing personnel has been sourced from, all testers must undertake some form of GxP awareness training so that they can understand and appreciate the significance and impact of the work.

8.0 TEST STAFF ATTRIBUTES

Testers should be selected based on their ability to effectively participate in the testing process.

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