

1 Purpose

To provide requirements for management and documentation of training and also to outline recommendations on how the requirements can be met.

2 Scope and Applicability

This Guideline is applicable to all sites, functions and departments undertaking work or providing support services required to meet Good Manufacturing Practice (GMP) and/or Good Distribution Practice (GDP) and/or International Organization for Standardization (ISO) standards. Personnel comprise both internal employees and external contract personnel conducting work in the facilities.

3 Definitions

3.1 Contract Personnel

Contract personnel provide a service or perform a task on behalf of a company and do so within the company facilities, but are not employed by the company itself.

4 Responsibilities

Management is responsible for defining and establishing robust training systems and allocating adequate resources and competency to ensure that the appropriate training is provided, undertaken, and that evidence of this training is properly recorded.

5 Guideline

5.1 Job Description

All employees must have an approved job description defining at least their GMP/GDP accountabilities and responsibilities. Job descriptions can be individual or general, e.g. applicable for a group of persons. Job descriptions must be current and reviewed on a regular basis, for example yearly.

5.2 Training Procedures

There must be written procedures, defining accountabilities and responsibilities for establishing and maintaining systems for training. These procedures must define the requirements and scope of training. It is recommended that the training procedures define elements such as:

- General training plan / training program for individuals or general, e.g. applicable for a group of persons
- Training frequency
- Training assessment
- Training records

5.5.1 Basic Training

Basic training should cover the applicable essential areas of GMP, GDP and/or ISO in theory and practice in order to provide an understanding of how these regulations apply to the pharmaceutical industry and to the business area in which the trainee is employed.

5.5.2 Job Specific / Task Related Training

Job specific/task related training covers the essential GMP, GDP and/or ISO skills related to tasks performed within specific jobs in order to ensure individuals are able to demonstrate practical and competent application of these skills.

5.5.3 Continuing Training

The purpose of continuing training is to maintain and enhance current GMP, GDP and/or ISO awareness, knowledge, know-how and best practice for the appropriate personnel, concerning new or changed regulations, regulatory guidance or current initiatives.

5.5.4 Refresher Training

Refresher training is repeated training to ensure that the required level of knowledge, awareness and competence is maintained. The need for refresher training should be assessed on an individual basis to a time scale defined by the site/function, e.g. a defined period of time since last performing a task or tasks. It is recommended to provide refresher training on a regular basis, for example yearly.

In addition, certain incidents might warrant the need for refresher training, e.g.:

- A compliance weakness/breakdown, such as a quality incident, deviation, procedural failure
- An adverse trend is detected
- An extended absence

5.6 Identifying Needs for Training

The needs for training must be regularly evaluated. Areas to consider in such evaluation should include:

- New or revised global or local procedures (which should identify the scope of training required)
- Review of inspection outcomes
- Changes to facilities, processes, systems, etc.
- Changes within organization and/or teams
- Recurring problems
- Quality incidents or findings

The areas to be considered should be based on the responsibilities of a person or