Procedure: Training, Awareness and Competency

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This procedure is based on ISO 13485 clause 6.2.2. It assumes that general training is provided by Human Resources, while specific skill and operator training is provided within the work environment. Note, a written procedure for training is explicitly required in CFR 820.

# Purpose

This procedure describes a system, provides instructions and assigns responsibilities for identifying training needs, providing the necessary training and awareness programs and maintaining training records.

# Scope

The scope of this procedure includes all training and awareness programs at [Company].

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| All personnel |  |
| Training Manager |  |
| Human Resources Manager |  |

Amend roles and responsibilities as applicable for your company processes and structure.

# Procedure

## General

The objectives of the training program are to ensure that:

* employees possess the necessary knowledge and competencies to perform their assigned tasks
* they are familiar with relevant requirements of the quality system pertaining to their job functions

Awareness programs focus on:

* understanding the importance of customer requirements
* the relevance of an individual’s contribution to meeting requirements
* achieving the company’s quality policy and objectives

Employees are made aware of the types of device defects which may occur from the improper performance of their specific jobs.

The last sentence (above) is a direct quote from CFR 820.25(1).

## Competence and training requirements

This section is based on ISO 13485 clause 6.6.2(a) and CFR 820.25(b). The former identifies the need to determine the necessary competences for each task and the latter requires that training needs be identified. This procedure is sufficient for a smaller company but may require expansion for a larger organisation (it does not define any methods for identifying training needs).

If the company has more specific procedures, document it in this section. It can include qualification and experience requirements for vacant or new positions, employee performance evaluations, operator certification programs, etc.

Training and awareness programs are provided to all employees, regardless of their function or position. Programs include orientation, rules and regulations, quality systems, safety and other company-wide systems. The Human Resources department is responsible for determining requirements and identifying training and awareness needs for company-wide programs.

Departmental training is focused on the skills required for employee to perform their assigned tasks, e.g. operate equipment, run processes, inspection and testing, analytical/statistical techniques, etc. Departmental managers are responsible for determining competence requirements, identifying training needs and establishing appropriate training programs.

Modify the preceding paragraph to reflect the skills required at the company.

Competence requirements and training needs for specific positions and tasks are defined in the Competence Requirements Matrices maintained by relevant departments.

A Competence Requirements Matrix is not a specific requirement but is useful in identifying a company’s training needs. Similar information may be documented in job descriptions. Edit this clause to reflect the company’s practices (refer also Section 5 of this procedure).

Training needs of individuals are determined on the basis of their education and experience and in light of the tasks they are required to perform. It includes periodic re-evaluation of their competencies and further (re)training if required.

Periodic re-evaluation is not explicitly required but it helps to satisfy the requirement for evaluating the effectiveness of training (refer to the last section in this procedure).

## Company-wide training and awareness programs

Modify this section to suit the company’s practices. Clause 3.3.1 (below) is explicitly required by the standard; all other parts of this section are optional.

### General orientation and quality system training

The Human Resources section provides orientation training to new and existing employees.

Training Depts may provide this function in some companies – amend as required.

This training familiarises staff (and contractors and visitors, if appropriate) with administrative rules, employee programs and benefits, etc. and explains the product, product requirements and the company’s quality management system. The product and quality system training includes -

* product orientation with emphasis on critical quality characteristics and consequences of a failure or malfunctioning of the device
* an overview of the company's quality system
* discussion of the company’s quality policy
* an explanation of how individual employees can contribute to maintaining and improving the quality system
* participation in the employee training is recorded and these records are maintained by Human Resources

### Safety training

Employees are trained in safe work practices, first aid, use of personal protective equipment and emergency procedures, etc. Training records are maintained by Human Resources.

### Use of company-wide systems

Groups of employees are trained in the use of interdepartmental systems such as parts and materials numbering, bar-codes, retrieval and creation of electronic (computer) documents and records. Training is provided by the department responsible for the system and records are maintained by that department.

Name only those examples relevant in the company.

### External training

[Company] has a reimbursement policy for employees participating in seminars, conferences and other forms of external training. Requests for external training are evaluated by Human Resources.

Include details of company requirements or reference appropriate HR documentation describing the reimbursement details.

### Self-study

[Company] encourages personnel on all levels to read professional reports, magazines and books. Requests for magazines and books are evaluated and processed by individual departments. Self-study is considered in formal recognition of skills as an alternative form of training. Where appropriate, self-study is recorded.

Include criteria that describe what can and cannot be recorded as self-study.

## Departmental training

This section can be used as a checklist of items to be addressed. Modify each clause to describe more specifically the practices of the company.

Each department is responsible for providing the necessary training to ensure its employees are skilled, capable and competent to perform their duties.

As part of training, personnel are made aware of the importance of correct performance of their tasks and the consequences of improper actions. Personnel performing verification and validation activities are made aware of the defects and errors that may be encountered.

The above Clause is a requirement of CFR 820. Delete this to comply with ISO 13485 and/or ISO 9001 only.

On-the-job training (i.e. working under the supervision of an experienced employee) must be provided to all personnel performing a new or modified task.

The above clause is referred to as 'grandfathering' and is only relevant on initial implementation of a procedure. Delete this clause later when the system matures and grandfathering is no longer relevant.

On-the-job training is recorded using Form FM601-1: Training Record Form including:

* the nature of the task
* its scope
* duration
* the success, or otherwise, of the training
* name and signature of the person supervising the training

Alternatives to using FM601-1 should be detailed.

Production, materials handling, packaging, shipping and other personnel who handle products may only be assigned to those tasks for which they have been formally trained. Relevant departments maintain a Personnel Qualification Matrix documenting which employees are trained for which tasks (refer Section 4.5 of this procedure).

The goal is to train employees in a range of tasks to provide maximum flexibility of staff deployment. Personnel training records are maintained by the Human Resources department.

Quality Control inspectors are trained, as appropriate, in calibration, in use of measuring and testing equipment and in inspection and testing techniques. QA maintains a Personnel Qualification Matrix documenting which inspectors are trained in particular tasks (refer Section 4.5). The company aims to train its QC inspectors in all relevant skills and functions. Training records are maintained by Human Resources.

Experienced employees, who have been performing their functions for at least six months, may have their competence formally confirmed by their supervisor, without further training. This confirmation is documented in writing. As with other training records, this record is maintained by Human Resources.

Employees who fail to perform satisfactorily, or fail the training assessment, are provided with additional or repeat training.

## Competence requirements matrix

A Competence requirements matrix is not explicitly required by any standard. However, it is an effective method for documenting competence requirements for specific positions and tasks. Competence requirements for managerial and "office" positions are better documented in job descriptions.

A Competence Requirements Matrix and a Personnel Competence Matrix should be maintained by departments where personnel perform work affecting product quality. This is especially applicable to manufacturing processes, materials handling, packaging, monitoring, measurement and other functions related to product quality.

A Competence Requirements Matrix lists jobs and positions in each department and specifies education, training and experience requirements.

A Personnel Competence Matrix lists employees in the department and records each person’s competencies (i.e. what tasks each person is qualified to perform). Records are maintained by Human Resources.

The matrices are updated by departmental managers.

## Training effectiveness evaluation

This section identifies several approaches to evaluating training effectiveness. Identify which are appropriate to the company and develop further as required.

Each training session delivered should have documented measurable objectives and should have a systematic method for determining they have been achieved. Evaluation is typically based on follow-up assessment of individual performance and/or analysis of trends in performance.

Consideration should be given to developing a specification sheet for each training presentation defining the objectives, scope, form, duration, etc. and a method for evaluating its effectiveness.

The following methods and approaches are used for evaluating the effectiveness of training provided:

Delete any that are not appropriate.

### Follow-up evaluation of individual employees

Following training, employees are evaluated by their supervisors to assess whether the particular training has achieved its objectives and whether the employee is sufficiently competent in the new skill. Results of this evaluation are recorded and are kept together with the original training record.

The original training record may have an additional column for the follow-up evaluation sign-off.

### Review performance in areas related to particular training

When groups of employees are trained in safety, emergency procedures or interdepartmental systems, training can be evaluated by comparing statistical performance data from before and after the training, e.g. effectiveness of safety training can be measured by tracking rates of work-related accidents.

### Correlation of training with non-conformities and system failures

Training and competency are considered when investigating causes of non-conformities. If inadequate training is identified as a cause, determine which areas of training are deficient. Training must then be reviewed and improved, as appropriate, and staff retrained with the revised presentation.

### Global evaluation of training by management review

Training and awareness programs and their effectiveness are evaluated by management reviews. This includes presentation and discussion of data correlating quality performance in particular areas with specific training and awareness programs. Procedure QP501: Management Review, defines this process.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP501 | Management Review |
| FM601-1 | Training Record Form |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
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List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

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