Procedure: Training, Awareness and Competency

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# Purpose

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

# Scope

The scope of this procedure includes all training and awareness programs for all operations relating to the development, manufacture, packaging, testing, dispatch and after-sales care of products covered by the [Company] Quality Management System (QMS).

# Responsibilities

Amend this section to reflect the organisational structure in your company

|  |  |
| --- | --- |
| Role | Responsibility |
| Managing Director | Ensures appropriate communication processes are implemented throughout [Company]. |
| Quality Manager | Maintains the storage and control of training records. |
| Managers | Ensures all staff and contractors are trained and have the appropriate combination of education, training and experience to competently perform the tasks assigned to them; and that they have an up-to-date training record. |
| All employees | * Ensure they have full understanding and requisite experiences to competently carry out the tasks assigned to them * Keep their training records up to date. |

# Procedure

## General

The objectives of the training program are to ensure that employees:

* possess the necessary knowledge to perform their assigned tasks
* are familiar with requirements of the QMS relevant 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.

Internal communications are to ensure that product quality and pharmaceutical quality system issues are escalated to appropriate levels of management in a timely manner.

## Training records

Employee training is recorded in Form FP601-3: Individual Training Record. Participation by the employee in group training may first be recorded in Form FP601-2: Training Course Record. These records are stored centrally and maintained by the quality manager according to Procedure QP403: Control of Records.

## Competence and training requirements

### Awareness programs

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

### Training

Training is focused on the skills required for employees to perform their assigned tasks, e.g. operate equipment, run processes, carry out inspection and testing, analytical/statistical techniques, etc. Individual managers (including the Managing Director) are responsible for determining competence requirements, identifying training needs and establishing appropriate training programs.

Competence requirements and training needs for specific positions and tasks are defined in the Form FP601-1: Competency Requirements Matrix.

Training needs of individuals are determined on the basis of their education, skills and experience and in light of the tasks they are required to perform. Re-evaluation of competencies is to be undertaken at least annually.

### Internal communications

A system of internal communications is provided to ensure that the flow of information throughout [Company] is timely and effective.

## Awareness programs

The Managing Director provides orientation training to all new and existing employees and contractors. This training explains:

* background to and objective of the company
* the company’s administrative arrangements, safety requirements and facilities
* the company’s products and processes with emphasis on critical quality characteristics and consequences of a failure
* an overview of the company's QMS
* discussion of the company’s quality policy
* an explanation of how individual employees can contribute to maintaining and improving the QMS

### Safety training

Employees are trained in safe work practices, use of personal protective equipment and emergency procedures, etc.

### Use of company-wide systems

Groups of employees are trained in the use of interdepartmental systems such as parts and materials numbering, retrieval and creation of documents and records. Training is provided by the person or department responsible for the system.

### External training

[Company] may provide resources such as leave, costs and travel facilities for employees to participate in seminars, conferences and other forms of external training. Requests for external training are evaluated by the Managing Director.

### Self-directed study

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

## Training

Personnel only undertake those tasks for which they have been trained and have sufficient education and experience.

All training is recorded. Each person has an individual training record.

Managers are responsible for providing the necessary training to ensure personnel are skilled, capable and competent to perform their duties.

Training is undertaken in a variety of ways:

* On the job training
* Classroom style sessions
* Individual reading.

### On the job training

When practice is required to ensure staff are competent, they work under the supervision of an experienced staff member.

On-the-job training is recorded 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.

The company maintains individual training records documenting which employees are trained for which tasks (refer Section 4.6 of this procedure).

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 on their training record.

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

## Competence requirements matrix

The company’s Competency Requirements Matrix is to be maintained. This is especially applicable to manufacturing processes, materials handling, packaging, monitoring, measurement and other functions related to product quality.

Form FP601-1: Competency Requirements Matrix lists jobs and positions in each department and specifies education, training and experience requirements.

Form FP601-3: Individual Training Record when completed lists each person’s competency description and what training is required (and has been undertaken) to fulfil this competency.

The Competency Requirements Matrix is maintained by department managers. Individual training records are maintained by each employee.

## Training effectiveness evaluation

The following methods and approaches may be used for evaluating the effectiveness of training provided.

|  |  |
| --- | --- |
| Training Evaluation | Description |
| 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. |
| 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. |

## Internal Communication

A system of internal communication is to be set up to ensure:

* all levels of the company are kept regularly informed and briefed on pharmaceutical quality issues
* all company personnel can effectively escalate product quality and QMS issues to the appropriate manager in a timely manner.

This may include the use of the corrective and preventative action process Procedure QP809: Corrective and Preventative Action.

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 |
| QP403 | Control of Records |
| QP501 | Management Review |
| QP809 | Corrective and Preventative Action |
| FP601-1 | Competency Requirements Matrix |
| FP601-2 | Training Course Record |
| FP601-3 | Individual Training Record |

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

| Associated records | |
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| 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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