

Quality System Procedure
Training Program



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1 Purpose

This procedure describes how:

- to get and/or maintain competent employees at the level required to adequately perform their assigned responsibilities within the organization,
- to develop the skills of individuals so they can perform their roles effectively and efficiently,
- training needs are identified, either by the organization, projects or individuals, and the way to fulfil the training needs.

2 Scope

This procedure is applicable to all permanent and temporary employees, including contractors and consultants, within the organization that perform work affecting product quality and/or have assigned responsibilities within the organization’s Quality Management System (QMS). The training program covers all activities related to the identification of required competence and the way the required skills, technical and non-technical, are trained. Identification of training needs, training and training registration is an ongoing activity.

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3 Responsibilities

QMS Role	Responsibilities
Employee	Complete assigned training by indicated due date or before independently executing a process.
People Manager *	<ul style="list-style-type: none"> Correct execution of this procedure, both for permanent as well as temporary employees. Select employees that are qualified for the role(s) the employee will be assigned to, by considering the employee's work experience, education and training completion in relation to the assignment given. Ensures (QMS) responsibilities are identified and transferred when employee changes positions or leaves the organization and any related trainings are put in place.
Process Owner	Develop learning material (if applicable).
Quality Systems Engineer (QSE)	<ul style="list-style-type: none"> Maintain QMS training allocation requirements and roll-out of these trainings. Responsible for QMS-role allocation for employees that have managers outside the scope of the organization. Maintain Person-Role-Task Assignment in the organization's electronic Training Management System (eTMS). Work with the Process Owner to confirm QMS role definitions in eTMS.

* Note: This is not a QMS role. Typically a department manager, but may also be an assigned other person (supervisor, functional manager) who manages people or performs certain tasks of this procedure.

4 Definitions and Acronyms

4.1 Definitions

Term	Definition
Not applicable	Not applicable

4.2 Acronyms

Short	Long
eDMS	electronic Document Management System
eTMS	electronic Training Management System
PRT	Person Role Task (Matrix)
TSA	Training System Administrator

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5 Procedure

The procedure starts with the definition of the requirements and ends with the registration of the training status. During the process of resource planning within the organization, training needs are identified for permanent and temporary employees (e.g. hired employees such as contractors and consultants). The training requirements of hired employees are established by the organization and the organization's hiring people manager assures the hired employee meets these.

The identified training shall be provided, their effectiveness shall be evaluated and records of training shall be maintained.

The organization can utilize two primary training management mechanisms:

1. Person Role Task Matrix

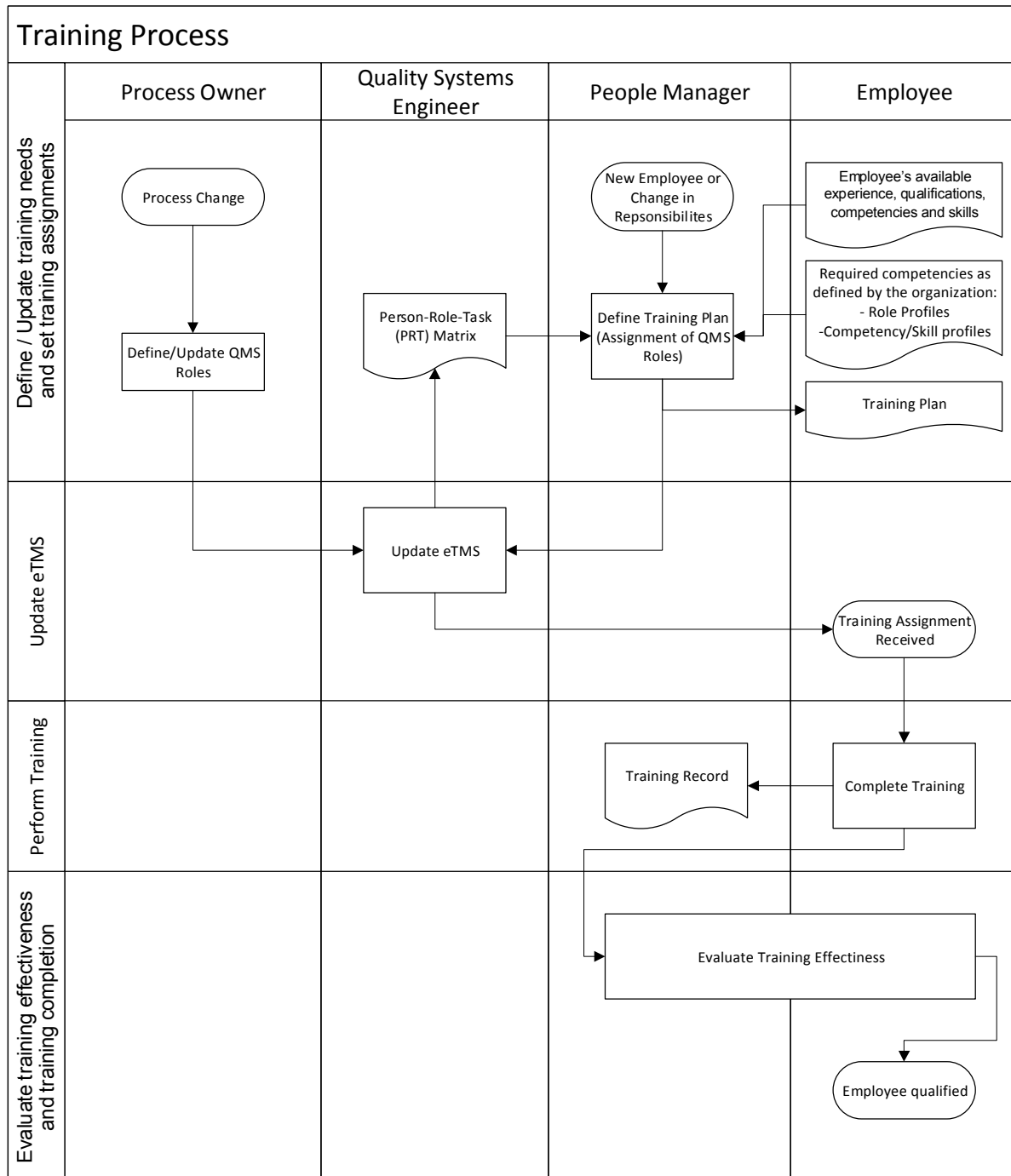
The Person Role Task Matrix (PRT) is used to assign each employee to one or more QMS roles (depending on the employees responsibilities under the QMS). A QMS role contains the training activities (referenced to as "tasks") that the employee needs to fulfill/complete in order to be qualified to the role.

2. Training Plan / To-Do List

The training plan [0810-01-T1] is a possible supplement to the PRT. It covers all those qualifications that are not covered by the PRT, such as individual development. This plan is also the suggested place to document training and other learning objectives that are not in scope of the organizations QMS. An alternative to the training plan can be the organization's human resource management year-cycle for training need discussions between People Manager and employee.

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5.1 Define/Update training needs

5.1.1 Process Owners

Training on QMS documentation is determined and maintained per QMS role by the applicable Process Owner. These QMS roles with the associated QMS documentation are identified in the Person-Role-Task matrix.

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5.1.2 People Managers

People Managers must ensure that training needs are identified and training is assigned for all of their employees, related to their assigned responsibilities. This assessment shall be repeated when changes in assigned responsibilities occur and periodically repeated to ensure that all their employees maintain or develop the required competences.

For new employees, it is advised that a training plan is documented which provides an overview of all identified training needs. If such a training plan is made it shall be archived in eDMS.

For employees changing position or leaving organization, ensure all responsibilities are identified and transferred, taking into account any training needs of employees assuming the additional/new responsibilities. Attention should also be given to QMS related responsibilities. The QMS Responsibilities Transfer Checklist [0810-01-C1] can be used as a guidance to ensure the employees QMS responsibilities are reviewed.

The people managers use the Person-Role-Task matrix (PRT) to assign applicable QMS roles to their employees and review these QMS role assignments on a regular basis. Refer to the guidance document on Review of QMS Role Assignment [0810-01-G1].

When a People Manager is unfamiliar with organization's QMS, the Quality Systems Engineer shall ensure that role assignment takes place by someone who can replace the People Manager for this task. For instance in the case of the Management Team this can be done by the Q&R Manager. The Quality Systems Engineer is responsible for the Person-Role-Task matrix maintenance, and that review by the People Managers and approval by the Q&R Manager(s) is performed.

The following inputs are used to determine the training needs:

- Competencies required for the assigned responsibilities and related to the activities that are performed by an employee in specific role(s). The required skills for the assigned responsibilities are derived from:
 - the technical and non-technical skills required by the organization
 - the roles identified in the organization's QMS
 - findings during monitoring of processes and audits.
- Employee's competencies that are already gained in the past by training or experience.
- Specific skills required for execution of a project shall be identified based on the project scope. The Project Manager shall document the specific skills required in the project plan and shall request the applicable people managers to provided qualified employees that are competent to fulfil the assigned responsibilities. The people manager shall determine if competent personnel is available, plan to get competent personnel and/or if necessary assign required training.
- If applicable, training defined by the Philips organization and/or local site requirements such as:
 - Customer feedback procedures,
 - Site safety procedures.

Based on the training needs identified, the People Manager shall select appropriate training. Training may be performed in different ways e.g. classroom training, self-study of training material, on the job training, mentoring/coaching, and computer aided instruction.

Based on the identified training needs and method selected, the People Manager assures training assignment takes place:

- For training which is identified via the Person-Role-Task matrix, the Quality Systems Engineer will ensure assignment in the organization's electronic Training Management System (eTMS).

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- Depending on the selected training method, other training assignments are placed by e.g. registering for a course or e-training, entering an employee for classroom training, requesting an account and associated training for a tool.

5.2 Update Training Management System

For training which is identified via the Person-Role-Task matrix, the Quality Systems Engineer will ensure assignment in the organization's Training Management System (eTMS).

5.3 Perform Training

The employee is responsible to plan, if applicable attend and complete the training by assigned due date.

A training record shall be generated and archived. For training completed in eTMS a training record is generated and archived in eTMS. If the Training Completion Form [0810-01-F1] is used as record, it shall be signed with date and archived in eDMS. The people manager verifies whether the training completion has been registered and the applicable training record is archived.

5.4 Evaluate Training Effectiveness

The methodology used to check effectiveness shall be proportionate to the risk associated with the work for which the training or other action is being provided. If training needs are not met, additional action is required. Training effectiveness is evaluated by the organization at several levels on a direct and indirect basis:

1. Evaluation by people manager
The employee and people manager shall evaluate training effectiveness in relation to the required skills and determine whether the training need is met.
2. Evaluation by exam or quiz
The process owner may develop an exam, that an employee has to pass prior to getting training participation recognized in their training history record. This could be a written (proctored) examination, an electronic quiz after working through training material, an oral examination by a qualified trainer/colleague or any other appropriate method. The criteria for passing the exam are defined by the process owner.

Indirect evaluation by audit results

The organization evaluates all findings and recommendations received from internal and external audits. If such results indicate that an audit finding or recommendation originated from the non-proper execution of a process rather than from insufficient process content, this is understood as a weakness of the training delivery chosen. In such case additional measures are taken to resolve the lack in training effectiveness.

5.5 Training Completion

Assigned training must be completed before related activities are performed. If the assigned training is not completed:

- the employee shall work under supervision of a peer/mentor who is trained and qualified for the assigned responsibilities; or
- the work product of the non-trained person shall be checked/approved by a person who is qualified for the assigned responsibilities.

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Training completion means that the employee understands the key concepts of the assigned responsibilities, is ready and able to perform required activities and has closed the training gap for the subject. If applicable for the role this includes also awareness of:

- Product defects which may occur from improper performance of a specific role,
- Product defects likely to be encountered by personnel performing verification and validation activities, and
- Employee's contribution to the Quality Objectives when performing work affecting quality and compliance.

6 Records

Record Name	Description
Person-Role-Task Matrix	Overview of person-role assignment of all employees within the organization and overview of task-role assignment for all QMS roles
Training Plan	Identifies training needs for employee (optionally documented in (0810-01-T1)
Training (History) Record	Record of training history completion
Training Completion Form	Record of training completion (0810-01-F1)

7 References

Reference Number	Description
0810-01-G1	Review of QMS Role Assignment
0810-01-C1	QMS Responsibilities Transfer Checklist

8 Document History

Revision	Description of changes
1.0	Initial release
2.0	Administrative changes
3.0	<ul style="list-style-type: none">• Transferred procedure content to new template 0730-01-T1 (Rev 2.0).• Updated title from "Training Program" to "Training Process".• Section 3, added requirement for employee selection. Added responsibility for Process Owner and QSE.• Updated flow chart and reorganized chapters to match flow chart.• Section 5.1.2 updated "Introduction Plan" to "Training Plan" and removed reference to the Personnel procedure.• Section 5.4 updated training effectiveness to be proportional to risk and added direct and indirect evaluation levels.• Section 5.5, added that employee should be aware of Quality Objectives if applicable.• Aligned with ISO 13485: 2016.

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Revision	Description of changes
4.0	<ul style="list-style-type: none">Updated title from “Training Process” to “Training Program”.Editorial corrections made.Removed reference to 0730-02-P since it’s not referenced in the procedure.Added information for the transfer of QMS responsibilities when employee leaves postion or organization.Implemented CR598 to add QMS Responsibilities Transfer Checklist.

9 Document Control

Process	Owner(s)
Approval	Quality & Regulatory Manager
Review	Quality System Engineer Department Manager Human Resource Manager
Author	Daniela Mlcouskova
Approval date	See eDMS
Effective date plan	Standard

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