[Organization logo]

[Organization name]

PROCEDURE FOR HUMAN RESOURCES

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Date	Version	Created by	Description of change
	0.1	Advisera	Basic document outline

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1. Purpose, scope and users

The purpose of this Procedure is to define need, planning, methods for training and assessment of training results in order to provide competent employees whose work influences quality and effectiveness of documented processes and realization of quality objectives.

This Procedure is applied to all processes and/or areas (parts of organization) within the QMS (Quality Management System) according to ISO 13485:2016.

A user of this document is [management representative] of [organization name].

> **Commented [AES4]:** This can also be CEO, Head of HR department, etc.

> **Commented [AES5]:** Include the name of your organization.

2. Reference documents

- ISO 13485:2016 standard, clause 6.2
- MDR 2017/745, article 10(9) and Annex IX – Chapter I
- Quality Manual

> **Commented [AES6]:** Delete this if your organization does not need to be complaint with MDR.
>
> You can find the full text of the MDR on the following link https://advisera.com/13485academy/mdr/

> **Commented [AES7]:** You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "03_Quality_Manual".

3. Planning and conducting training

3.1. Defining and providing human resources

[HR department together with department heads] define all working positions, number of employees needed for every work position and their competence based on appropriate education, training, skills and experience.

[HR department] forms a document [name of document] that contains above mentioned data.

> **Commented [AES8]:** Adapt to organization practice.

> **Commented [AES9]:** Adapt to organization practice.

> **Commented [AES10]:** This can be "Working Place Requirements", "Job Description", "Competence Requirements", or other document in which organization defines requirements for competence.

3.2. Defining need for training

The purpose of this activity is to define the gap between existing and required competence of employees, and necessary training to overcome this gap. [Job title] is responsible for conducting this activity and to define need for training according to:

- Organizational or technical change that influences working processes or types of products that the organization delivers
- Effectiveness records of previous or current trainings
- Assessment of organization about competence of employees to perform specific work tasks
- Records about change of skill needed or seasonal fluctuation of labor force (temporary employees)
- Internal or external certification, needed for performing specific work tasks
- Requirements of employees who identified a possibility for personal improvement that contributes to the quality objectives of the organization
- Legal and regulatory requirements

> **Commented [AES11]:** This can be HR Manager, process owner, CEO, or similar, for example.

> **Commented [AES12]:** For example, when organization introduces new product or process.

> **Commented [AES13]:** If records show that previous trainings did not have desired result.

> **Commented [AES14]:** This should be deleted if organization does not have employees.

> **Commented [AES15]:** This should be deleted if such certificates do not exists.

- Market survey that identifies and forecasts new customer requirements, and therefore new skills that need to be trained for

3.3. Training planning

According to defined needs for training, [job title] creates a Training Program, which is approved by [job title].

Commented [AES16]: This can be HR Manager, process owner or CEO.

Commented [AES17]: This is usually CEO.

Commented [AES18]: E.g., HR Manager, process owner or CEO.

While planning the training, [job title] must consider limitations that may affect the training process, such as deadlines and schedules, financial resources, availability of trainees, motivation and capability of trainees, availability of trainers and limitations regarding other resources.

3.4. Defining objectives and organizing training

[Job title] defines the training objectives and enters them into the Training Program. Defining objectives and organizing training are done considering the following:

Commented [AES19]: E.g., HR Manager, process owner or CEO.

- Expertise and competence of employees, education, need for additional training and specific knowledge and experience
- Results of previously conducted trainings
- Special requirements of clients
- Competence testing of individuals to perform specific work

3.5. Conducting training

[Job title] organizes and coordinates the conducting of training according to the approved Training Program. Training can include taking courses outside the organization and in-house training and can be performed by experienced workers within the organization.

Commented [AES20]: E.g., HR Manager, process owner or CEO.

After completion of each training, [Job title] creates a Training Record, or for trainings that don't require follow-ups, fills in the Record of Attendance.

3.6. Assessing training effectiveness

This can be conducted by trainers (confirmation or certificate if training was outsourced), or [job title] based on monitoring and interviewing trainees.

Training effectiveness is the ratio between realized and planned activities during training.

Commented [AES21]: Other criteria can be e.g. ratio of trained staff, successful use of the training tool in their number of trainees, or number of employees who attained each gained working capacity, or other criteria which organization finds relevant describing its training objectives.

[Job title] enters results of the assessment into the Training Program.

The employee assessment sheet in the Training Record contains all duties, knowledge, awareness, and aspects that are necessary for fulfilling the job position. [Job title] is responsible for maintaining these records.

Commented [AES22]: E.g., Department Manager, HR Manager, Department Director.

[Job title] must ensure that employees meet the requirements to perform the particular job.

Commented [AES23]: E.g., Department Manager, HR Manager, Department Director.

4. Managing records kept on the basis of this document

Record name	Code	Storage		Responsibility
		Retention time	Location	
Training Program	PRO5.1	2 years	[Office of Management Representative]	[job title]
Training Record	PRO5.2	2 years	[Office of Management Representative]	[job title]
Record of Attendance	PRO5.3	2 years	[Office of Management Representative]	[job title]

> **Commented [AES24]:** If the record is in electronic form, write the name of the folder in the appropriate location field.

5. Appendices

- Appendix 1 – Training Program
- Appendix 2 – Training Record
- Appendix 3 – Record of Attendance

[job title]
[name]

_____

[signature]

> **Commented [AES25]:** Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.