

Medical Company	Human resources management and training	Doc. nº: SOP-01 Rev: 1.0 Date: 03-APR-2025
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Human resources management and training

1 Introduction

1.1 Document objective

The present procedure aims to define the rules in terms of staff management to ensure the right level of collaborators skills, adequate awareness and appropriate training.

1.2 Scope

This procedure applies to all employees of the company including, when relevant, interns and trainee. It describes the process to hire an employee and to define the training needs of the staff.

1.3 References

EN ISO 13485:2012 Medical devices QMS — Requirements for regulatory purposes

1.4 Responsibilities

The resource management process is owned by the Human resources Manager (HRM). He/she has the responsibility to ensure:

- That competence and resources are hired as needed for the company
- Training needs are identified and addresses
- Yearly evaluations are conducted for all employees

1.5 Related Documents

FOR-01 - Employee evaluation

FOR-02 - Job description

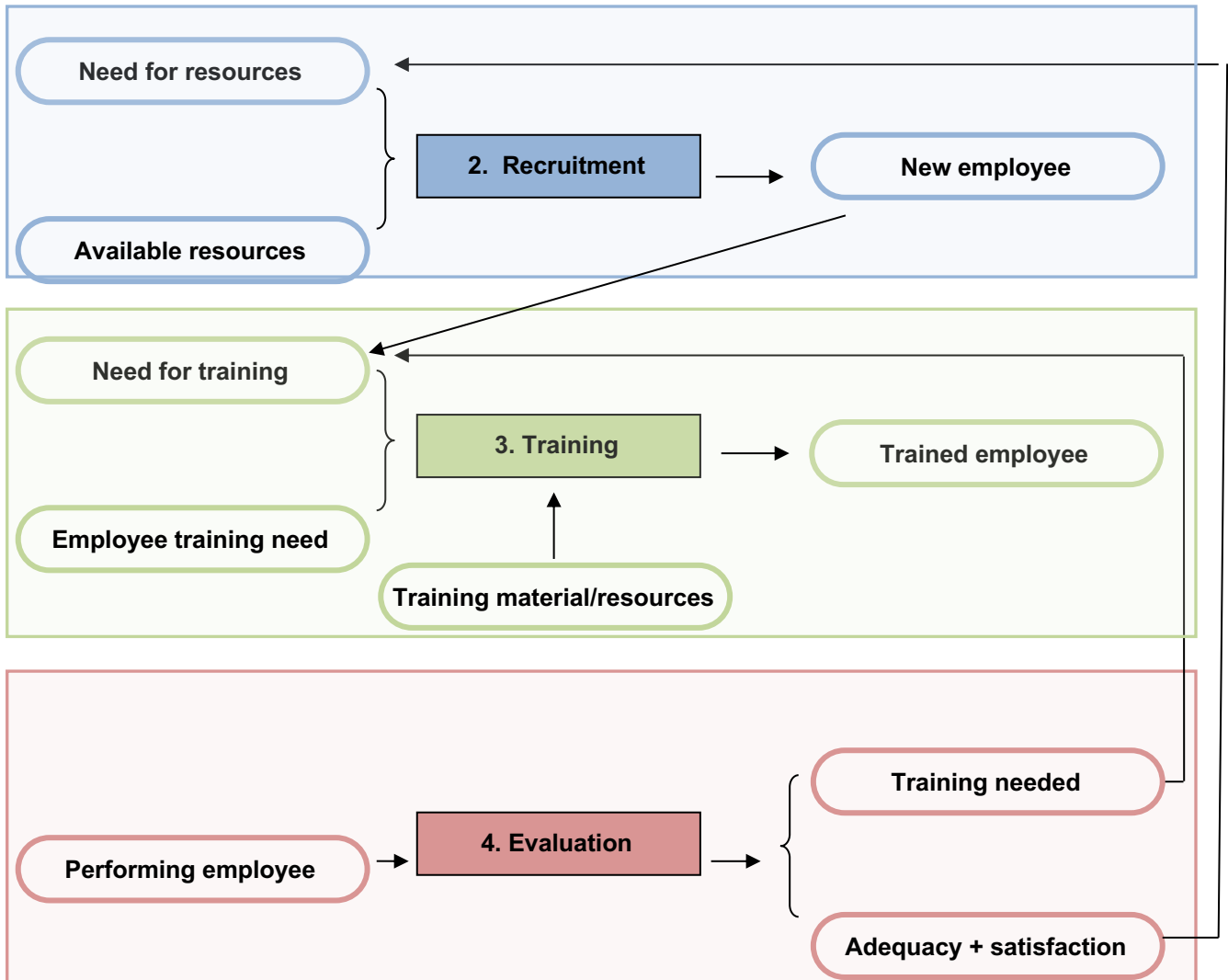
FOR-03 - Training record

TMP-01 – Working contract

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2 Overall human resource management

The schematic below illustrates the overall management of human resources. This process consists of three key sub-processes: recruiting new personnel as needed, providing training to maintain the required level of competence, and evaluating employees to identify opportunities for improvement and growth.



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3 Recruitment

#	What	Who	Detail	Document
1	Trigger: expressed need	Manager	Resource / competence need is identified by a manager. It is communicated to the HRM.	N/A
2	Identify needs & provide resources	Manager	The competences and qualifications needed are defined. They are documented in the job description.	<u>FOR-02 - Job description</u>
3	Identify candidates	HRM	Identify potential profiles using regular channels. (e.g. word-of-mouth, advert, agency, etc.)	<u>FOR-02 - Job description</u>
4	Select candidates	HRM	Based on received application files, select potential candidates.	Application files
5	Interview candidates	Manager / HRM	Interview selected candidates.	N/A
6	Choose the candidate	Manager / HRM	Best profile should be selected and hired.	Working contract
7	Evaluate training needs	Manager / HRM	Evaluate the necessary training to be performed as soon as the new employee arrives.	N/A
8	Prepare (for) arrival	HRM	Inform staff to prepare all relevant equipment & documents needed for day 1 (e.g. office, software, accesses, etc.)	N/A
9	Training on Quality Management System	Quality Manager	During the first days, the new employee must be trained on the Quality Management System. The training shall be recorded.	<u>FOR-03 - Training record</u>

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4 Training

#	What	Who	Detail	Document
1	<div>Trigger: identified training need</div> <div>↓</div>	Manager	Identify employee needs for training. Min. once a year, review each employee's skills / capabilities with the requirements of the tasks actually performed and the ones expected in a near future, i.e. evolution of job and company's activities. Compare employees' evolution perspectives & desires with company's evolution & goals.	N/A
2	Evaluate relevance for employee's + company's evolution	Manager	Verify the training is necessary and/or it benefits the company.	N/A
3	Identify training method	Manager	Once training relevance is established, defined how training will be performed (by internal or external provider, online, etc.)	N/A
4	Plan training	Manager	Plan the training	N/A
5	Perform training	Employee	The training is performed	N/A
6	Log training	CEO or manager	Once the training is performed, record it in the employee training record.	Employee's file <u>FOR-03 - Training record</u>
7	Verify training efficacy	CEO or manager	If possible and applicable, verify the training efficacy (internal audit, interview, evaluation, etc.)	<u>FOR-03 - Training record</u>

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5 Evaluation

#	What	Who	Detail	Document
1	Trigger: yearly assessment meeting or intermediate evaluation	All	A performance evaluation should be realized once a year or when: <ul style="list-style-type: none"> One or more critical mistake(s) have been made by an employee An employee performances evolution is subject to questions, concerns and/or complaints (in quality and/or quantity). An employee requests an intermediate evaluation. 	N/A
2	Collection of facts/preparation of interview	Manager	Manager collects tangible facts & figures about employee (e.g. performances / contribution, number of training hours, training budget, etc.)	N/A
3	Perform the evaluation	Manager / Employee	Perform the evaluation. Share facts & figures with the employee. Collect information from employee.	<u>FOR-01 - Employee evaluation</u>
4	List of improvement opportunities	Manager	List the improvements that would benefit to the company's performances & sustainability.	N/A
5	Identify solutions/bridge gap(s)	Manager / Employee	Identify potential solutions able to improve negative outcome if any.	N/A
6	Issue report	Manager	The agreed actions shall be documented in the employee evaluation form, to be signed by the 2 parties involved.	<u>FOR-01 - Employee evaluation</u>
7	Implement improvement	Employee	The agree actions are implemented by employee and reviewed at the next follow up	N/A
8	Follow up	CEO or manager	Regularly follow-up on decided actions and reevaluate if needed.	N/A