




	HUMAN RESOURCES	SOP-101
		Rev. E

## APPROVAL

Role	Name	Function	Signature
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Approval	Mathieu Horras	CEO	

## PURPOSE

This document outlines the human resources process at ASPIVIX, ensuring that each employee is fully aware of their responsibilities and receives the necessary training. All required training sessions are carefully planned, executed, and evaluated for effectiveness.

## SCOPE

This procedure applies to all ASPIVIX employees, both full-time and part-time.

The definition of responsibilities for various positions, required qualifications, and the organizational structure are outside the scope of this document. These details are provided in individual job descriptions and the organization chart.

## RESPONSIBILITIES

The Head of Human Resources, who also serves as ASPIVIX's CEO, is responsible for the establishment, implementation, and ongoing maintenance of this SOP.

Line Managers and/or the Regulatory Affairs and Quality Management (RAQM) team are tasked with ensuring that each collaborator receives the necessary training to effectively perform their responsibilities.

## DOCUMENT HISTORY

Description of Changes	Version
Initial version	A
Add associate appraisal form + employee appraisal on a quarterly basis + new training plan & records + T-101-11 attendance sheet	B
Add INS-101-5 PRRC + T-101-12 + T-101-13 appointment PRRC	C

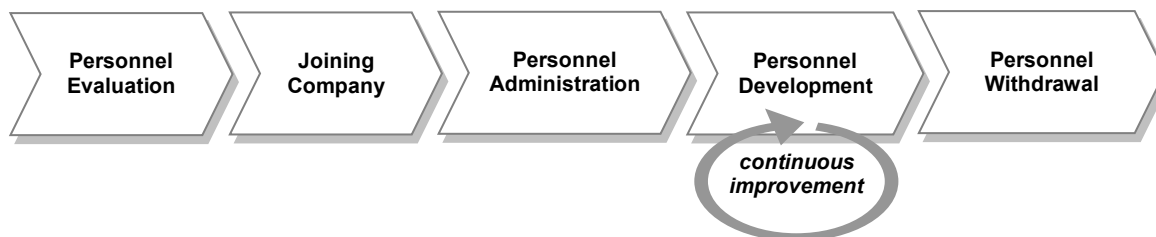
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Update of employee appraisal to an annual basis (section 2.2) & enhancement to improve clarity of text	D
Remove T-101-9 as it has been replaced by Odoo, T-101-8 and T-101-11. Clarify that external training shall be captured in T-101-2 Training Plans & Records	E

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## 1 PROCEDURE FLOWCHART



## 2 PROCEDURE DESCRIPTION

### 2.1 PERSONNEL EVALUATION

✈ Activity	† Resp.	✂ Documents
<ul style="list-style-type: none"> <li>Create job description according to:               <ul style="list-style-type: none"> <li>input from general management and line manager,</li> <li>input from necessary competence for personnel performing work affecting product quality</li> </ul> </li> <li>Start search for new staff</li> <li>Pre-evaluation based on CVs</li> <li>Interviews and tests (if applicable)</li> <li>Decision</li> <li>Providing and signing of contract (including but not limited to confidentiality and non-competition)</li> <li>Create staff dossier and archive documents (contract, CV...)</li> </ul> <p>One role in the company requires a specific evaluation/verification process: The Person Responsible for Regulatory Compliance (PRRC) under the EU Medical Devices Regulation 2017/745 (Article 15). Refer to the instruction INS-101-5 PRRC to identify the requirements and the tasks of the PRRC and the interfaces with other Aspivix SA processes.</p> <p>Appointment of the PRRC is required as well as PRRC deputy.</p>	HR	T-101-5 Job Description  Employment contract Personnel dossier  INS-101-5 PRRC  T-101-12 Appointment PRRC T-101-13 Appointment PRRC deputy

Note: Outsourcing some activities such as first part of the hiring process (candidates' selection) or payroll is possible.

### 2.2 JOINING OF COMPANY

✈ Activity	† Resp.	✂ Documents
<ul style="list-style-type: none"> <li>Update organizational chart (if necessary)</li> <li>Plan and conduct appropriate trainings</li> <li>Provide work instructions / guides for employees (*)</li> <li>After qualifying period (3 months): First appraisal interview and evaluation of training needs and/or performed.</li> <li>Appraisals are conducted on an annual basis</li> </ul>	QA	T-101-1 Personnel Introduction T-101-2 Training Plan T-101-10 Associate appraisal Form

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⚡ Activity	👤 Resp.	📄 Documents
<p>(*) the following instructions explain ASPIVIX SA's internal rules for the respective activities:</p> <ul style="list-style-type: none"> <li>- <b>INS-101-1 Employee Rules &amp; Regulations Guide</b></li> <li>- <b>INS-101-2 Expense Reimbursement Guide</b></li> <li>- <b>INS-101-3 Expense Form Guide For Corporate Cards</b></li> <li>- <b>INS-101-4 Travel Business Expense Policy</b></li> </ul> <p>Related forms for such activities are the following:</p> <ul style="list-style-type: none"> <li>- T-101-6 Expense Report Form</li> <li>- T-101-7 Leave Request Form</li> </ul>		

## 2.3 PERSONNEL ADMINISTRATION

⚡ Activity	👤 Resp.	📄 Documents
<ul style="list-style-type: none"> <li>- Pay salaries, expenses, social security, insurances etc. as applicable</li> <li>- Conduct mutations (e.g. name change due to marriage etc.)</li> </ul>	HR	T-101-1 Personnel Introduction (Checklist for review)

## 2.4 PERSONNEL DEVELOPMENT

⚡ Activity	👤 Resp.	📄 Documents
<ul style="list-style-type: none"> <li>- Evaluate training needs</li> <li>- Plan, conduct, record and list trainings / certificates</li> <li>- Verify effectiveness of training</li> <li>- Perform annual performance review</li> </ul> <p><i>Please refer to chapter Training below for details.</i></p>	QA	T-101-2 Training Plan & Records  Odoo e-learning & survey apps. (INS-300-5- Training Validation Questionnaires)

## 2.5 PERSONNEL WITHDRAWAL

⚡ Activity	👤 Resp.	📄 Documents
<ul style="list-style-type: none"> <li>- Plan leave and succession</li> <li>- Conduct exit interview</li> <li>- Providing a testimonial</li> <li>- For the storage of the personnel dossiers the data safety requirements of the Swiss authorities need to be followed</li> </ul>	HR	T-101-4 Personnel Withdrawal

## 3 TRAINING

The training needs for each employee are determined based on their individual experience, knowledge, and skills. Following this assessment, training is planned and documented using the T-101-2 template.

Training may be categorized as either informative or formative, focusing on its impact on product quality and conformity, as well as its relevance to the employee's job description and role.

### 3.1 TRAINING OF NEW EMPLOYEES

The training for new employees must include, at a minimum:

- Initial Training, which covers:
  - Company activities
  - Company products
  - The Quality Management System (QMS) and Quality Policy (as outlined in the Quality Manual)

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- Relevant SOP Training, which consists of the specific procedures applicable to the new employee's role.

### 3.2 ADDITIONAL TRAINING

Additional training is necessary if:

- There is a gap between the new employee's skill set and the requirements of their position.
- It is mandated by legal requirements.
- An employee assumes a new task within the company.
- New knowledge would contribute to the company's development.
- There are fundamental changes to the company's methods and procedures.
- Quality issues indicate the need for further training.

Training can be conducted internally by a qualified individual, through external workshops, or by specialized training companies. Continuous development and self-training via webinars are encouraged.

Training needs and balances are evaluated during the Management Review, and each training requirement must receive approval from the CEO. Training of QMS documents, as well as external trainings are documented in the training plan.

### 3.3 EVALUATION OF EFFECTIVENESS

The evaluation of internal training can be conducted through various methods, including:

- Tests or Questionnaires
- Interviews with the employee (e.g., during the annual management review)
- Observation of the trained employee's behavior within their work context

The effectiveness of the training, along with validation criteria, must be documented and maintained in the Training Plan & Record (T-101-2).

For external trainings, the effectiveness is evaluated through course confirmations, certificates, or similar documentation, in addition to the annual management review.

### 3.4 DOCUMENTATION

Training and Documentation Procedures:

- T-101-1, Personnel Introduction: This record documents the onboarding of a new employee and is archived in the personnel dossier.
- T-101-2, Training Plan & Record: This document captures both internal and external training activities. Confirmations of external training, such as certificates, will be archived in the personnel dossier and referenced in the Training Plan.
- T-101-3, Training Record: External Training Documentation: If applicable, training for distributors, importers, and other external individuals involved in selling our products, as well as any collaborations requiring SOP training, must be planned and recorded.

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## 4 REFERENCES

### 4.1 PROCEDURES, INSTRUCTIONS AND GUIDELINES

- [1] QM\_Aspivix\_Quality Manual
- [2] INS-101-1 Employee Rules & Regulations Guide
- [3] INS-101-2 Expense Reimbursement Guide
- [4] INS-101-3 Expense Form Guide For Corporate Cards
- [5] INS-101-4 Travel Business Expense Policy
- [6] INS-101-5 PRRC

### 4.2 TEMPLATES AND FORMS

- [7] T-101-1 Personnel Introduction
- [8] T-101-2 Training Plan & Record
- [9] T-101-3 Training Record
- [10] T-101-4 Personnel Withdrawal
- [11] T-101-5 Job Description Form
- [12] T-101-6 Expense Report Form
- [13] T-101-7 Leave Request Form
- [14] T-101-10 Associate Appraisal Form
- [15] T-101-12 Appointment PRRC
- [16] T-101-13 Appointment PRRC deputy

# Certificate of Completion

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