Regulatory Requirement	Document Section
ISO 13485:2016, sections 6.2 and 7.1	All

Summary

This SOP provides instructions for the management of personnel in the organization.

It covers the onboarding and offboarding of employees, initial and continuous employee training, and feedback processes between supervisors and team members. Thereby, this process shall ensure that the organization retains sufficient qualified and motivated staff.

> NOTE: As your organization grows, the following updates to this process can be considered:
>
> - *Job descriptions* are formulated as part of a general template and respective records instead of sections in the quality manual.
> - Team compositions and hierarchies are outlined as part of an *organizational chart* instead of a table section in the quality manual.
> - Design of a *competency matrix* assigning to each role its required training.

Process Owner	*<enter role of process owner>*
Key Performance Indicators	*<enter KPIs to be tracked for the Management Review>*

General Considerations

1.1 Role Description and Role Assignment

Each employee of the organization is assigned a specific job role for which respective tasks and responsibilities as well as the required qualifications are outlined as part of the quality manual. Team leaders / supervisors are responsible to ensure that the employees working in their team are trained and qualified for the tasks assigned to them. Employee qualification is reviewed against predetermined requirements every time before an employee assumes a new task or role.

The QMO, together with an HR Manager, determines the training and qualification requirements per individual role that are outlined in the quality manual.

1.2 HR File

The organization keeps certain records on every employee, which combined make up the employee's HR File. These include:

- Employee contract and contractual agreements
- Health insurance documentation
- Personal identification (e.g., passport scan)
- Payroll documentation
- Proof of qualifications (where relevant)

  NOTE: such files are subject to stricter data protection requirements and should be made available to external parties (e.g., auditors, authorities) only upon request. You may want to add instructions on how the files should be protected (for example: access limited to HR staff only).

1.3 Training

Training Provision and Documentation The general aim of the employee training is to ensure the necessary competence of employees to perform their tasks. At minimum, it must ensure that employees are aware of the relevance of their tasks and how they contribute to achieving the quality objectives of the organization (ISO 13485, para. 6.2).

Training may take different forms as deemed most suitable by the instructing employee. Training methods may entail:

- Internal or external workshop
- Media and self-study material (e.g., videos, training documents)
- Talks and interviews with coworkers or supervisors, supervised working

The QMO should be involved anytime alternative training methods are chosen, in order to ensure appropriate training evaluation is guaranteed.

Completed training is documented as part of the organization's training documentation. For external seminars, respective training records (e.g., certificates) are saved as part of the HR file (see 1.2.) of each employee and should include at minimum: employee name, training method and content, date and signature of an instructor.

  NOTE: in a larger organization, consider creating a template for a training form that employees can use to document their training.

Training Effectiveness Evaluation Completed training is evaluated to ensure the effectiveness of training and that employees are qualified to perform their job. For effectiveness evaluation, different methods can be used:

- Test / questionnaire
- Monitoring job performance
- External testing

Where no evaluation is included in the training, effectiveness is typically confirmed by the supervisor after completion of training and also documented by the QMO as part of the organization's training documentation.

NOTE: some collaboration tools like Google Workspace allow you to set up questionnaires through which you can test and document(!) your colleague's self-study success quite easily.

Role-Specific Training   Training needs may arise from specific roles within the organization:

Person Responsible for Regulatory Compliance (PRRC)

Before assuming their role, the PRRC is instructed by the QMO on the tasks and responsibilities of this role according to Art. 15 of the Medical Device Regulation. Specifically, the QMO checks if the candidate's qualification meets all the requirements.

Medical Device Consultants

Employees speaking to a professional community or instructing on the handling of the organization's medical devices may be subject to Chapter 6 and §83 of the German MPDG. They must receive training on their tasks and responsibilities and regulatory requirements according to the law as well as product-specific training that should be repeated regularly or based on substantial product changes. The QMO is responsible to keep a list of the organization's trained medical device consultants including the date of their latest training.

Process Steps

NOTE: depending on your current processes in place, feel free to add provisions for:

- The recruitment of employees (for example: are you using software tools like BambooHR or Personio for the application process? How do you document hiring decisions? What kind of data protection requirements, like data deletion periods, must be met?)
- Onboarding checklists for HR staff / new employees (including, for example: onboarding meetings a new hire should complete with relevant coworkers, social insurance registration that HR managers must complete for new employees)

2.1 Onboarding of New Employees

Upon a signed employment contract and before the start date for a new employment, the HR manager is responsible to perform administrative onboarding for the new employee, including:

- Creating an HR file for the new employee (see section 1.2)
- Health and social insurance documentation
- Payroll administration
- Ordering required hardware (e.g., laptop, company mobile phone)

- Granting access rights to relevant software tools (e.g., company messenger, project management tools). Consider: no access should be granted before contractual agreements are signed!

Upon the first day, the direct supervisor or team leader is responsible to ensure that the new employee receives and completes initial training. QMO is responsible for determining required QMS training. Completed training is documented as part of the list of training documentation. Initial training must be completed within the first week.

Participants	New employeeHR ManagerTeam Lead / SupervisorQMO
Input	Signed employment contract
Output	Completed onboarding process

2.2 Continuous Training

Besides initial onboarding, new training need may arise from one of the following:

- Annual due date: the QMO may define annually recurring training.
- Changes in job role: certain job roles require role-specific training (see 1.3).
- Nonconformities: root cause analysis of CAPAs may reveal a lack of training.
- Regulatory changes: based on updates to the QM system (e.g., new processes) or to applicable regulation, the QMO may determine further training need.

Participants	QMOEmployeeTeam Lead / Supervisor
Input	Additional training need
Output	Updated training documentation

2.3 Employee Development

At minimum once per year, supervisors schedule meetings with their employees to exchange feedback, to discuss the employee's personal development and also to identify additional training needs required to reach development goals.

Participants	EmployeeTeam Lead / Supervisor
Input	Development interview due
Output	Interview records (e.g., protocol)

2.4 Offboarding of Employees

Upon notification that an employment contract is terminated, the HR Manager is responsible to perform administrative offboarding. This includes:

- Timely removal of access rights to software tools and company premise
- Observing data deletion periods:
  - Payroll data is deleted 10 years after termination of employment according to German law (§257 HGB).
  - Administrative data (name, address, title, dates of employment) is deleted 3 years after termination of employment according to German law (§195 BGB).
  - The employee's business email account is suspended and deleted 60 days after termination of employment.
  - All other personal data is deleted immediately after termination of employment.
  - Where applicable, third-party processors are notified to also delete personal data.

Participants	HR Manager
Input	Termination of employment
Output	Removal of access rightsUpdated documentation: deleted data