**Document approval**

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| --- | --- | --- | --- |
|  | **Name** | **Date** | **Signature** |
| **Author’s designation**  **e.g., Quality Specialist** |  |  |  |
| **Reviewer’s designation**  **e.g., Quality Management Director Deputy** |  |  |  |
| **Approver’s designation**  **e.g., Quality Management Director** |  |  |  |

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**Table of Contents**

[1 Purpose 3](#_Toc121134539)

[2 Scope 3](#_Toc121134540)

[3 Responsibilities 3](#_Toc121134541)

[4 Definitions, terms and abbreviations 5](#_Toc121134542)

[5 Workflow 5](#_Toc121134543)

[5.1 Training needs 6](#_Toc121134544)

[5.2 Annual trainings planning 6](#_Toc121134545)

[5.3 Job Description 7](#_Toc121134546)

[5.4 Training of permanent employees 8](#_Toc121134547)

[5.5 Change of Responsibilities or Job Title 8](#_Toc121134548)

[5.6 Training methods 9](#_Toc121134549)

[5.6.1 Self-study 9](#_Toc121134550)

[5.6.2 Classroom-training 9](#_Toc121134551)

[5.6.3 On-the-job Training 9](#_Toc121134552)

[5.7 Skill Acquisition and success monitoring 10](#_Toc121134553)

[5.7.1 Read confirmation 10](#_Toc121134554)

[5.7.2 Knowledge test 10](#_Toc121134555)

[5.8 Successful qualification 11](#_Toc121134556)

[5.9 Retraining 11](#_Toc121134557)

[5.9.1 Missed training dates 11](#_Toc121134558)

[5.9.2 Training courses not passed 11](#_Toc121134559)

[5.9.3 Training objectives not achieved 11](#_Toc121134560)

[5.10 Training Documentation 12](#_Toc121134561)

[5.11 Effectiveness monitoring 12](#_Toc121134562)

[5.12 Evaluation and review of the training system 12](#_Toc121134563)

[6 Applicable documents 12](#_Toc121134564)

[7 Appendices 13](#_Toc121134565)

[8 Document revision history 13](#_Toc121134566)

# Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide the framework for the training and qualification system within NBE-Therapeutics, to ensure an adequate training and qualification level and to ensure that all legal requirements are met so that all NBE-Therapeutics employees or persons performing their activities within NBE-Therapeutics facilities can fulfill their duties and responsibilities.

# Scope

This SOP is valid at NBE-Therapeutics for all Organization. The respective training shall be given in accordance with **SOP-10 Training Management**.

This SOP also applies to persons who only enter NBE-Therapeutics within a short-term or temporary basis and/or perform GMP-relevant activities, such as external service providers, students (internship, master, PhD students) or apprentices.

# Responsibilities

Responsible for the content of this SOP is e.g., Quality Management Director.

|  |  |
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| **Role** | **Definition/Task** |
| Department Head | contributes with development, reviews Annual Training Plan, thereby assuring that the necessary training measures are taken for the relevant Department,  reviews the Job Descriptions of Team Leads and their substitutes, and  conducts initial training of new Team Leads in their Department. |
| Line Manager | adds full information for and finalizes Job Descriptions of Team members,  conducts initial training of new employees in their Team,  ensures that the Team members complete the Skill Acquisition within the deadline and before performing any task-related activity, selects and proposes internal and external training  informs the Team members immediately about upcoming training dates,  coordinates employee participation in external training,  release the employees from work for the duration of the scheduled training courses, including examinations,  appoints qualified substitutes to represent the training participants in urgent day-to-day business for the duration of the training measures,  checks, in the case of new tasks or job changes, whether the qualification status of the employees concerned is sufficient,  determines special training measures beyond routine training together with the employees,  identifies special training needs or topics specifically relevant to own employees and communicates these to e.g., Training QA Specialist, |
| Employee | performs Review of Job Description after discussion with Line Manager  attends the training measures according to the Annual Training Plan,  informs the responsible Line Manager about attendance or absence to planned training events,  attends alternative appointments/re-training sessions in the event of unavoidable incapacity,  asks for further clarification during training sessions until the training content is understood,  participates in Skill Acquisition conscientiously and without outside help,  puts the training content into practice,  consults immediately the responsible trainer in the event of any ambiguities or conflicts during practice implementation  completes associated training records |
| e.g., CEO | approves Training Matrix, Annual Training Plan, thereby assuring that the necessary resources are made available.  ensures the availability of all necessary resources for the implementation of the training programs and personal development. |
| e.g., Training QA Specialist | first contact person for training issues,  organizes revision and approval process flows for Annual Training Plan, Training Matrix  monitors the timely completion of training,  plans training events, costs and capacities, assists Trainers in the organization of training events,  manages the evaluation and review of the training system,  collects and stores all training process associated records such as Training Records, training materials (presentations, etc), Annual Training Plan, Training Matrix  Monitoring:  oversees the evaluation and review of the training system,  checks the efficiency of the training concept within the framework of internal audits and document reviews.  oversees onboarding of new employees,  oversees the maintenance and archiving of training documents (e.g., materials and certificates, and lists of participants),  ensures that internal and external training is documented in accordance with internal requirements  Execution of training:  determines training methods in cooperation with the Line Managers,  selects internal and external trainers  determines risk-based measures together with the respective Line Managers if training targets are not met |
| e.g., Quality Management Director | defines training approach, scope and strategy for all departments, Roles, groups.  Reviews Annual Training Plan, Training Matrix |
| Trainer | Prepares training materials,  Plans, executes training sessions,  Prepares Training Records,  tracks the attendance and ensures that, the participants confirm the training in Training Record,  prepares and corrects questions for Skill Acquisition, if required,  forwards completed Training Record,to Quality Organization. |

# Definitions, terms and abbreviations

|  |  |
| --- | --- |
| **Term/abbreviation** | **Definition at NBE-Therapeutics** |
| Basic Training (BT) | Yearly repeated training to ensure that all employees are always informed and instructed on the latest internal and regulatory requirements. |
| Classroom-training | Classroom-training refers to training that takes place in groups away from the workplace. |
| Job Description (JD) | JD refers to Job Description, which is a document summarizing the duties of an employee with regard to the tasks and responsibilities assigned to the employee in a particular role(s). |
| On-the-job Training | On-the-job Training refers to training that takes place on-site at the workplace, either individually or in small groups to learn practical skills, e.g., a working method or how to operate a machine. |
| Qualified Employee | Employee for whom suitability to perform the defined activities according to the Job Description can be proven in writing (training certificate, training documents, Skill Acquisition). |
| Role | A Role is an organizational entity used to define distinct functions within an organization (e.g., assessor, reviewer, auditor, SME). |
| Self-study | A regular training method in which the employees whose activities could influence the quality of the products or services learn about a subject through document reading. |
| Skill Acquisition | Skill Acquisition refers to the obtainment of the qualification necessary for performing a task. |
| Training Module | Topic-related training categories given in the Training Matrix. |

# Workflow

Training and qualification are an essential elements of QMS in NBE-Therapeutics to train and instruct all employees and external persons in such a way that they understand the impact of their activities on the quality of the NBE-Therapeutics manufactured products as well as the provided services.

Therefore, each NBE-Therapeutics employee must be qualified and must conscientiously perform the assigned tasks as outlined in the Job Description. The suitability for a task must always be acquired before conducting the task, e.g., through a combination of training, further training, experience, or instruction.

**Employees who have not yet successfully completed the required training must be instructed and supervised by a Qualified Employee.**

e.g., Quality Management Director, e.g., Training QA Specialist, Department Heads define training approach, scope and strategy for all departments, Roles, groups.

## Training needs

Training shall be, in principle, provided when an employee is recruited or by change of role, and take place on an ongoing basis thereafter. Instructions must cover the theory and application of the QMS as well as the Team-related activities. The content and frequency of the training actions align with:

* + - the nature of the activities specified in the Job Description,
    - the proven or verified level of knowledge of the respective employee, and
    - the impact of consequences in the event of misconduct.

The general training requirements are specified for each workplace as a training module in approved Training Matrix. Each job holder has the obligation to complete training requirements for their Training Group.

**Additional training is needed**

* + - in the event of changes to work or decision-making processes/activities,
    - in the event of accumulated deviations, nonconformances, incidents and/or trends,
    - if desired by employees, Line Managers or e.g., Training QA Specialist,
    - if observations during internal audits give cause to do so,
    - for products or activities with increased quality risk, and
    - for individual difficulties of employees.

Any employee (e.g., job holder, Line Manager, Trainee) who identifies such a need for additional training is committed to request this from his Line Manager of e.g., Training QA Specialist.

If Trainee or Trainer believes that the form of training is not appropriate for successful training (e.g., due to extensively changed workflows or editorial changes), suitable training measures and the aspects to be trained shall be proposed.

## Annual trainings planning

Once the training needs have been defined, the Annual Training Plan is generated by defining suitable training measures. e.g., Quality Management Director, e.g., Training QA Specialist, Department Heads determine the training requirements for each training group and based on the employee's field of activity each year and define the learning objectives and training content.

e.g., Training QA Specialist prepares annually Training Matrix and Annual Training Plan drafts according to **Training Matrix Form** and **Annual Training Plan Form** respectively.

e.g., Quality Management Director, Department Heads review proposed Training Matrix and Annual Training Plan.

e.g., CEO approves proposed Training Matrix and Annual Training Plan.

## Job Description

Each employee within NBE-Therapeutics must have a Job Description (JD). Job Descriptions describe the requirements for the qualifications of the employees to be able to fill the corresponding position. A Job Description is based on the Role(s) assigned to the employee in accordance with NBE-Therapeutics’s Role concept and completes the defined Role with specific tasks and responsibilities of the respective employee.

**Job Descriptions shall include but are not limited to:**

* + - purpose of the job (in accordance with the description of the assigned focus Role),
    - a description of the Role and responsibilities,
    - authority to issue directives and authorizations (including the decision domain of the assigned focus Role),
    - educational and soft skill requirements (including, but not limited to the requirements of the assigned focus Role),
    - substitute for the job holder, and
    - detailed description of the key accountabilities (including key accountabilities of the assigned focus Roles) and duties.

**Job Descriptions must be developed for:**

* + - the establishment of a new position, or
    - the re-occupation of an existing position.

**Job Descriptions need to be reviewed and revised:**

* + - after change of the role profile, or
    - after organizational changes.

**Job Descriptions for new positions**

The Line Manager notifies the Heads of relevant Departments and Team Leads of relevant Teams of the opening of a new position when the proposed new position is assigned, including joint execution of processes and responsibilities together with other Roles in other Teams or Departments. The Line Manager takes into account all provided inputs when preparing the Job Description. At this stage, the Line Manager shall open a Change in accordance with **SOP-05 Change Management** if the new Role significantly affects established processes or documents (SOPs, WIs). In such case, Job Description preparation will be part of the Action Plan of proposed change implementation.

**For tracking purposes, each Job Description is assigned a Job Description number (JD-No.) as follows:**

* + - JD for Job Description,
    - Dash,
    - Consecutive numbering in format XXX (XXX starting with 001) e.g., JD-001 for the first Job Description.

**Revision of a Job Description**

If necessary, the Line Manager will initiate a re-assessment of the current JD. If a change in the JD is required due to a change in the established processes (valid SOPs, WIs, etc.) or in connection with changes in organizational structure and functions, the change in the JD should be considered as part of the Action Plan for the proposed change. Such change must be carried out in accordance with the **SOP-05 Change Management**.

In other cases, when a change in the current JD provides for clarification and detailing, but does not affect the established processes, the Line Manager makes appropriate changes to the new draft, signs it, acquaints the employee with the new edition and changes, determines the training required, if necessary.

The employee (job holder) signs the document after the revision of the new version of JD.

The signed JD is stored in related Department until the moment of dismissal, change of position or change of the current role. After the occurrence of one of these events, the JD is subject to archiving according to the SOP.

After joining the company, new employees will be trained in the following categories within six (6) months:

* + - Onboarding (company introduction overview),
    - Document Self-study,
    - Basic Training (BT) courses,
    - On-the-job Training, and
    - Special Training.

Line Manager and e.g., Training QA Specialist determine scope, areas, methods of such trainings, skill acquisition methods taking into account the requirements of JD, Training Matrix, Annual Training Plan.

## Training of permanent employees

The obligation to provide training extends to all employees working within the QMS scope. They receive training on specific workplace topics and documents as well as annual training.

Attendance at training sessions and the success of training for each employee shall be verified by the trainer using **Training Record Form**.

The aim is to ensure that employees are always informed and instructed on the latest internal and regulatory requirements. There is the possibility of participating in external training courses.

e.g., Training QA Specialist collects and stores all signed **Training Records**.

## Change of Responsibilities or Job Title

In the case of an employee's Change of Responsibilities or Job Title, their Line Manager and e.g., Training QA Specialist determine the need for additional training as well as their scope, areas, methods of such trainings, skill acquisition methods.

## Training methods

The Training methods are as follows:

* + - Self-study and/or
    - Classroom-training (presentation in-person or remote)
    - On-the-job Training

If, while training, it becomes apparent that the information provided is ambiguous or requires explanation, the Authors of the respective documents/Trainer must be informed. This applies to all training methods. Employees are trained with the latest approved revision of a document.

### Self-study

Self-study is carried out for master documents, SOPs, Wis, etc. For this purpose, documents are read, and the understanding of the content is confirmed and signed by the learner's. Responsibility for the successful training and implementation of the document content lies with the responsible Line Manager.

**Self-study is required for all employees (including the employees who were involved in the creation, review, and approval of a document) in the scope of validity of the relevant document. The involvement of the respective employees shall be maintained in the Training Records.**

### Classroom-training

Classroom-training can be conducted in larger groups as lectures or presentations (both, in-person and remote), in small groups or individually. Employees with comprehension difficulties are preferably trained individually or in small groups.

For Classroom-training presentations, it is possible to assign particular employees from within the scope to the Training and exempt others.

### On-the-job Training

The practical implementation of certain **process-**, or **product-related** training contents must be checked on site. Examples of suitable training contents are record keeping, personnel and production hygiene, cleaning procedures, logbook recording. Self-studies with “read confirmation” of the related document(s) are pre-requisites to complete On-the-job trainings. On-the-job Trainings offer the opportunity to point out innovations, explain backgrounds, motivate implementation, practice with practical examples, and clarify understanding of questions.

On-the-job Training generally takes place in the three (3) phases explained below ([***Figure 1***](#_bookmark16)). Training of changed processes or after the introduction of new equipment does not necessarily take place in all three (3) phases. For given activities (e.g., analytical performance), an add-on phase will be needed to verify the reproducibility in the results and consistency in the operating. The responsible Line Manager decides on the procedure in a risk-based manner:

***Figure 1 Phases for On-the-job Training***

The three phases of On-the-job Training are documented by the learner and the trainer in **Training Records**.

## Skill Acquisition and success monitoring

Skill Acquisition is used to demonstrate achieving the theoretical learning objectives and the qualification to apply them in the respective workplace, or to determine a potential need for follow- up training.

Completion of training/SOPs, and the skill acquisition for them applies to each employee as follows:

* + - always before performing the task(s) described
    - at the latest 8-weeks after the implementation of an SOP/WI, or
    - at the latest 8-weeks after a training event

The monitoring of learning success can take place immediately after the training event or at within eight

(8) weeks after the document implementation date. It serves to prove that the training conducted was suitable for achieving the intended learning objectives.

The following control methods for Skill Acquisition are established in NBE-Therapeutics in accordance with the training methods.

### Read confirmation

At minimum, read confirmations are required after reading appendices and documents.

### Knowledge test

Knowledge tests are used to evaluate whether the content and basic statements of the respective documents or presentations have been understood. The knowledge test consists of classical questionnaires or multiple-choice questions. The questionnaire and multiple-choice questions are provided by the trainer or document owner.

For knowledge testing, NBE-Therapeutics will consider it a pass if **at least 80%** of the questions are answered correctly.

## Successful qualification

Authorization to independently perform certain work steps (according to the Job Description, e.g., equipment operation, certain control steps, critical analyses) or procedures (completion of e.g., protocols and forms) is granted on an individual basis. Prerequisites for this are:

* + - participation in the theoretical and/or practical training provided for this purpose,
    - passing the practical (individual) examination, and
    - participation in the annual repeat examination, if applicable.

Substitutions at such workplaces are possible only by equally Qualified Employees.

## Retraining

### Missed training dates

GxP training is mandatory for all employees in its scope of validity. Requests for postponement or exchange of dates must be discussed with the trainer after consultation with the Line Manager. If a training session cannot be attended due to illness or other unavoidable reasons, the employee must contact the trainer immediately upon return so that the necessary follow-up training can be scheduled.

In any case, the e.g., Training QA Specialist must be informed, and it must be ensured by the Line Manager that the employee takes note of any necessary changes to the relevant documents before resuming work.

### Training courses not passed

Training courses that are not passed must be repeated. In the case of process- or device-related training, the employee is blocked from the affected process until proven successful training.

### Training objectives not achieved

If deficits are identified after training measures that indicate that specified training objectives have not been achieved, the employee is requested to repeat the training within four (4) weeks, provided that the quality of the product or service is not at risk. In the event of an immediate threat to the quality of the product, the responsible Line Manager, after consultation with e.g., Training QA Specialist, will report a deviation according to **SOP-06 Deviation and Nonconformance Management** and immediate measures must be taken according to **SOP-07 CAPA Management.** These can be documented special training measures (ad hoc briefings) on-site and/or increased control measures. If possible, the cause of the deviation should be clarified beyond doubt and measures taken to prevent a recurrence.

## Training Documentation

e.g., Training QA Specialist collects and stores all training process associated records such as Training Records, training materials (presentations, etc), Annual Training Plan, Training Matrix.

These data must be available in the framework of internal review and official audits.

## Effectiveness monitoring

Effectiveness monitoring is carried out to ensure that the acquired knowledge is being applied or implemented in practice.

It can be used, for example,

* + - to determine if there is a need for retraining,
    - for the purpose of investigating deviations,
    - to determine СAPA measures,
    - to define personal development plan,
    - to check if the documents created by the employee are in accordance with the requirements that were dealt with during training.

## Evaluation and review of the training system

In addition to the assessment of the employees, an ongoing review of the training system should be carried out (e.g., as part of internal audits and Management Review). In this context, the quality of the training measures carried out, as well as the trainer, are evaluated, e.g., on the basis of the satisfaction of the participants and the proven training success by the e.g., Training QA Specialist.

# Applicable documents

SOP-01 Documentation Management

SOP-04 Management Review

SOP-05 Change Management

SOP-06 Deviation and Nonconformance Management

SOP-07 CAPA Management

SOP-08 Audits Management

SOP-13 Supplier Management

SOP-16 Archiving

# Appendices

The following appendices are integral part of this SOP:

Appendix Training Matrix

Appendix Annual Training Plan

Appendix Training Record

# Document revision history

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| --- | --- | --- | --- |
| **Version** | **Valid from** | **Description of the revision** | **Reason for the revision** |
| 1 | See header | Document created | QMS implementation |