Document Type:	Standard Operating Procedure (SOP)	**SOP Code:**	SOP-QA-002
Title:	Employee Training and Qualification	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
Location:	Pune, India	**Review Date:**	2026-01-01

Employee Training and Qualification

Category: Quality Assurance

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Quality Assurance

Title: Employee Training and Qualification

SOP No.: SOP-QA-002

Version No.: 1.0

Effective Date: 2025-01-01

1.0 PURPOSE

This procedure defines the requirements and methods for providing and documenting employee training and qualification at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India, to ensure all personnel involved in pharmaceutical manufacturing activities are properly trained and competent to perform their assigned tasks in compliance with Good Manufacturing Practices (GMP). This SOP ensures consistent and effective training programs are implemented and maintained to support the production of safe, efficacious, and high-quality pharmaceutical products.

2.0 SCOPE

This Standard Operating Procedure (SOP) applies to all personnel involved in pharmaceutical manufacturing, testing, packaging, storage, and distribution activities at NovaThera Pharmaceuticals Pvt. Ltd. This includes, but is not limited to, personnel from Production, Quality Control, Quality Assurance, Engineering, and Warehouse departments. This SOP covers all types of training, including initial onboarding training, on-the-job training, refresher training, and training on new or revised procedures, equipment, or systems. This SOP applies to all materials and products handled within the facility.

3.0 RESPONSIBILITY

QC Inspector:

- Participates in required training programs as defined by the training matrix.
- Performs assigned tasks according to established SOPs and work instructions after successful completion of training.
- Reports any deviations or inconsistencies observed during training to the Production Supervisor or QA Manager.
- Maintains personal training records.

Production Supervisor:

- Identifies training needs for personnel within their department.
- Ensures personnel are scheduled for and complete required training programs.
- Provides on-the-job training and guidance to personnel.
- Verifies competency of personnel to perform assigned tasks.
- Maintains departmental training records.
- Evaluates the effectiveness of training programs.

QA Manager:

- Develops and maintains the overall training program for NovaThera Pharmaceuticals Pvt. Ltd.
- Ensures training programs comply with GMP requirements and regulatory guidelines.
- Approves training materials and curricula.
- Oversees the administration of training programs.
- Maintains the master training records for all personnel.
- Conducts periodic audits of training records and programs to ensure compliance.
- Develops and maintains the training matrix.
- Ensures training is current and relevant to job functions.

Head of QA:

- Provides overall oversight and approval of the training program.
- Ensures adequate resources are allocated to support the training program.
- Reviews and approves training policies and procedures.
- Ensures training effectiveness is periodically assessed.
- Acts as the final authority on all training-related matters.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Gloves (appropriate for the training activity)

- Lab coats
- Hearing protection (if applicable)
- Safety shoes

Equipment:

- Computer with internet access
- Projector
- Whiteboard or flip chart
- Specific equipment used in training (e.g., BLN-04, TCP-01, SFT-02, analytical instruments)
- Calibration standards (as applicable)

Documentation:

- Training matrix (identifies required training for each role)
- Training curricula and materials
- Training attendance logs
- Training evaluation forms
- Training record forms
- SOPs and work instructions related to the training topic
- GMP guidelines
- FDA 21 CFR Part 210 and 211

5.0 PROCEDURE

5.1 Training Program Development

5.1.1 The QA Manager will develop and maintain a training matrix that outlines the required training for each role within the organization. The training matrix will be reviewed and updated at least annually or more frequently as needed to reflect changes in regulations, procedures, or equipment. Effective Date: 2025-01-01

5.1.2 The QA Manager, in consultation with department heads, will develop training curricula and materials for each training program. The curricula will include clear learning objectives, content outlines, and assessment methods. Effective Date: 2025-01-01

5.1.3 Training materials will be reviewed and approved by the QA Manager prior to use. Materials may include SOPs, work instructions, videos, presentations, and other relevant documents. Effective Date: 2025-01-01

5.1.4 All training materials will be maintained in a controlled document management system to ensure version control and accessibility. Effective Date: 2025-01-01

5.1.5 Training programs will be designed to be interactive and engaging, utilizing a variety of training methods to accommodate different learning styles. Effective Date: 2025-01-01

5.2 Conducting Training

5.2.1 The Production Supervisor will schedule personnel for required training programs based on the training matrix and individual needs. Effective Date: 2025-01-01

5.2.2 Training sessions will be conducted by qualified trainers who have demonstrated expertise in the subject matter. Effective Date: 2025-01-01

5.2.3 Training sessions will include a combination of classroom instruction, hands-on exercises, and demonstrations. Effective Date: 2025-01-01

5.2.4 Attendance at training sessions will be documented in a training attendance log, which will include the date, time, topic, and names of attendees. Effective Date: 2025-01-01

5.2.5 During equipment training, the trainer will demonstrate proper operation, maintenance, and troubleshooting procedures for the specific equipment (e.g., BLN-04 blender, TCP-01 tablet press, SFT-02 sifter). Effective Date: 2025-01-01

5.2.6 Trainees will be given the opportunity to practice operating the equipment under the supervision of the trainer. Effective Date: 2025-01-01

5.2.7 If applicable, specific training will cover calibration of equipment using appropriate calibration standards and procedures. Effective Date: 2025-01-01

5.2.8 The Production Supervisor will ensure that the QC Inspector receives the necessary training and guidance on quality control procedures related to raw materials, in-process materials, and finished products. Effective Date: 2025-01-01

5.3 Assessment and Qualification

5.3.1 Following training, personnel will be assessed to determine their understanding of the training material and their ability to apply it to their job duties. Effective Date: 2025-01-01

5.3.2 Assessment methods may include written exams, practical demonstrations, and observation of job performance. Effective Date: 2025-01-01

5.3.3 Personnel must achieve a satisfactory score on the assessment to be considered qualified to perform the trained task. The passing score will be defined in the training program documentation. Effective Date: 2025-01-01

5.3.4 If personnel do not achieve a satisfactory score, they will be provided with additional training and re-assessed. Effective Date: 2025-01-01

5.3.5 The Production Supervisor will verify the competency of personnel to perform assigned tasks through observation and performance reviews. Effective Date: 2025-01-01

5.3.6 The Production Supervisor will document the qualification of personnel in their training records. Effective Date: 2025-01-01

5.4 Training Records Management

5.4.1 The QA Manager will maintain master training records for all personnel. Effective Date: 2025-01-01

5.4.2 Training records will include the individual's name, job title, training courses completed, dates of training, assessment results, and qualification status. Effective Date: 2025-01-01

5.4.3 Training records will be stored securely and confidentially. Effective Date: 2025-01-01

5.4.4 Training records will be retained for the period specified in the company's record retention policy. Effective Date: 2025-01-01

5.4.5 Departmental training records will be maintained by the Production Supervisor and will be readily accessible for audits and inspections. Effective Date: 2025-01-01

5.5 Refresher Training

5.5.1 Refresher training will be provided to personnel on a periodic basis to reinforce key concepts and ensure continued competency. Effective Date: 2025-01-01

5.5.2 The frequency of refresher training will be determined by the QA Manager based on the complexity of the task, the potential for errors, and regulatory requirements. Effective Date: 2025-01-01

5.5.3 Refresher training may be conducted through classroom instruction, online modules, or on-the-job training. Effective Date: 2025-01-01

5.5.4 Attendance and completion of refresher training will be documented in the individual's training record. Effective Date: 2025-01-01

5.6 Training on New or Revised Procedures, Equipment or Systems

5.6.1 When new or revised procedures, equipment, or systems are introduced, personnel will be provided with training on the changes. Effective Date: 2025-01-01

5.6.2 The training will cover the purpose of the changes, the specific steps involved, and any potential risks or hazards. Effective Date: 2025-01-01

5.6.3 Training materials will be developed and approved by the QA Manager prior to use. Effective Date: 2025-01-01

5.6.4 Personnel will be assessed to determine their understanding of the changes and their ability to apply them to their job duties. Effective Date: 2025-01-01

5.6.5 Qualification on the new or revised procedures, equipment or systems will be documented in the individual's training record. Effective Date: 2025-01-01

5.7 GMP Training

5.7.1 All personnel involved in pharmaceutical manufacturing, testing, packaging, storage, and distribution activities will receive initial and ongoing GMP training. Effective Date: 2025-01-01

5.7.2 GMP training will cover the principles of GMP, the importance of following SOPs, and the consequences of non-compliance. Effective Date: 2025-01-01

5.7.3 GMP training will be tailored to the specific roles and responsibilities of each individual. Effective Date: 2025-01-01

5.7.4 GMP training will be documented in the individual's training record. Effective Date: 2025-01-01

6.0 POST-TRAINING ACTIVITIES

6.1 The Production Supervisor ensures the trainee demonstrates the learned skills under direct supervision for a defined period after training. Effective Date: 2025-01-01

6.2 The Production Supervisor documents the successful completion of supervised practice in the employee's training record. Effective Date: 2025-01-01

6.3 The QC Inspector reviews and approves the training documentation to ensure completeness and accuracy. Effective Date: 2025-01-01

6.4 The QA Manager reviews and approves the completed training record and updates the training matrix as necessary. Effective Date: 2025-01-01

6.5 The Head of QA is notified of any significant training gaps or issues identified during the training process. Effective Date: 2025-01-01

6.6 Periodic audits of the training program will be conducted by the QA Manager to ensure compliance with GMP requirements and effectiveness of the training. Effective Date: 2025-01-01

6.7 The QA Manager will review training records periodically to identify areas where refresher training or additional training may be needed. Effective Date: 2025-01-01

6.8 Evaluation forms will be collected and analyzed by the QA Manager to assess the effectiveness of the training program and identify areas for improvement. Effective Date: 2025-01-01

7.0 SAFETY PRECAUTIONS

7.1 All personnel participating in training activities must wear appropriate PPE, as specified in Section 4.0.

7.2 When training involves the use of equipment, personnel must follow all safety procedures outlined in the equipment's operating manual and SOPs.

7.3 Personnel must be aware of potential hazards associated with the training activity and take appropriate precautions to prevent accidents or injuries.

7.4 Any accidents or incidents that occur during training must be reported immediately to the Production Supervisor and the QA Manager.

7.5 Ensure adequate ventilation is present when training involves handling chemicals or hazardous materials.

7.6 Follow proper ergonomic practices when using computers or other equipment to prevent repetitive strain injuries.

7.7 During equipment operation training, the emergency stop procedures must be clearly explained and understood by all trainees. Effective Date: 2025-01-01

8.0 APPROVALS

Prepared By: Training Coordinator

Reviewed By: QA Manager

Approved By: Head of QA

Date:

Controlled Document Notice

Document Approval

Role	Name	Signature	Date
Prepared by:	_____	_____	_____
Reviewed by (QA):	_____	_____	_____
Approved by (Head QA):	_____	_____	_____

Document Control Information

Document ID: SOP-QA-002

Version: 1.0

Effective Date: 2025-01-01

Next Review Date: 2026-01-01

Generated by: NovaThera SOP Generator System