Document Type:	Standard Operating Procedure (SOP)	**SOP Code:**	SOP-QA-004
Title:	Change Control Management	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
Location:	Pune, India	**Review Date:**	2026-01-01

Change Control Management

Category: Quality Assurance

Standard Operating Procedure (SOP)

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Department: Quality Assurance

Title: Change Control Management

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1.0 PURPOSE

This procedure defines the system for managing changes to equipment, facilities, materials, processes, computer systems, documentation, and other controlled aspects of pharmaceutical manufacturing at NovaThera Pharmaceuticals. The purpose is to ensure that all changes are evaluated, approved, implemented, and verified to minimize potential adverse impacts on product quality, patient safety, and data integrity, in compliance with GMP regulations.

2.0 SCOPE

This SOP applies to all departments and personnel at NovaThera Pharmaceuticals involved in activities that could potentially impact the identity, strength, purity, quality, and safety of pharmaceutical products, including but not limited to manufacturing, packaging, testing, storage, and distribution. This includes changes to raw materials, equipment, processes, analytical methods, computer systems, facilities, utilities, and documentation used in the production, testing, and release of all pharmaceutical products manufactured at NovaThera Pharmaceuticals. This SOP excludes routine maintenance activities that are explicitly defined and controlled within existing maintenance procedures.

3.0 RESPONSIBILITY

QC Inspector:

- Reviews change control documentation for completeness and accuracy.
- Performs testing of materials and products as required by the change control.
- Documents all test results accurately and promptly.
- Notifies the QA Manager of any deviations observed during testing.

Production Supervisor:

- Initiates change control requests when a change is required in the production process.
- Implements approved changes in the production area.
- Provides training to production personnel on the implemented changes.
- Monitors the effectiveness of the implemented changes.
- Ensures compliance with all relevant SOPs and GMP regulations during the implementation of changes.

QA Manager:

- Reviews and approves change control requests.
- Ensures that all change control requests are adequately assessed for potential impact on product quality.
- Coordinates the change control process across different departments.
- Tracks the progress of change control requests.
- Ensures that all change controls are closed out in a timely manner.
- Ensures that all necessary documentation is completed.

Head of QA:

- Provides final approval for major or critical change control requests.
- Oversees the overall change control system to ensure compliance with GMP regulations.
- Periodically reviews the effectiveness of the change control system.
- Approves changes to the change control SOP itself.
- Ensures adequate resources are available for effective change control management.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Laboratory coat
- Gloves (nitrile or equivalent)
- Safety shoes

Equipment:

- Computer with access to the Document Management System (DMS)
- Printer
- Calibrated measuring instruments (as required by the specific change)

Documentation:

- Change Control Request Form (CCRF-001)
- Change Control Impact Assessment Form (CCIAF-002)
- Change Control Implementation Plan (CCIP-003)
- Change Control Verification Report (CCVR-004)
- Deviation Report Form (DRF-001)
- Equipment Logbooks
- Training records

5.0 PROCEDURE

5.1 Initiation of a Change Control Request

5.1.1 Any personnel identifying a need for a change must initiate a Change Control Request using the Change Control Request Form (CCRF-001).

5.1.2 The initiating personnel must complete all relevant sections of the CCRF-001, providing a clear and concise description of the proposed change, the reason for the change, and the potential impact of not implementing the change.

5.1.3 The initiating personnel must submit the completed CCRF-001 to their respective supervisor for review and approval.

5.1.4 The Production Supervisor (or equivalent) reviews the CCRF-001 for completeness and accuracy, and approves or rejects the request based on their assessment of the need for the change. If rejected, the Production Supervisor documents the reason for rejection on the CCRF-001 and returns it to the initiator.

5.1.5 If the CCRF-001 is approved, the Production Supervisor forwards it to the QA Manager.

5.2 Impact Assessment

5.2.1 The QA Manager receives the approved CCRF-001 and assigns it a unique change control number.

5.2.2 The QA Manager, in consultation with relevant personnel (e.g., Production Supervisor, QC Inspector, Engineering), conducts a thorough impact assessment using the Change Control Impact Assessment Form (CCIAF-002).

5.2.3 The impact assessment considers the potential impact of the proposed change on:

- Product quality
- Patient safety
- Data integrity
- Equipment performance
- Process validation
- Analytical methods
- Regulatory compliance

5.2.4 The impact assessment classifies the change as:

- Minor: Minimal impact on product quality, patient safety, and data integrity.
- Major: Significant impact on product quality, patient safety, or data integrity.
- Critical: Potentially life-threatening impact on product quality or patient safety.

5.2.5 The QA Manager documents the impact assessment findings, including the rationale for the classification, on the CCIAF-002.

5.2.6 The QA Manager obtains approval of the CCIAF-002 from the Head of QA, especially for Major and Critical changes.

5.3 Planning and Approval

5.3.1 Based on the impact assessment, the QA Manager develops a Change Control Implementation Plan (CCIP-003) in collaboration with relevant departments.

5.3.2 The CCIP-003 outlines the specific steps required to implement the change, including:

- Tasks to be performed
- Responsible personnel
- Required resources
- Timelines
- Training requirements
- Testing requirements
- Documentation updates
- Validation or verification activities

5.3.3 The CCIP-003 includes a risk assessment to identify potential risks associated with the implementation of the change and mitigation strategies.

5.3.4 The QA Manager reviews and approves the CCIP-003. For Major and Critical changes, the CCIP-003 requires approval from the Head of QA.

5.4 Implementation

5.4.1 The designated personnel implement the change according to the approved CCIP-003.

5.4.2 The Production Supervisor ensures that all personnel involved in the implementation are adequately trained on the new procedures or equipment.

5.4.3 All activities performed during the implementation are documented accurately and contemporaneously in the appropriate logbooks or records.

5.4.4 Deviations from the approved CCIP-003 must be documented as deviations using the Deviation Report Form (DRF-001) and addressed according to the Deviation Management SOP.

5.4.5 Any changes to equipment (e.g., BLN-04, TCP-01, SFT-02) require updates to the equipment logbooks.

5.4.6 If a change involves computer systems, the applicable change management procedures for computer systems must be followed.

5.5 Verification and Validation

5.5.1 After the implementation of the change, the QC Inspector performs the required testing to verify that the change has been implemented correctly and that it meets the specified acceptance criteria.

5.5.2 The type and extent of testing depend on the nature of the change and the potential impact on product quality. Testing may include:

- Raw material testing
- In-process testing
- Finished product testing
- Cleaning validation
- Process validation
- Analytical method validation

5.5.3 The QC Inspector documents all test results in the appropriate laboratory notebooks or electronic systems.

5.5.4 The QA Manager reviews the test results and determines if the change has been successfully implemented.

5.5.5 A Change Control Verification Report (CCVR-004) is prepared by the QA Manager summarizing the implementation activities, test results, and the overall conclusion regarding the success of the change.

5.5.6 For Major and Critical changes, process validation studies must be conducted to demonstrate that the change has not adversely affected the validated state of the process. Validation protocols and reports must be approved by the QA Manager and Head of QA.

5.6 Closure

5.6.1 Once the QA Manager is satisfied that the change has been successfully implemented and verified, the QA Manager prepares the Change Control Verification Report (CCVR-004).

5.6.2 The QA Manager obtains final approval for the closure of the change control from the Head of QA.

5.6.3 The QA Manager archives all change control documentation, including the CCRF-001, CCIAF-002, CCIP-003, CCVR-004, deviation reports, test results, and validation reports, in accordance with the document retention policy.

5.6.4 The change control record is updated in the change control tracking system to indicate that the change is closed.

6.0 POST-CHANGE ACTIVITIES

6.1 The Production Supervisor monitors the performance of the changed equipment or process for a defined period to ensure that it is functioning as expected.

6.2 The QA Manager periodically reviews the change control system to identify areas for improvement.

6.3 The Head of QA conducts an annual review of the change control system to ensure its effectiveness and compliance with GMP regulations.

7.0 SAFETY PRECAUTIONS

7.1 All personnel involved in the implementation of changes must wear appropriate PPE, including safety glasses, laboratory coats, gloves, and safety shoes.

7.2 Follow all applicable safety procedures for the equipment or process being changed.

7.3 Ensure that all electrical equipment is properly grounded and that all electrical connections are secure.

7.4 Use caution when handling chemicals or hazardous materials.

7.5 Dispose of waste materials properly in designated containers.

7.6 If any unsafe conditions are observed, immediately stop work and notify the Production Supervisor or QA Manager.

7.7 If any incident or accident occurs, report it immediately to the appropriate personnel and follow the company's incident reporting procedures.

8.0 APPROVALS

Prepared By: QA Specialist

Reviewed By: QA Manager

Approved By: Head of QA

Date: [Leave blank for manual completion]

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-004

Version: 1.0

Effective Date: 2025-01-01

Next Review Date: 2026-01-01

Generated by: NovaThera SOP Generator System