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Vendor Qualification and Management

Category: Quality Assurance

Standard Operating Procedure (SOP)

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Department: Quality Assurance

Title: Vendor Qualification and Management

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1.0 PURPOSE

This procedure defines the requirements and responsibilities for the qualification, evaluation, and management of vendors supplying materials, equipment, and services used in pharmaceutical manufacturing at NovaThera Pharmaceuticals to ensure compliance with GMP and regulatory requirements.

2.0 SCOPE

This SOP applies to all vendors who supply raw materials, packaging materials, critical equipment, components, and services (e.g., calibration, maintenance, transportation) used in the manufacturing, testing, and storage of pharmaceutical products at NovaThera Pharmaceuticals. It covers the entire vendor lifecycle, from initial qualification through ongoing performance monitoring and re-evaluation. This SOP is applicable to all products and batches manufactured by NovaThera Pharmaceuticals.

3.0 RESPONSIBILITY

QC Inspector:

- Performs visual inspection and sampling of incoming materials as per approved sampling plans.

- Reviews vendor-provided Certificates of Analysis (CoAs) and other relevant documentation.
- Performs identification testing of incoming materials.
- Reports any deviations or discrepancies to the QA Manager.
- Maintains accurate records of inspections and testing.

Production Supervisor:

- Identifies and communicates the need for new vendors for specific materials, equipment, or services.
- Participates in the vendor selection process as required.
- Provides feedback to the QA Manager regarding vendor performance.
- Ensures that materials and equipment received from qualified vendors are properly stored and handled.

QA Manager:

- Oversees the vendor qualification and management program.
- Develops and maintains the Approved Vendor List (AVL).
- Reviews and approves vendor qualification documentation.
- Conducts or arranges for vendor audits.
- Investigates and resolves vendor-related quality issues.
- Tracks vendor performance and initiates corrective actions as needed.
- Ensures compliance with GMP and regulatory requirements related to vendor management.

Head of QA:

- Approves the vendor qualification and management SOP.
- Provides overall oversight of the vendor qualification program.
- Approves the Approved Vendor List (AVL).
- Makes final decisions on vendor qualification and disqualification.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Lab coats
- Gloves (nitrile or appropriate material for the material being handled)
- Safety shoes

Equipment:

- Calibrated weighing balances (BAL-01, BAL-02)
- Reference standards (as required for material testing)

- Identification test kits (e.g., FTIR spectrometer - FTIR-01)
- Sampling tools (e.g., scoops, spatulas)
- Temperature and humidity monitoring devices (THM-01, THM-02)
- Hardness tester (HRD-01)
- Disintegration tester (DSG-01)
- Dissolution tester (DSL-01)
- pH meter (PHM-01)

Documentation:

- Vendor Qualification Questionnaire (F-QA-009-01)
- Vendor Audit Checklist (F-QA-009-02)
- Approved Vendor List (AVL) (F-QA-009-03)
- Material Receiving Log (F-LG-001-01)
- Certificate of Analysis (CoA)
- Purchase Orders
- Material Safety Data Sheets (MSDS)
- Vendor Agreements
- Change Control Forms (F-CC-001-01)
- Deviation Report Forms (F-DV-001-01)

5.0 PROCEDURE

5.1 Vendor Selection and Initial Qualification

5.1.1 The Production Supervisor or other relevant department identifies the need for a new vendor for a specific material, equipment, or service and informs the QA Manager.

5.1.2 The QA Manager, in collaboration with the relevant department, develops a list of potential vendors based on market research, industry recommendations, and other relevant sources.

5.1.3 The QA Manager sends the Vendor Qualification Questionnaire (F-QA-009-01) to each potential vendor.

5.1.4 The QA Manager reviews the completed Vendor Qualification Questionnaires to assess the vendor's capabilities, quality systems, and regulatory compliance.

5.1.5 The QA Manager, based on the questionnaire responses, performs a risk assessment to determine the level of qualification required for each vendor. This risk assessment considers factors such as the criticality of the material/service, the vendor's experience, and the vendor's quality history.

5.1.6 For vendors deemed high-risk or critical, the QA Manager schedules a vendor audit. The vendor audit is conducted using the Vendor Audit Checklist (F-QA-009-02).

5.1.7 The QA Manager, or a designated auditor, conducts the vendor audit, assessing the vendor's facilities, equipment, processes, and quality systems.

5.1.8 The QA Manager documents the findings of the vendor audit in an audit report.

5.1.9 The QA Manager reviews the vendor's response to the audit findings and verifies the implementation of corrective actions.

5.1.10 For vendors supplying critical raw materials, the QA Manager requests samples of the material for testing.

5.1.11 The QC Inspector performs testing of the vendor-supplied samples according to approved test methods.

5.1.12 The QC Inspector documents the results of the sample testing in a test report.

5.1.13 The QA Manager reviews all qualification documentation, including the Vendor Qualification Questionnaire, audit report (if applicable), and sample testing results.

5.1.14 The QA Manager makes a recommendation regarding vendor qualification to the Head of QA.

5.1.15 The Head of QA approves or rejects the vendor's qualification based on the review of all qualification documentation.

5.1.16 If the vendor is approved, the QA Manager adds the vendor to the Approved Vendor List (AVL) (F-QA-009-03) along with the approved materials or services.

5.1.17 The QA Manager informs the relevant departments (e.g., Purchasing, Production) of the vendor's qualification.

5.2 Ongoing Vendor Management and Monitoring

5.2.1 The QA Manager monitors vendor performance on an ongoing basis.

5.2.2 The QC Inspector reviews vendor-provided Certificates of Analysis (CoAs) for each shipment of material received.

5.2.3 The QC Inspector performs visual inspection and sampling of incoming materials according to approved sampling plans.

5.2.4 The QC Inspector performs identification testing of incoming materials using appropriate methods (e.g., FTIR-01).

5.2.5 The QC Inspector records all inspection and testing results in the Material Receiving Log (F-LG-001-01).

5.2.6 The QA Manager tracks the number of deviations, complaints, and recalls associated with each vendor.

5.2.7 The QA Manager conducts periodic vendor audits based on risk assessment and performance data.

5.2.8 The QA Manager reviews vendor performance data annually and determines if any corrective actions are required.

5.2.9 If a vendor's performance is unsatisfactory, the QA Manager initiates a corrective action plan.

5.2.10 The QA Manager monitors the implementation of corrective actions and verifies their effectiveness.

5.2.11 If a vendor fails to meet the required performance standards, the QA Manager may suspend or disqualify the vendor from the AVL.

5.2.12 The Head of QA approves any vendor disqualification.

5.2.13 The QA Manager communicates any changes to the AVL to the relevant departments.

5.3 Re-Qualification of Vendors

5.3.1 The QA Manager re-qualifies vendors periodically, based on risk assessment and regulatory requirements.

5.3.2 The re-qualification process includes a review of the vendor's current quality systems, performance data, and compliance history.

5.3.3 The QA Manager may conduct a vendor audit as part of the re-qualification process.

5.3.4 The QA Manager documents the results of the re-qualification process.

5.3.5 The Head of QA approves the re-qualification of the vendor.

5.4 Handling of Non-Conforming Materials

5.4.1 If the QC Inspector identifies a non-conforming material, the QC Inspector quarantines the material and notifies the QA Manager.

5.4.2 The QA Manager initiates a deviation investigation using the Deviation Report Form (F-DV-001-01).

5.4.3 The QA Manager investigates the cause of the non-conformance and determines the appropriate corrective action.

5.4.4 The QA Manager communicates the findings of the investigation to the vendor.

5.4.5 The QA Manager works with the vendor to resolve the non-conformance and prevent future occurrences.

5.4.6 The Head of QA approves the final disposition of the non-conforming material.

5.5 Change Control

5.5.1 Any changes to the vendor's processes, materials, or equipment must be communicated to NovaThera Pharmaceuticals.

5.5.2 The QA Manager evaluates the impact of the proposed change using the Change Control Form (F-CC-001-01).

5.5.3 The QA Manager determines if any additional qualification activities are required as a result of the change.

5.5.4 The Head of QA approves the change control request.

6.0 POST-ACTIVITY ACTIVITIES

6.1 The QA Manager maintains accurate records of all vendor qualification and management activities, including Vendor Qualification Questionnaires, audit reports, sample testing results, deviation reports, corrective action plans, and communications with vendors.

6.2 All records are stored in accordance with NovaThera Pharmaceuticals' record retention policy.

6.3 The Approved Vendor List (AVL) is reviewed and updated regularly by the QA Manager.

7.0 SAFETY PRECAUTIONS

7.1 When handling chemical materials, always wear appropriate PPE, including safety glasses, lab coats, and gloves.

7.2 Refer to the Material Safety Data Sheet (MSDS) for each material before handling.

7.3 Follow all safety procedures outlined in NovaThera Pharmaceuticals' safety manual.

7.4 Ensure proper ventilation when working with volatile materials.

7.5 Dispose of waste materials according to approved waste disposal procedures.

7.6 When operating equipment, follow all manufacturer's instructions and safety guidelines.

8.0 APPROVALS

Prepared By: Quality Assurance 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:	_____	_____	_____
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