



# Pharmaceutical Vendor Qualification Checklist

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## Vendor Information & Initial Assessment

Collection of basic vendor details and a preliminary risk assessment.

### Vendor Legal Name

Write something...

### Vendor Contact Person

Write something...



### Vendor Address

Write something...

### Years in Business

Enter a number...

### Primary Business Type

- Raw Materials
- Packaging
- Equipment
- Services
- Other

### Initial Risk Assessment Level

- Low
- Medium
- High

### Initial Assessment Date

Enter date...

# Financial Stability & Business Practices

Evaluation of vendor's financial health and ethical business conduct.

## Annual Revenue (USD)

Enter a number...

## Debt-to-Equity Ratio

Enter a number...

## Credit Rating Agency

- Moody's
- Standard & Poor's
- Fitch
- Not Rated

## Summary of Financial Stability Assessment

Write something...

### **Business Ethics Program**

- Yes, documented program
- Yes, informal policy
- No program in place

### **Date of Last Financial Review**

Enter date...

## **Quality Management System (QMS)**

Assessment of the vendor's QMS, including policies, procedures, and documentation.

### **QMS Documentation Availability**

- Complete & Current
- Partially Available
- Not Available

### **Summary of QMS Documentation Reviewed**

Write something...

### Number of Documented Procedures

Enter a number...

### Date of Last QMS Audit

Enter date...

### QMS Elements Assessed (Select all that apply)

- Document Control
- CAPA
- Change Management
- Training
- Internal Audits
- Management Review

### Copy of QMS Manual (if available)

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### Evidence of Management Review

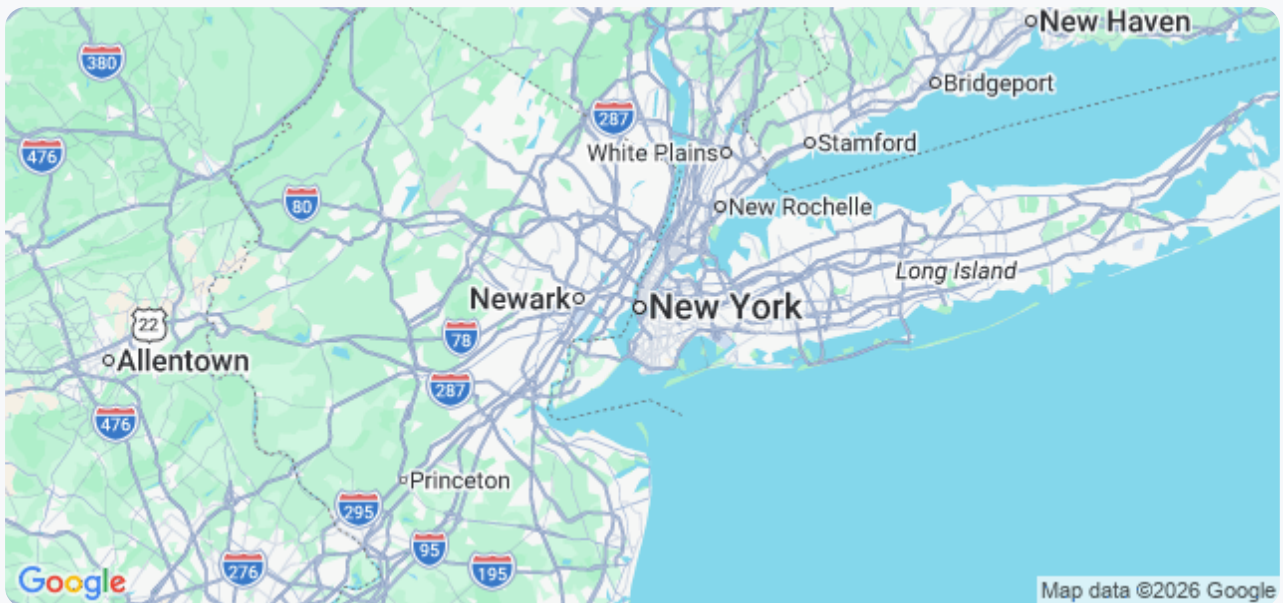
- Yes
- No
- Not Applicable

# Facility & Equipment

Verification of the vendor's facilities and equipment suitability for pharmaceutical materials or services.

## Facility Address

 [Set My Current Location](#)



## Square Footage of Manufacturing Area

Enter a number...

### Equipment Types Present (Select all that apply)

- Reactors
- Dryers
- Mills
- Filters
- Packaging Equipment
- Analytical Instruments

### Last Facility Inspection Date

Enter date...

### Facility Layout Diagram

 Upload File

### HVAC System Temperature Control Range

Enter a number...

### Description of Cleaning and Sanitation Procedures

Write something...

# Personnel & Training

Review of vendor's personnel qualifications and training programs.

## Number of Qualified Personnel


## Key Personnel Qualifications (e.g., GMP, Degree)

- GMP Training
- Relevant Degree
- Other

## Last Training Completion Date (Key Personnel)

## Brief Description of Key Personnel Training Program

## Training Records (Example)

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### Verification of Personnel Background Checks

- Yes
- No
- N/A

### Details on Background Check Procedures (if applicable)

Write something...

## Regulatory Compliance & Audits

Confirmation of adherence to relevant regulatory requirements and history of audits.

### Last Audit Score

Enter a number...

### Date of Last Regulatory Inspection

Enter date...

## Summary of Findings from Last Regulatory Inspection

Write something...


## Compliance with GMP Guidelines?

- Yes
- No
- N/A

## Relevant Regulatory Frameworks (Select all that apply)

- FDA
- EMA
- WHO
- PIC/S
- Other

## Copy of Latest Regulatory Audit Report

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# Product/Service Specifications & Testing

Validation of product/service specifications and testing protocols.

## Detailed Product/Service Specifications

Write something...

### Testing Methodology Alignment (e.g., USP, EP, JP)

USP

EP

JP

Other (Specify)

### Acceptance Criteria Limit (e.g., Purity %)

Enter a number...

### Certificate of Analysis (CoA)

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### CoA Issue Date

Enter date...

### Testing Parameters Verified (Select all that apply)

- Identity
- Purity
- Assay
- Impurities
- Water Content
- Other (Specify)

### Deviations & Resolutions (if any)

Write something...

## Change Control & Corrective Actions

Review of vendor's change control process and management of corrective and preventive actions.

### Change Request Originated From:

- Quality Assurance
- Manufacturing
- Engineering
- Regulatory Affairs
- Other

### Description of Change/Deviation

Write something...

### Risk Score (assigned)

Enter a number...

### Date of Deviation/Change Initiation

Enter date...

### Root Cause Analysis Findings

Write something...

### Potential Impact Areas (select all that apply)

- Manufacturing Process
- Product Quality
- Equipment
- Documentation
- Regulatory Compliance

### Corrective Actions Planned

Write something...

### Planned Completion Date of Corrective Actions

Enter date...

### Signature of Responsible Person

## Contractual Agreements & Performance Monitoring

Assessment of contractual obligations and ongoing performance monitoring processes.

### Contract Start Date

Enter date...

### Contract Expiration Date

Enter date...

### Agreed Upon Price/Rate

Enter a number...

### Payment Terms

- Net 30
- Net 60
- Other (Specify)

### Key Performance Indicators (KPIs)

Write something...

### Performance Rating (Scale 1-5)

Enter a number...

### Performance Review Comments

Write something...

### Contract Renewed?

- Yes
- No

## Requalification & Periodic Review

Establishing a schedule for requalification and periodic reviews of vendor status.

### Last Requalification Date

Enter date...

### Review Frequency (in months)

Enter a number...

### Review Type

- Document Review
- On-site Audit
- Combination

### Summary of Review Findings

Write something...

### Reviewer Signature

\_\_\_\_\_

### Next Review Date

Enter date...