ChecklistGuro

Pharmaceutical Vendor Qualification Checklist

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

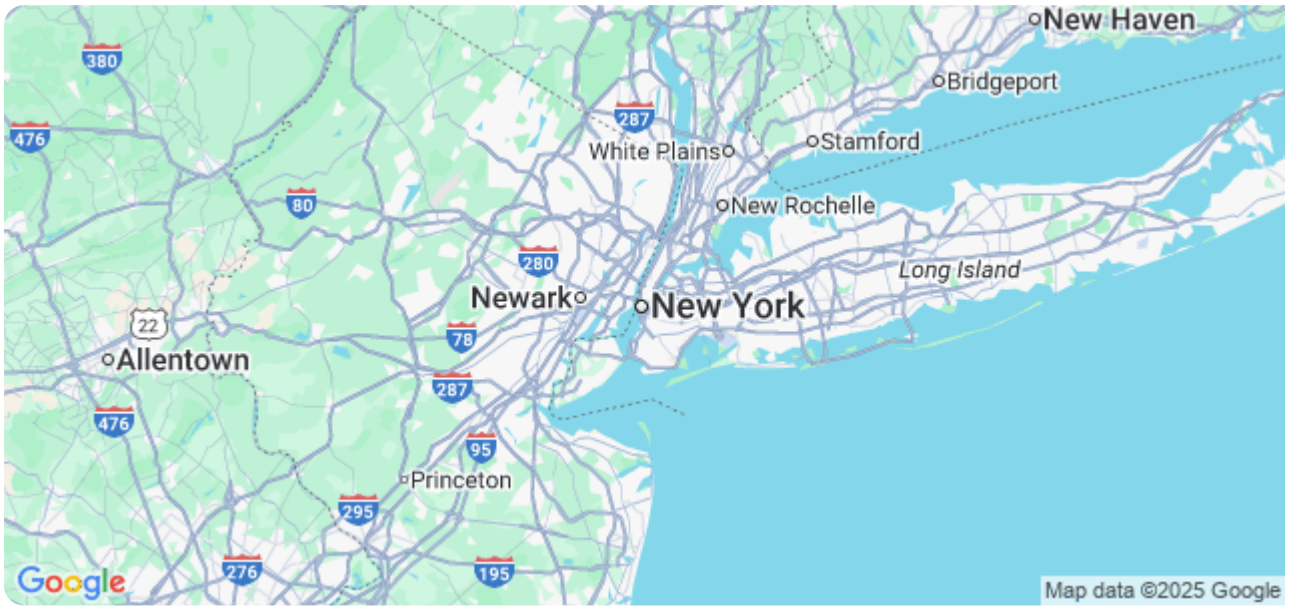
- [ ] Yes
- [ ] No
- [ ] Not Applicable

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

Enter a number...

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

- [ ] GMP Training
- [ ] Relevant Degree
- [ ] Other

Last Training Completion Date (Key Personnel)

Enter date...

Brief Description of Key Personnel Training Program

Write something...

Training Records (Example)

Upload File

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

Upload File

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...