

Supplier Qualification

Use this template to gMP supplier qualification package for [supplier_name].

Template Metadata

Field	Details
Category	Pharma & Biotech
Owner	[Team or owner]
Version	[Version number]
Effective Date	[Date]
Review Cycle	[Monthly / Quarterly / Annual / Event-based]
Status	[Draft / In Review / Approved]

Supplier Profile

Identify supplier, site address, contacts, certifications, regulatory history, and supplied materials or services.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

Material or Service Scope

Define item codes, specifications, criticality, intended use, markets, and alternate suppliers.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

Risk Classification

Assess patient safety, product quality, supply continuity, complexity, and prior performance risk.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

Qualification Evidence

Summarize questionnaire, audit, sample testing, validation, quality agreement, and regulatory checks.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

Quality Requirements

Define change notification, CoA expectations, deviation reporting, data integrity, and subcontracting controls.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

Monitoring Plan

Set incoming inspection, scorecard metrics, periodic review frequency, and requalification triggers.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

Approval Decision

State approval status, restrictions, open actions, effective date, and required approvers. Use supplier-quality terminology and concrete evidence tables.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]