Docsie Free Template | Pharma & Biotech

Validation Protocol

Use this template to protocol for validating [process_system_or_method] under GMP.

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]

Purpose

State what is being validated and the validation objective.

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.]

Scope

Define included systems, products, processes, locations, and exclusions.

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.]

Responsibilities

List Validation, QA, Operations, Engineering, and SME responsibilities.

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.]

Prerequisites

Identify approved procedures, training, calibration, utilities, materials, and readiness 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.]

Test Plan

Describe test cases, sampling plan, critical parameters, data to record, and execution sequence.

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.]

Acceptance Criteria

Define clear pass/fail criteria for each test or process attribute.

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.]

Deviations and Report

Explain deviation handling, data review, final report content, and approval requirements. Use Markdown tables for tests and criteria, and write in protocol-ready language.

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.]

Review and Signoff

Document review conclusions, approvals, unresolved items, and next review date.

Role	Name	Date	Notes
Preparer	[Name]	[Date]	[Notes]
Reviewer	[Name]	[Date]	[Notes]
Approver	[Name]	[Date]	[Notes]