

Technology Transfer Package

Use this template to manufacturing and analytical transfer package for [product_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]

Transfer Scope

Identify product, sites, dosage form, markets, transfer stage, and deliverables.

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.]

Product and Process Knowledge

Summarize formulation, process flow, control strategy, development history, and scale-up experience.

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.]

Critical Quality Attributes

List CQAs, acceptance criteria, clinical or regulatory relevance, and monitoring approach.

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.]

Process Parameters

Identify CPPs, key process parameters, normal ranges, proven acceptable ranges, and control rationale.

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.]

Analytical Methods

List release, in-process, stability, cleaning, and characterization methods with transfer status.

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.]

Readiness Plan

Define documents, equipment, materials, training, engineering batches, validation batches, and owners.

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.]

Knowledge Gaps

Document open questions, risks, mitigation actions, and decisions needed before PPQ. Use structured technical transfer language and include traceable 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.]

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]