CMO / CDMO PROJECT READINESS

Pharmaceutical Technology Transfer Readiness Checklist

A public, non-confidential framework for deciding whether product knowledge, methods, materials, receiving-site capability and governance are sufficiently defined to begin a controlled technology-transfer program.

> Core principle: a complete dossier, familiar dosage form or available manufacturing line does not by itself prove transfer readiness. The decision should be based on product-, process-, site-, market- and evidence-specific gaps.

Five readiness domains

Domain	What readiness should mean	Decision output
1. Product and process knowledge	Critical quality attributes, process rationale, development history, known sensitivities, control strategy and lifecycle knowledge are decision-ready.	**Knowledge-gap register**
2. Analytical methods and reference system	Methods, specifications, reference standards, transfer strategy, acceptance criteria and laboratory responsibilities are clear.	**Method-transfer plan**
3. Materials and container system	Critical material attributes, suppliers, variability, sampling, container closure and change risks are understood.	**Material-risk map**
4. Receiving-site and equipment fit	Equipment design, scale, utilities, environment, process interfaces, automation and facility controls are assessed against the product.	**Site-fit assessment**
5. Governance, quality and regulatory impact	Decision rights, quality agreements, change control, deviations, dossier impact, validation and post-transfer ownership are defined.	**Stage-gate governance plan**

Three questions before authorizing engineering work

01 What is known, and what remains assumption?
Separate source documents from verified knowledge, development rationale, receiving-site evidence and unresolved gaps.

02 Which differences could change product quality or control?
Assess equipment, scale, materials, methods, environment, interfaces, sequence, ownership and regulatory context.

03 What evidence is required for the next decision?
Define studies, engineering work, analytical acceptance, comparability, validation, escalation and hold/no-go criteria.

EVIDENCE-BASED TRANSFER

Questions for technical and quality due diligence

01 Transfer package

Ask: Does the package explain the rationale behind the process, or only reproduce instructions and historical values?

Evidence examples: development reports, risk assessments, process description, control strategy, deviations, changes and batch history

02 Analytical methods

Ask: Can the receiving laboratory reproduce intended method performance with defined responsibilities and acceptance criteria?

Evidence examples: method validation/verification records, transfer protocol, standards, instruments, system suitability and investigation history

03 Materials and container

Ask: Are critical attributes, sources, variability, comparability and container-closure risks linked to product and process performance?

Evidence examples: material specifications, supplier controls, change history, sampling, compatibility, CCI and stability evidence

04 Facility and equipment

Ask: Which design, scale, control-system, utility or environmental differences could alter process performance?

Evidence examples: site-fit assessment, equipment comparison, scale model, utilities, process interfaces, automation and contamination controls

05 Engineering and validation

Ask: What development or engineering evidence is needed before PPQ or other validation commitments?

Evidence examples: gap-closure studies, engineering batches, sampling plans, comparability, acceptance criteria and stage gates

06 Quality and regulatory governance

Ask: Who owns decisions, deviations, change control, release, dossier impact, escalation and post-transfer monitoring?

Evidence examples: quality agreement, RACI, change plan, regulatory assessment, governance forums, CAPA and continued process verification

> Recommended readiness output: one controlled gap register linking each gap to its impact, owner, evidence required, timing, decision gate and residual risk. This is more useful than a simple document-received checklist.

Red flags

- A dossier is treated as a complete transfer package without a knowledge-gap assessment.
- Methods are transferred as files, with no performance protocol or investigation route.
- Equipment is declared equivalent based only on equipment name or nominal capacity.
- Material, supplier or container differences are deferred until after engineering batches.
- Validation dates are committed before gap closure and engineering evidence are defined.
- Quality and regulatory responsibilities remain implied instead of documented.
- Sensitive data are requested before an appropriate confidentiality arrangement.

CONTROLLED PROJECT PATH

From initial screen to transfer governance

01	Non-confidential fit screen Confirm legal entity, site, dosage form, target market, project stage, high-level product profile and intended cooperation model.
02	Confidentiality and transfer scope Define purpose, permitted use, access, disclosure controls, work packages, responsibilities and decision rights.
03	Knowledge and site-fit gap assessment Compare product/process knowledge, methods, materials, equipment, utilities, environment, scale and regulatory context.
04	Gap-closure and engineering plan Agree studies, methods, batches, sampling, acceptance criteria, escalation, hold/no-go rules and evidence owners.
05	Validation and dossier readiness Connect comparability, process validation, cleaning/sterility needs, regulatory impact and quality agreements.
06	Commercial and lifecycle governance Confirm release, change control, supply continuity, trending, stability, continued verification and post-transfer ownership.

Non-confidential information for the first discussion

- Dosage form, presentation, high-level product characteristics and current development/commercial stage
- Available transfer history, broad process platform and proposed CMO/CDMO cooperation model
- Target market, dossier status, regulatory objective and intended timing
- Indicative batch-size range, supply objective and receiving-site decision to be evaluated
- The specific knowledge, method, material, site-fit, scale-up or governance gap to be resolved

> Information boundary: do not send patient information, prescriptions, complete formulas, detailed process instructions, unpublished dossiers or trade secrets before an appropriate confidentiality arrangement. An initial discussion does not confirm project acceptance, capacity, price, regulatory outcome or service commitment.

Discuss a non-confidential technology-transfer project fit

Steven Li (李一青), President of Hainan Hailing Chemipharma Co., Ltd.
lyq@cjrf.com | stevenyiqingli.com

Authoritative references

1. WHO TRS 1044, Annex 4 - Technology transfer in pharmaceutical manufacturing
2. ICH Q10 - Pharmaceutical Quality System
3. ICH Q9(R1) - Quality Risk Management
4. U.S. FDA - Process Validation: General Principles and Practices
5. NMPA - Contract-manufacturing supervision requirements