CMO / CDMO / TECHNOLOGY TRANSFER

Pharmaceutical Outsourcing Due-Diligence Checklist

A public, non-confidential framework for screening a named legal entity and manufacturing site against a defined product, target market, responsibility model and evidence plan.

> Decision rule: do not select a pharmaceutical outsourcing partner by country, group brand, dosage-form label, capacity claim or historical inspection statement alone. Fit is product-, process-, site-, market- and evidence-specific.

Eight diligence domains

01 Legal entity and site
Who will contract, manufacture, test, store, release and hold records?

Evidence examples: legal names, identifiers, site address, authorisation scope, subcontracting map

02 Product and market fit
Can this site support the exact dosage form, presentation, process and destination market?

Evidence examples: product profile, target country, route, scale, container system, gap assessment

03 Quality and regulatory history
What current evidence supports control, compliance and inspection context?

Evidence examples: QMS evidence, deviations, CAPA, changes, complaints, recalls, inspection scope and status

04 Manufacturing and process fit
Which equipment, utilities, environment, scale or co-line differences affect risk?

Evidence examples: equipment train, facility fit, process rationale, contamination-control and scale-up review

05 Analytical, stability and CCS
Are methods, specifications, standards, stability and container-closure responsibilities defined?

Evidence examples: method package, transfer plan, stability protocol, standards, CCI/CCS evidence

06 Materials and supply continuity
Can critical materials, suppliers, packaging and logistics remain controlled through the lifecycle?

Evidence examples: supplier map, lead times, alternates, inventory ownership, shortage and continuity plan

07 Governance and agreements
Who decides, performs, reviews, approves, communicates and escalates each activity?

Evidence examples: RACI, quality agreement, governance cadence, change/deviation and authority-response workflow

08 Commercial continuity and exit
Are assumptions, milestones, liabilities, data/IP rights and exit support contract-ready?

Evidence examples: critical path, acceptance gates, pricing assumptions, insurance, termination and transfer assistance

> Initial contact boundary: use a non-confidential project brief. Do not send patient information, prescriptions, complete formulas, detailed process instructions, unpublished dossiers or trade secrets before an appropriate confidentiality arrangement.

STAGE-GATED EVIDENCE

Ask for the right evidence at the right stage

Stage	Purpose	Examples of appropriate evidence	Decision output
1. Public screen	Confirm identity, site and basic relevance without sensitive disclosure.	Official registers; legal names and identifiers; public licence/registration and inspection context; site address; public product and service scope.	Reject obvious mismatch or define a focused NDA request.
2. NDA diligence	Test product, quality, regulatory, technical and supply assumptions.	Targeted QMS evidence; product/process package; equipment fit; methods; materials; stability; change history; project plan and gap log.	Conditional fit, unresolved gaps, owners and evidence required.
3. Site and technical assessment	Verify operations, people, facilities, records and data trails.	Source records; facility/lab walkdown; process and data review; interviews; equipment/utilities; governance demonstration; sample traceability.	Site-fit conclusion and controlled gap-closure plan.
4. Contract readiness	Align quality, technical, regulatory, commercial, IP and continuity responsibilities.	Quality and technical agreements; RACI; milestones; acceptance criteria; authority support; insurance; supply/exit and data-access terms.	Go, conditional go, hold or no-go with documented rationale.

Red flags that require escalation

Red flag	Why it matters	Required response
Legal name, site or contracting entity is unclear	Licences, records, obligations and payment may attach to different entities.	Reconcile exact legal names, identifiers, addresses and responsibility map.
Dosage-form capability is treated as product acceptance	Formulation, process, equipment, materials and market requirements can create unassessed gaps.	Complete a product-to-site and target-market gap assessment.
Inspection history is described as certification or approval	Inspection, closure, application approval and certification are not interchangeable.	Record authority, site, date, scope, classification/outcome and current status.
Schedule or price precedes technical assumptions	A quote can hide missing studies, methods, materials, validation or regulatory work.	Define assumptions, evidence gates and exclusions before commitment.
Quality responsibilities remain implied	Critical communication, investigation, release and change duties can fall between parties.	Create a detailed responsibility matrix and quality agreement.
Sensitive files are requested during first contact	Uncontrolled disclosure creates privacy, IP and data-governance risk.	Use a non-confidential screen, then NDA and controlled data-room plan.

> Evidence standard: request source records and scope-specific evidence, not superlatives. A public checklist supports screening; it does not replace a quality audit, technical assessment, legal review or target-market regulatory advice.

DECISION RECORD

Turn gaps into an auditable next step

Decision field	Record
Named legal entity and site	_____
Product / dosage form / presentation	_____
Target market and applicant/MAH model	_____
Requested scope	[ ] CMO [ ] CDMO [ ] Technology transfer [ ] Registration support
Decision	[ ] Go [ ] Conditional go [ ] Hold [ ] No-go
Critical unresolved assumption	_____
Evidence required and source	_____
Owner and acceptance criterion	_____
Target decision date	_____

Safe first-contact information

Include	Keep out of the initial submission
Organisation and contact; dosage form and presentation; development/commercial stage; target market; requested cooperation model; approximate scale range; desired timeline; known non-confidential constraints.	Patient information; prescriptions; complete formulas; detailed process instructions; unpublished dossiers; raw confidential datasets; trade secrets; files without a defined confidentiality and access-control basis.

Selected primary references

NMPA — Drug Administration Law of the People's Republic of China, including MAH and contract-manufacturing responsibilities. NMPA — Announcement No. 134 (2025) on contract manufacturing, evaluation, technology transfer and quality-system interfaces. WHO TRS 1044, Annex 4 — Technology transfer in pharmaceutical manufacturing. European Commission — EU GMP Chapter 7: Outsourced Activities. U.S. FDA — Contract Manufacturing Arrangements for Drugs: Quality Agreements.

Discuss a non-confidential project fit

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