DECISION TOOL

CMO vs CDMO: Project Selection Brief

A practical, non-confidential starting point for deciding whether a pharmaceutical project should begin as contract manufacturing, development plus manufacturing, or a structured technology-transfer programme.

CMO

Best starting point when the product and transfer package are sufficiently mature for a defined manufacturing scope.

CDMO

Best starting point when formulation, process, analytical, scale-up or regulatory-development gaps remain.

TECHNOLOGY TRANSFER

A controlled transfer of product, process, methods and knowledge; it can sit inside either model.

Comparison at a glance

Decision area	CMO starting point	CDMO starting point	Technology-transfer focus
Product maturity	Defined product and reasonably transfer-ready package	Material development or scale-up work remains	Knowledge and evidence must move to an agreed receiving system
Typical work	Commercial manufacture, release and supply within agreed scope	Formulation, process, analytical, scale-up and manufacturing work	Transfer plan, gap assessment, training, methods, process and verification
Main early question	Is the package ready for the proposed product, site and market?	Which development gaps must be closed before routine manufacture?	What knowledge, evidence and responsibilities must transfer, and how will success be accepted?
Core governance	Supply, change control, release, deviations and quality agreement	Stage gates, development decisions, IP, data, change control and quality agreement	Sending/receiving responsibilities, acceptance criteria, comparability and lifecycle control

Use the operating question, not the acronym, to select the starting model. One project can move between these models as evidence and maturity change.

Authoritative references

1. U.S. FDA - Contract Manufacturing Arrangements for Drugs: Quality Agreements
2. WHO TRS 1044, Annex 4 - Technology transfer in pharmaceutical manufacturing
3. NMPA - Contract-manufacturing supervision requirements

FIVE DECISION QUESTIONS

What to resolve before defining scope

01 What is already mature?
Clarify formulation, process, methods, specifications, validation status, dossier status and commercial experience.

02 What still needs development?
Identify gaps in formulation, analytical methods, scale-up, process control, registration support or supply design.

03 What must transfer?
Define product knowledge, process parameters, methods, standards, training, documents and acceptance evidence.

04 Who owns each decision?
Assign quality, technical, regulatory, supply, data, IP, deviation, change-control and batch-release responsibilities.

05 What is the stage-gate evidence?
Agree deliverables, acceptance criteria, decision authorities, escalation routes, schedule and change process.

Non-confidential information for a preliminary assessment

- Dosage form, presentation and high-level product characteristics
- Development or commercial stage and proposed cooperation model
- Target market, dossier status and intended regulatory route
- Indicative timing, batch-size range and supply objective
- The specific technical, quality, regulatory or supply decision to be made

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 project fit

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