PSH **Guides**

Selecting a Contract Manufacturing Organisation (CMO)

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Pharma Services Hub

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Selecting a Contract Manufacturing Organisation (CMO) is one of the most important decisions a pharmaceutical company can make.

Unlike many outsourced services, a manufacturing partner is directly responsible for ensuring product quality, supply continuity and regulatory compliance. The consequences of selecting the wrong provider can include delayed licence (MA) applications, supply interruptions, regulatory observations, increased supply chain costs and reputational damage.

The good news is that with the right preparation, structured information sharing and a consistent evaluation process, it is possible to identify manufacturing partners that align with your product, programme and commercial objectives.

PREPARATION

1. What is to be achieved?
Before beginning your search, be clear about the purpose of the outsourcing activity.

What are you trying to achieve?
- What manufacturing activities are being outsourced?
- What activities will remain internal or with existing service providers?
- What product lifecycle stage(s) are you supporting?
- What are the project's critical success factors?
- What does success look like in 6-24 months?

Examples may include:
- Technical/site transfer
- Registration batch production/process validation
- Commercial launch
- Capacity expansion
- Supply chain diversification/derisking
- Secondary packaging
- Warehousing and distribution
- These answers help define your manufacturing strategy.

2. What is the outsourcing strategy
Not all manufacturing partnerships are the same. Before contacting CMOs, define the type of support required.

Are you looking for:
- A specialist manufacturer for a specific modality e.g. Sterile products, Potent compounds, Controlled substances, Biologics, Cell & gene therapies
- A clinical supply manufacturer (with expertise supporting trials in Phase III supply and clinical distribution) or a commercial stage manufacturing partner that supports launch, validation, commercial supply or lifecycle management? Some CMOs will support both
- A packaging and distribution partner
- This decision will influence which CMOs you approach and how you compare them.

To get the most value out of the outsourcing process, make sure not to send the same request to providers with different skills and experience.

Before reaching out, ask:
- Do we need specialist expertise/handling capability or routine manufacturing support?

- Is this a short-term manufacturing requirement or long-term partnership?
- Do we need one manufacturing site or multiple locations?
- What supply risks need to be managed?
- Do we require a regional or global supply partner?
- Do we need to minimise cross-border product flow and associated regulatory testing and release activities?
- How important is future scalability/flexibility in regard to capacity

RFI AND RFP

3. What to provide to the service provider?
A service provider is unlikely to have any background on your project unless you are continuing to the next milestone with an existing vendor. To get the best information back from your request for information (RFI) or request for proposal (RFP) and to save time in discussions and negotiation, you must be able to convey simply and exactly what you need.

If you don't know exactly what you need in specific areas tell this to the service provider too. How they respond to questions is a great indication of they engage with clients, solve problems and understand your needs from the outset. If they can't help or provide the services you need, they should point you towards who can.

To provide a comprehensive proposal for a manufacturing engagement is an investment for the service provider also. They to need to understand quickly if the project fits their service provision, experience and capabilities (handling, scale, licensure etc), capacity and commercial expectations.

Note: Some companies have minimum project revenue targets, below which they won't quote against.

Generally, the service provider needs to meet three main categories of requirements:
1. Project expectations
2. Technical expectations
3. Target cost of goods expectations/your anticipated annual demand forecasts.

Project expectations include:

- Business context – company stage, funding, product importance, commercial objectives
- Timelines, phase, project history
- Modality, molecule specifics
- Quality & regulatory expectations – GMP, licence requirements, filing strategy, inspection history, target markets
- Handling requirements

Technical details include:

- Product and process specifics - dose form, manufacturing process, product characteristics, batch size, equipment requirements
- Manufacturing requirements – clinical/ commercial supply, primary, secondary packaging and labelling, testing and release.

Target cost of goods:

Service providers will always request a target cost of goods to help them determine whether they meet your price per unit expectations. However, it is really important to understand how the target cost of goods is derived and when comparing values across sites, a number of considerations are necessary:

Comparing manufacturing sites based only on costs derived from API, excipients, packaging materials, direct labour and manufacturing/ quality overhead, can lead to suboptimal decisions because the "cheapest" manufacturing site may create significant downstream quality and supply chain costs.

For supply-chain rationalisation, companies increasingly use a **landed cost** or **total cost-to-serve** approach.

This includes factoring in not only the aforementioned manufacturing costs, but also much more:

Manufacturing Cost
• API, excipients, packaging materials, direct labour and manufacturing/quality overhead
And additional quality and logistics costs:

Quality Cost
• Import testing (e.g. EU-based batch control for UK supply), local release testing, QP certification, method transfer activities, additional stability requirements

Logistics Cost
• Freight, cold-chain handling, customs clearance, warehousing, inventory carrying costs

Regulatory Cost
• Site registrations, variations, market-specific compliance activities, inspections

Supply Chain Cost
• Safety stock, inventory buffers

A better measure to improve the cost accuracy could use a **Total Delivered Cost / Total Delivered Cost per Saleable Unit** when discussing pricing options with service providers.

To supply an indicative cost of goods, the service provider will need you to provide indicative anticipated annual demand forecasts across dose and batch size estimations. The more accurate these values are, the more realistic the COGS supplied will be.

Sharing known challenges upfront also is advisable such as scale-up risks, robustness of the process, any supply chain concerns or resource limitations. The quality of information shared often determines the quality of the responses received.

4. What to send out - RFI versus RFP
Before asking service providers for a full proposal, decide whether you need an **RFI** or an **RFP**.

An **RFI** — request for information — is useful when you are still learning the market. It helps you understand who has the right capability, experience, capacity and interest before asking for detailed proposals. This is most appropriate when screening companies.

An **RFP** — request for proposal — is used when you are ready to ask selected providers to propose a specific approach, timeline and cost for your project.

Both have value, but they are not the same.

Use an **RFI** when:
- You have a broad requirement but are not sure which providers are suitable
- You need to understand capability, technology fit, experience or capacity
- You want to screen a longlist before investing time in detailed discussions
- You do not yet have enough information to support a detailed proposal

Use an **RFP** when:
- Your scope is well defined for providers to price and plan against
- You have enough technical and project information to share
- You want comparable proposals from a smaller number of providers
- Your timelines are established and budget expectation understood, you are ready to assess approach, timeline, assumptions, risks and cost

A common mistake is to issue an RFP too early. If the scope is unclear, the responses will be difficult to compare and the real work will move into clarification calls. Another mistake is to send an RFI to too many providers without clear screening questions. You may get a lot of information back, but not necessarily the information needed to make a decision.

Before deciding, ask:
- Are we trying to identify suitable providers or select a final partner?
- Do we have enough information to support accurate pricing?
- How many providers can we realistically evaluate?
- What assumptions still need to be tested?

Screen quickly with an RFI, this allows you to focus on those service providers who engage, understand your needs and may provide further considerations which help make your RFP more robust.

Once you have finalised your scope, assumptions, deliverables and decision criteria, move to an RFP, this should make the RFP process more efficient and no need for multiple rounds of further discussion and a more focussed set of service providers that you know can provide what you need.

5. Structuring an RFI/RFP
Keep the document simple. The aim is not to show how much you know, but to get the information needed to make a decision.

For an **RFI**, focus on screening questions: capability, relevant experience, capacity, technology fit, GMP status, location, licensing, and whether the provider is interested in the project.

For an **RFP**, provide enough detail for a realistic proposal: scope, assumptions, deliverables, timelines, technical information, quality expectations, commercial requirements and decision criteria.

Ask providers to respond in a consistent format. If every response is structured differently, comparison becomes harder than it needs to be.

Be clear where you want a firm answer and where you are asking for advice. This helps separate capability from sales messaging.

Don't make the RFP too long, too vague or too restrictive. The best responses usually come from a clear scope, sensible assumptions and room for the CMO to explain how they would approach the work.

COMPARING

6. Comparing manufacturing providers
Once proposals are received, avoid comparing providers on cost alone. Your preparation should drive your selection weighting. The cheapest proposal may not be the lowest risk, and the most detailed proposal may not be the best fit. The objective is to identify the provider most likely to deliver quality product, regulatory compliance and reliable supply.

Proposals should all provide assurance in meeting the technical requirements such as manufacturing capability (e.g. facility, equipment); relevant experience with working with your dosage form, technology and process stages; quality and compliance (e.g. capacity, lead times, resourcing); ability to provide technical support (e.g. process expertise, tech transfer capability, problem-solving approach); provision of project management through governance, communication and issue-escalation; and be a commercial fit for your organisation.

- Compare each provider against the same criteria.
- Separate those must-have requirements from nice-to-have features.
- Score what matters to the project.
- Challenge assumptions, exclusions and dependencies in the proposal.
- Make sure the provider's proposed approach matches your milestone, budget and internal capability.
- A common mistake is to score the proposal rather than the provider. A good proposal is useful, but you are selecting the organisation that will deliver the work.
- Typical scorecard areas include technical fit, relevant experience, quality and GMP status, regulatory track record, capacity, timeline realism, project management, communication style, commercial transparency and cultural fit.
- It is also important to consider some of the less tangible aspects of your interactions.
  - Did they listen to what we needed
  - Do they really understand what we are trying to achieve by when.
  - Are the 'delivery' team engaged during these discussions.
  - Who will actually be 'delivering' / 'overseeing' and 'accountable' on their side.
  - During early discussions the 'A-team' is generally rolled to win new clients and showcase expertise. How close will that A-team be to you project when its starts.
  - If multiple sites will be involved with project delivery, how does the service provider manage these interactions. One 'brand' does not always mean a harmonious team

all working to drive the same profit and loss sheet.

DUE DILIGENCE

7. What to check during due diligence
Once preferred providers have been shortlisted, due diligence helps validate whether the proposed partnership can be successfully delivered.

The objective is not to identify minor issues but to understand genuine risks before committing. Selecting a CMO can be viewed as a risk management exercise, with the right manufacturing partner helping to reduce technical, quality, supply chain and regulatory risks. The wrong partner can introduce delays, compliance issues and additional costs that may impact development timelines and commercial success.

Good due diligence will mitigate that risk:

- Technical risk - verify experience with similar products, processes and development stages. This provides the assurance that process, formulation or methods are sufficiently understood. It cannot be assumed that a small-scale development will automatically translate into successful commercial manufacture.
- Quality and Reg risk - Review GMP status, inspection history and quality system maturity. Understand how deviations, CAPAs and change controls are managed. Since manufacturing quality failures can lead to batch rejections, supply interruptions and regulatory observations, you will need to ask yourself whether you would be comfortable defending the CMO during a regulatory authority inspection
- Capacity risk – if the project timelines changes, is there flexibility in scheduling? Assess utilisation levels, lead times, competing client projects, expansion plans and operational/resourcing constraints.
- Supply chain risk - Review supply chain robustness and business continuity plans. Consider critical raw materials, single-source suppliers, long lead-time materials, inventory management processes.
- Project management risk - Understand project management and communication arrangements. Confirm who will be responsible for day-to-day delivery. Speak to references where possible. The best manufacturing relationships typically will have strong PM as well as strong technical capabilities.
- Future scalability risk - Evaluate the CMO's ability to support future scale-up and commercialisation, by considering your future batch size requirements and geographic expansion plans. Can they support from a commercial and regulatory perspective?

Long-term success is often influenced as much by communication, responsiveness and partnership quality as by technical capability.

PRICING

8. Understanding CMO pricing models
If you do not specify how you want the service provider to quote, cost and present the commercial model in response to your RFP, there is a strong chance that each provider will respond in a different format. One proposal may emphasise fixed project costs, another may separate time and materials, while another may include milestone payments, capacity charges or batch-based pricing. Without a defined pricing structure and clear expectations for assumptions, exclusions and optional costs, it becomes difficult to compare proposals on a like-for-like basis.

Understanding how CMOs structure pricing helps to manage expectations across the board. You should be clear in your brief how you want the costs to be presented. This makes it much easier to compare and contrast responses fairly.

CMO PRICING MODELS

Pricing model	How it works	Best used when	Advantages	Points to check / risks
Fixed price projects	The CMO agrees to deliver a defined scope for an agreed cost.	Scope, technical risk and deliverables are clearly understood.	Budget certainty, easier internal approvals and simpler comparison.	Check assumptions, scope boundaries and potential change-control costs.
Time and materials (T&M)	The client pays for actual resources used.	Process development, troubleshooting, analytical development or early-stage projects.	Flexible and easier to manage where requirements may change.	Less budget certainty; costs can increase if the project scope expands.
Milestone-based pricing	Payments are linked to predefined project milestones.	Defined stages such as project initiation, process transfer completion, batch manufacture or product release.	Aligns payment with progress and can improve cashflow management.	Confirm how milestones are defined and compare payment schedules carefully.
Capacity reservation fees	Reservation payments secure manufacturing slots or facility access.	Capacity is limited, timing is critical or scheduling conflicts need to be reduced.	Protects manufacturing capacity and reduces scheduling uncertainty.	Confirm whether fees are refundable, offset future manufacturing charges or still apply if timelines change.
Campaign and batch-based pricing	Commercial manufacturing is quoted per batch or manufacturing campaign.	Commercial or repeat manufacturing where batch, campaign and volume assumptions are central to cost.	Supports comparison of recurring manufacturing costs and scale assumptions.	Review batch size, yield assumptions, number of batches included, validation requirements and release testing costs.

Additional Costs Often Overlooked
Many manufacturing proposals exclude activities that may become significant cost drivers later.

- Common examples include:
- Technology transfer
- Method transfer
- Stability studies
- Process validation
- Additional regulatory support
- Change controls
- Additional project management
- Storage and distribution
- Shipping and import/export support

Comparing Pricing Fairly
Before comparing costs, ensure you understand:

- Scope differences between providers
- Assumptions and exclusions
- Included services
- Resource allocation
- Quality and regulatory support levels

An effective approach to evaluation of a potential engagement would factor in cost of course but as part of a number of other attributes:

Overall Value = Technical Fit + Quality Confidence + Delivery Confidence + Cost

It could help running the numbers on the project cost when it goes according to plan, and cost when it doesn't, as this will reveal more about a proposal than the headline price.

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Summary
Selecting a Contract Manufacturing Organisation is not about finding the largest manufacturer or the lowest-cost option.

It is about identifying the manufacturing partner whose technical capabilities, quality systems, people and capacity are best aligned with your product and business objectives.

Successful CMO selection starts with clear preparation, structured information sharing, objective comparison and focused due diligence.

By investing time upfront, companies can reduce risk, improve supply reliability and establish manufacturing partnerships that support both current and future milestones.

Use Pharma Services Hub to identify, compare and engage CMOs across a broad range of dosage forms, technologies and manufacturing capabilities.
www.pharmaservicehub.com