PSH Guides

Selecting a Drug Product CDMO

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Pharma Services Hub

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Selecting a CDMO to develop your drug product can feel like handing over your baby to a stranger.

It's probably one of the biggest decisions you can make as a product developer and let's be honest your mortgage may depend on you making the right decision. Complete success is what you require nothing less

Like most decisions, the devil is always in the detail. A quick search and a couple of AI generated emails to get the answers you need, won't cut it. But you can get to the detail quickly and with improved confidence when making your decision; here's how...

PREPARATION:

1. What is to be achieved?

Before beginning your search are you clear on what your project needs to achieve? This may seem obvious, but have you asked yourself the following questions?

What are the 'Target project milestones'?

- For examples completion of Preclinical studies, Proof of concept, first in human (FIH), End of Phase 2 studies etc

What exactly am I trying to outsource during this exercise?

- Development studies only, CT Manufacture, Packaging and labelling, Technical transfer etc.

What support do I need?

- Expertise to enable our ideas
- End to end support/one stop shop
- A platform technology to protect the asset

What activities will be managed internally or by other vendors?

- What don't we know?
  - Do we need additional expertise to manage this outsourcing activity?

What are our critical drivers in order of preference?

- Cost
- Duration to milestone delivery?
- Expertise
- Resource
- Quality

These questions help to form your outsourcing strategy.

2. What is our outsourcing strategy

Before contacting service providers, be clear on the type of support you need. Are you looking for:

- A provider to complete a defined activity?
  - e.g. formulation studies, analytical development, clinical manufacture, packaging/labelling
- A development partner to help shape the technical approach?
  - e.g. process strategy, formulation options, scale-up route, manufacturability
- A long-term manufacturing partner?
  - e.g. late-stage clinical supply, validation, commercial readiness, lifecycle support

This decision will influence which CDMOs you approach and how you compare them.

A common mistake is to send the same request to very different types of provider and then try to compare the responses directly. A specialist development provider, clinical manufacturer and large end-to-end CDMO may all be useful, but they may not be solving the same problem.

Before reaching out, ask:

- Do we need specialist expertise or broad end-to-end support?
- Do we want one accountable provider or several specialist vendors?
- What will remain internal?
- What must the CDMO own?
- Are we selecting for the next milestone or the full product lifecycle?
- What risks are we asking the CDMO to manage?

If you are not clear on your outsourcing strategy, the market may define it for you.

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 drug development 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 fall into two main categories of detail:

1. Project expectations
2. Technical expectations

Project expectations include:

- Timelines, phase, project history
- Modality, molecule specifics, TPP aims
- Quality requirements, license requirements
- H&S, safety and handling requirements

Technical details include:

- Analytical approach
- Pre-formulation/Formulation considerations
- Product and process specifics
- Techniques/scale/equipment requirements
- Primary, secondary and labelling requirements.
- Stability/distribution and release requirements.

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 clear enough for providers to price and plan
- You have enough technical and project information to share
- You want comparable proposals from a smaller number of providers
- 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:

- Do we know exactly what we want quoted?
- Do we have enough technical information to support a proposal?
- Are we trying to learn the market or select a partner?
- Do we need broad screening or detailed pricing?
- How many providers can we realistically manage through the process?

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. **You can now focus on the detail.**

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.

A common mistake is to 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 CDMO to explain how they would approach the work.

COMPARING

6. Comparing service providers

Once proposals are received, avoid comparing providers on cost alone. You 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.

- Compare each provider against the same criteria.
- Separate 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 you are down to your favoured providers, due diligence is where you test whether the proposal can actually be delivered. The aim is not to catch the provider out, but to understand the real risks before committing. It's important to remember that reputation isn't everything. Manchester United, Barcelona and Inter Milan don't win their respective leagues every season they are only as good as their last game. A CDMO is only as good as their current workforce and their last delivered project. You need to trust those you are passing your baby to.

- Check the provider's relevant experience with similar products, dosage forms, technologies and development stages.
- Confirm GMP status, licences, inspection history, audit readiness and quality system maturity.
- Review how deviations, CAPAs, change controls and investigations are managed.
- Check whether the proposed equipment, scale and facility fit the project need.
- Understand capacity, lead times, resource availability and competing priorities.
- Review analytical capability, method transfer expectations, stability support and release testing arrangements.
- Check supply chain assumptions, raw material availability, specialist handling requirements and business continuity.
- Assess project management, communication style, escalation routes and how issues will be handled.
- A common mistake is to treat due diligence as a quality audit only. Quality is critical, but technical fit, capacity, people, communication and commercial assumptions matter too.

Summary

Selecting the right CDMO is not about finding the best-known provider; it is about finding the right fit for your product, milestone, technical needs and risk profile. Clear preparation, structured information sharing, consistent comparison and focused due diligence will save time, reduce uncertainty and improve the chances of a successful partnership.

Use Pharma Services Hub to turn that preparation into action; search for providers now and get to the detail quickly: **www.pharmaserviceshub.com**