Selecting a Consultancy Service

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Pharma Services Hub

Selecting a consultancy can be one of the most important decisions an early-stage biotech company makes.

Unlike many outsourced activities, consultants often influence strategic decisions, development plans and investment choices that affect the future direction of a programme. They may help define regulatory strategy, support fundraising discussions, establish quality systems, manage CMC activities or coordinate complex development programmes.

Consultancy support can range from independent consultants, who often provide flexible, senior-level specialist input for defined needs, to consultancy service providers, which may offer broader teams, structured delivery models and the capacity to support multiple disciplines or longer-term programmes. The best fit will depend on the nature of the challenge, the expertise required, the level of support needed and how well the consultant or provider aligns with the company's objectives.

The challenge is that consultancy services can be difficult to compare. Proposals often look similar on paper, expertise can be hard to evaluate and the largest, most well well-known or established consultancy service provider is not always the best fit for your specific needs.

However, with the right preparation and a structured evaluation process, it is possible to identify consultants that genuinely add value and help accelerate development programmes

PREPARATION:

1. What is to be achieved?

To define the support that your team requires, start by asking the following questions:

- What decisions are we trying to make?
- What development milestone are we trying to achieve?
- What expertise is missing internally?
- Where are the biggest programme risks?
- What activities will remain internal?
- What support do we expect from a consultancy?
- What does success look like in six to twelve months?
- What don't we know or understand?
- What are our internal resource constraints?
- What risks can we mitigate with additional support?

Examples of milestones may include:

- Seed or Series A fundraising
- IND or CTA preparation
- First-in-human studies
- Technology transfer
- Due diligence preparation
- Partnering activities
- Inspection readiness

These questions help define your consultancy strategy.

2. What is our outsourcing strategy

Since not all consultancy engagements are the same, before contacting providers, it is important to be clear on the type of support required. This seems obvious, but it is important to define the type of consultancy support needed, which could be of several types, ranging from a

Specialist Advisor, providing expertise in fields such as

- Regulatory strategy
- CMC development
- Quality systems
- Drug safety
- IP
- Clinical – Key opinion leader (KOL)

Operational Resource, with specialism in
- Interim leadership / Fractional executive
- Programme management
- QP services
- PV support

A longer-term Strategic Partner, that will help shape future development decisions and support multiple milestones.

Virtual Function
Some early-stage companies, being lean on resource and more 'virtual', effectively need to outsource an entire capability, this is often the case with the Regulatory Affairs function.

It is important not to compare fundamentally different consultancy models against one another. A boutique consultancy, interim consultant, specialist advisor and global consulting organisation may all be capable of supporting the project, but they may not be solving the same problem.

Before making contact, ask:

- Are we looking for specialist expertise to solve a specific problem, or broader support across multiple activities?
- Do we need strategic advice, operational resource, or a combination of both?
- Is this requirement linked to a single milestone or likely to continue across future development stages?
- Do we require an individual consultant, a small specialist team, or access to a wider consultancy organisation?
- Are we looking for someone to advise, someone to deliver, or someone to lead?
- What responsibilities will remain within our organisation and what responsibilities will be delegated to the consultancy?
- Do we need additional resource capacity, expertise that does not exist internally, or independent external challenge?
- How much internal oversight and management can we realistically provide?
- Do we require support on a part-time, interim or full-time basis?
- Are we seeking a short-term engagement or a longer-term strategic partnership?
- Would a virtual outsourced function be more efficient than building internal capability at this stage?
- Are there likely to be future requirements that the consultancy should be capable of supporting?
- What level of flexibility will be needed as project priorities evolve?
- What would success look like at the end of the engagement?

RFI AND RFP

3. What information to share with the Consultant/Consultancy?

Consultants can only provide relevant advice if they understand the context of your programme.

A Consultant/Consultancy 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) 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, explain this to the consultancy provider too. How they respond to questions is a great indication of how 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 can be a significant time and resource investment for the consultancy provider. They to need to understand quickly if the project fits their service provision, experience, capacity and commercial expectations.

Note: Some consultancies might have minimum project revenue targets, below which they won't quote against. A large consultancy might not wish to take on a small and discrete consulting engagement, if it takes their resource away from longer term projects.

As a basic guide, providing sufficient information about the company's current situation, programme and/or assets, detailed scope of work and known business challenges will help give the consultancy valuable context. Some examples of the information types that would lead to a more relevant and useful response are as follows:

Business Context

- Company stage
- Funding position
- Development goals
- Target milestone

Programme Context (if known)

- Product type (e.g. modality, molecule specifics, TPP)
- Development stage (phase, timeline)
- Regulatory status (strategy for filing and beyond)
- Existing service providers

Support Required

- Scope (detailed)
- Deliverables
- Expected outcomes
- Internal responsibilities

Known Challenges

- Capability gaps
- Resource constraints
- Budget limitations
- Areas of uncertainty

The quality of information shared at the outset often determines the quality of the responses received.

4. What to send out - RFI first, proposal request where needed

For most consultancy engagements, particularly where the requirement is advisory, specialist or exploratory, a formal RFP is unlikely to be necessary at the outset. A short, well-structured RFI or briefing note is usually a better starting point.

An RFI — request for information — is useful when you are still clarifying the market, the type of expertise required or the most appropriate consultancy model. It helps you understand who has the right capability, experience, availability, capacity and interest before asking for a more detailed approach or cost estimate.

A more formal proposal request may be appropriate only once the requirement is clearly defined, the shortlisted consultancies understand the context and there is enough information for them to describe a realistic approach, timeline, assumptions and cost. In many consultancy engagements this can be handled through a focused proposal or statement of work rather than a full procurement-style RFP.

The key distinction is whether you are trying to learn who could help and how, or whether you are ready to ask a small number of shortlisted providers for a defined proposal:

Use an RFI when:

- You might have a broad requirement but are not sure which providers are suitable
- You need to understand expertise, 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

An RFI is particularly useful when assessing consultancy capability, relevant experience and cultural fit.

Ask for a focused proposal or statement of work when:

- Your scope is clear enough for providers to price and plan
- You have enough technical and project information to share

- You want comparable approaches from a small number of shortlisted consultancies
- You are ready to assess approach, timeline, assumptions, risks and cost

A focused proposal or statement of work should provide enough detail to confirm the proposed approach, resource model, assumptions, costs and governance without overburdening the process.

Requesting a full RFP-style response too early can make the process slower and harder to compare, particularly if the objectives, assumptions or scope are still developing. Early discussion is often more useful than asking multiple consultancies to prepare detailed proposals against an incomplete brief.

Sending an RFI to too many providers without a clear screening strategy may generate more responses, but not necessarily the right information for decision-making. Valuable time can then be lost filtering multiple responses to enable meaningful comparison and evaluation.

Before deciding whether to request only information or a more detailed proposal, ask:

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

Screening quickly with an RFI allows you to focus on consultancies that engage well, understand your needs and can identify considerations that may shape a clearer brief or statement of work.

Once the scope, assumptions, deliverables and decision criteria are clear, ask shortlisted consultancies for a focused proposal or statement of work. Reserve a formal RFP process for larger, multi-workstream or more procurement-led engagements where comparable detailed submissions are genuinely needed. At this stage, you can focus on the detail.

5. Structuring your RFI or consultancy brief
Keep the document simple. The aim is not to create a formal procurement burden, but to give consultancies enough context to confirm whether they can help and to explain how they would approach the requirement.

For an RFI or initial consultancy brief, focus on screening questions: relevant experience, team structure, availability, capacity, interest in the project and any early risks or assumptions the consultancy can identify.

For shortlisted consultancies, a focused proposal request or statement of work should provide enough detail for a realistic response: scope, assumptions, deliverables, timelines, quality expectations, commercial requirements and decision criteria. A full RFP should only be used where the engagement is sufficiently large, complex or procurement-led to justify that level of formality.

It would be worth asking providers to respond in a consistent format to allow for easier comparison.

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

The best responses will come from a clear brief, sensible assumptions and room for the consultancy to explain how it would approach the work. A document that is too long, generic or restrictive may discourage useful engagement and reduce the quality of the response received.

COMPARING

6. Comparing consultancies
Once responses or proposals have been received, avoid focusing solely on cost. The objective is to identify the consultancy most likely to help you achieve your target milestone, not simply the provider with the lowest fee.

Compare each consultancy against a consistent set of criteria before reviewing detailed responses. This helps ensure that selection decisions are based on project needs rather than presentation style or commercial attractiveness.

Key assessment areas typically include:

Relevant Expertise
The consultancy should demonstrate experience in the specific area where support is required. Generic pharmaceutical experience is useful, but direct experience of similar challenges is often more valuable.

- Have they solved similar problems before?
- Have they supported similar products, technologies or development stages?
- Do they demonstrate an understanding of the risks associated with our programme?

Experience with Emerging Companies
Not all consultants are accustomed to working with start-ups and emerging biotech companies.

Early-stage organisations operate under different constraints to large pharmaceutical companies, often balancing limited funding, lean internal teams and investor-driven timelines.

- Have they supported companies at our stage of development?
- Do they understand resource limitations?
- Are their recommendations realistic and commercially practical?
- Can they help prioritise activities and expenditure?

Some of the best consultants for start-ups are those who understand not only the science but also the realities of building a company.

Team Quality
One of the most important questions - Who will actually deliver the work?

Consultancy responses may highlight senior personnel, but day-to-day delivery may be performed by less experienced team members.

- Who will lead the engagement?
- Who will undertake the majority of the work?
- What level of senior oversight will be provided?
- Will subcontractors be involved?

A smaller consultancy with direct access to senior experts may sometimes provide greater value than a larger organisation with a more layered delivery model.

Strategic Insight
Look for evidence that the consultancy understands the broader context of your programme and is willing to challenge assumptions when appropriate.

Strong consultants should be able to

- Identify risks that have not been considered
- Suggest alternative approaches
- Highlight critical dependencies
- Help prioritise activities
- Explain what comes after the current project

Communication
Have they been responsive, clear and practical during the selection process? Early interactions often indicate how the relationship will operate once the project begins.

- Were responses timely?
- Did they answer questions directly?
- Did they listen carefully to your objectives?
- Did they explain complex issues clearly?
- Did they demonstrate genuine interest in the project?

Delivery Confidence
To have confidence that the consultancy can deliver, assess its response or proposed statement of work with the following in mind:

- Is the proposed approach realistic?
- Are timelines achievable?
- Have risks and assumptions been identified?
- Is there sufficient resource available?
- Is project governance clearly described?

Overly optimistic plans can create significant challenges later in the project!

Commercial Fit
Cost is important, particularly for early-stage companies, but it should be considered in the context of the value being delivered.

The cheapest option is not necessarily the lowest-risk option, and conversely the most expensive option is not necessarily the best.

The consultancy should provide the following in its response or statement of work:

- Transparency of pricing
- Clarity of assumptions
- Scope of services included
- Potential change-control costs
- Overall value relative to expected outcomes

A good response or statement of work should provide confidence that both parties understand what is included and what is not. However, the written response is only part of the decision. While it may be well-written, professionally designed and commercially attractive, ultimately you are selecting the people and organisation that will support your programme.

> *The strongest consultancy relationships should feel less like a supplier engagement and more like an extension of the internal team.*

Those qualities can be difficult to score in a spreadsheet, but they are often the factors that determine the long-term success of an engagement.

DUE DILIGENCE

7. What to check during due diligence
Once you have identified your preferred consultancy providers, due diligence is where you determine whether the proposal can genuinely be delivered in practice. The objective is not to catch the consultancy out, but to understand the real risks, assumptions and capabilities before making a commitment.
It is important to remember that reputation alone should not drive the decision. A consultancy may have an impressive brand, a strong website and a long client list, but what matters most is the team that will be supporting your project today. The quality of advice and delivery is ultimately dependent on the people assigned to your programme, their availability, experience and understanding of your objectives.
Use due diligence to validate the claims made during the proposal process. Confirm relevant experience, understand who will actually perform the work, speak to references where possible and assess whether the consultancy's working style aligns with your organisation.
You are not simply buying expertise; you are entering into a relationship that may influence critical development, regulatory and commercial decisions.

- Confirm the consultancy has relevant experience supporting similar projects, development stages and challenges.
- Verify who will lead the engagement and identify the key individuals who will actually deliver the work.
- Understand the level of senior oversight that will be provided throughout the project.
- Clarify whether any activities will be performed by subcontractors or external associates.
- Speak to previous clients, where possible, to validate delivery capability and working style.
- Confirm resource availability and ensure the proposed team has sufficient capacity to support your timelines.
- Review proposed governance arrangements, including communication frequency, reporting structure and escalation routes.
- Assess how risks, delays and changes in project scope would be managed.
- Determine whether the consultancy can support future milestones and evolving programme requirements.
- Evaluate whether the consultancy's communication style, responsiveness and culture are compatible with your organisation.

Long-term success will depend just as much on trust, communication, responsiveness and the ability to work as an extension of the internal team.

Summary
Selecting a consultancy is not about finding the largest organisation or the most recognised name.

It is about finding the provider whose expertise, experience, people and working style best align with your objectives.

Strong consultancy selection starts with clear preparation, structured information sharing, consistent comparison and focused due diligence.

By investing time upfront, companies can identify consultancy partners that help reduce risk, accelerate development and improve the probability of achieving key milestones.

Use Pharma Services Hub to identify, compare and engage consultancy providers across Regulatory Affairs, Pharmacovigilance, Quality, CMC, Drug Safety, Intellectual Property and Programme Management disciplines. Accelerate the search to start meaningful engagement at **www.pharmaserviceshub.com**