PSH **Guides**

Selecting an Analytical & Microbiological Testing Partner

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Pharma Services Hub

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Choosing an analytical or microbiological testing partner is a big decision, whether you are developing a new medicine or supporting commercial supply.

The work matters because these laboratories produce the data behind key programme decisions. Their results feed into development plans, regulatory filings, manufacturing decisions, product release, stability programmes and, ultimately, commercial success.

Analytical laboratories can support method development and validation, product characterisation, release and stability testing, cleaning and process validation, comparability studies, one-off project support, and data generation for regulatory submissions. Support may be commissioned for a single activity or project stage, or as part of an ongoing partnership. The scope should reflect the product's development stage, the expertise needed and whether the laboratory is supporting a sponsor directly or acting as a subcontractor to another service provider.

Microbiological laboratories may provide sterility assurance, environmental monitoring, water and bioburden programmes, endotoxin testing, microbial identification and support for contamination investigations. For sterile or biologically derived products, this work can sit directly on the programme's quality and regulatory critical path.

TESTING SUPPORT OPTIONS

Option	Typical scope	Selection emphasis
One-off / project-stage support	A discrete activity or milestone, such as a method transfer, comparability study or investigation.	Defined deliverables, relevant experience, sample requirements and achievable timing.
Niche capability	A tightly focused testing need, such as nitrosamines or extractables and leachables.	Direct experience of the specific challenge and sound interpretation of results.
Specialist development support	Method development, validation or characterisation requiring scientific judgement and troubleshooting.	Technical depth, product knowledge and the ability to adapt as the programme evolves.
Routine testing	Recurring release, stability or microbiological testing using established methods.	Quality systems, method suitability, capacity and dependable turnaround.
Service provider / B2B outsourcing	Subcontracting or partnership between service providers to fill capability gaps or support client delivery.	Clear responsibilities, confidentiality, data access, quality oversight and escalation routes.

Overview of testing support options
These options describe different aspects of the same requirement, rather than mutually exclusive types of laboratories. One-off or recurring work describes the duration and frequency of support; niche or specialist capability describes the expertise needed; and B2B outsourcing describes the relationship between providers. For example, a service provider may subcontract a one-off specialist study or recurring routine testing. Section 2 expands these choices into outsourcing models, including a Strategic Analytical Partner and a Virtual Analytical Function.

On paper, choosing a laboratory can look fairly simple. Many providers offer similar services, make similar GMP claims and list much the same equipment. Their websites and capability statements can be hard to tell apart, and their pricing is not always easy to compare.

In practice, projects rarely go wrong because a laboratory is physically unable to run a test. More often, problems arise because the testing strategy was poorly matched to the programme, methods were not sufficiently robust, validation expectations were interpreted differently or promised turnaround times were unrealistic. Unexpected capacity constraints, data-integrity concerns and regulatory misalignment can then turn testing into the critical path rather than a supporting activity.

That is why the decision needs to look beyond price and a list of capabilities. The real question is how well the provider will support the programme, manage risk, produce dependable data and help you reach the next milestone. Scale is not a reliable proxy for fit. A specialist laboratory with experience of the product type, analytical challenge or development stage may offer greater value than a larger organisation with broader but less focused capability. With clear preparation and disciplined evaluation, the right partner can accelerate development, reduce avoidable risk and strengthen regulatory outcomes.

Use this guide in four stages: define the outcome and outsourcing model in Preparation; share the programme context and develop a comparable brief in RFI and RFP; assess technical fit, quality, delivery and value in Comparing; and verify the preferred provider's commitments in Due Diligence. The same approach applies to analytical and microbiological testing, whether you are a sponsor appointing a laboratory or a service provider subcontracting client work.

PREPARATION

1. What is to be achieved?
Key abbreviations used in this guide: GMP means good manufacturing practice; RFI means request for information; RFP means request for proposal; IND means investigational new drug application; CTA means clinical trial application; MAA means marketing authorisation application; NDA means new drug application; CAPA means corrective and preventive action; and OTIF means on-time, in-full delivery. Submission terminology depends on the target market.

Before you contact any laboratories, be clear about why you need outside support in the first place.

The objective is rarely testing for its own sake. It is usually to support a decision or reach a defined milestone, such as candidate selection, IND or CTA preparation, a first-in-human study, end-of-Phase II readiness, technology or site transfer, process validation, commercial product release, or submission of an MAA or NDA. Testing is the mechanism used to generate the evidence needed for that outcome.

Start with the decision the data needs to support, the milestone you are working towards and the information you still do not have. Then look at which methods already exist, which need development, validation or transfer, and what you can realistically keep in-house. That should make the gap you need the external laboratory to fill much clearer.

Timing and risk also need to be explicit. Establish the dates that genuinely matter, the consequence of delayed testing and what successful support should look like over the next six to twelve months. A useful definition

of success may include a regulatory-ready data package, a transferred and performing method, or dependable release and stability turnaround—not merely completion of the contracted tests.

Organisations that begin the search before resolving these points often struggle to compare responses because each laboratory has interpreted the requirement differently. A clear outcome, evidence need and outsourcing boundary give providers a common basis for response and help the sponsor choose the right sourcing strategy.

2. What is our outsourcing strategy
Laboratory partnerships come in different shapes and sizes.

Some companies simply need reliable routine testing for an established product. Others need specialist development support for a new modality, or a longer-term partner that can stay with the programme through several phases. Service providers, such as CDMOS, may also subcontract testing or build laboratory partnerships to extend their capabilities, manage capacity or deliver an integrated service to their own clients. Being clear about which model you need will quickly narrow the field.

Before approaching providers, determine the type of support required.

Routine GMP Testing
Routine GMP support commonly covers release, raw-material and packaging testing, stability programmes and routine microbiology. Validated methods will usually already exist, but their transfer readiness and suitability for the receiving laboratory still need to be confirmed. Once those requirements are clear, the selection emphasis shifts from scientific development to compliance, dependable turnaround, reliability and available capacity.

Development Laboratory
A development laboratory may undertake method development, qualification and validation, forced-degradation studies and broader characterisation programmes. In this model, scientific judgement and the ability to investigate unexpected behaviour are generally more important than high throughput alone.

Specialist Analytical
Some programmes require niche capability in areas such as extractables and leachables, elemental impurities, nitrosamines, advanced mass spectrometry, particle or biophysical characterisation, oligonucleotide analytics, host-cell proteins and other process-related impurities, or cell and gene therapy testing. Here, directly relevant technical experience is often the primary selection criterion because the method and interpretation may be as important as the instrument itself.

Microbiological Testing
For sterile products, microbiological support can represent a critical quality and regulatory risk area. The provider may need to perform sterility and endotoxin testing, environmental monitoring, water testing, microbial identification and contamination investigations, with controls and response times appropriate to the product and manufacturing context.

Strategic Analytical Partner
Some organisations require longer-term relationships where the laboratory supports development, clinical programmes, technology transfer, commercial readiness, or lifecycle management.

Strategic partners can provide continuity, which may deliver advantages through retained product knowledge and reduced technology transfer effort.

Virtual Analytical Function
Some emerging biotechnology companies will operate with minimal in-house analytical expertise. In these situations, the laboratory effectively becomes an external analytical department. The support then might extend beyond testing into analytical strategy, regulatory support, validation planning and technical risk assessment.

B2B Subcontracting and Laboratory Partnerships

Outsourcing is not limited to sponsors placing work directly with a laboratory. A service provider may subcontract a defined testing package to fill a capability gap or manage additional demand or build an ongoing partnership with a complementary laboratory to offer broader support to its clients. The choice depends on whether the need is occasional or requires sustained coordination and continuity.

Agree who owns the client relationship, coordinates delivery, reviews and approves data, and leads investigations or escalations. Define confidentiality, data access, reporting formats, turnaround commitments and commercial responsibilities, and confirm any client consent or quality-agreement requirements before subcontracting. A clear division of work should preserve appropriate quality oversight and accountability to the end client.

These models should not be compared as though they are interchangeable. A specialist method-development laboratory, a routine stability provider and a global testing organisation may all be capable of contributing to the same programme, but they address different needs and carry different trade-offs in expertise, responsiveness, continuity and cost.

RFI AND RFP

3. What information should be shared?

A laboratory can only give you useful advice if it understands the wider programme.

A common source of frustration for both sponsors and laboratories is that too little information is shared at the start.

A request simply stating:

"We need stability testing."

is rarely enough information to generate a useful response.

To give a sensible answer, the laboratory needs to know what the product is, where it is in development, how far the methods have progressed, the likely sample volumes, the timescales and the regulatory goal. Without that background, even a very experienced provider has to guess.

Equally, sponsors often become frustrated because responses appear generic.
Usually, the problem is simply that both sides are trying to work with an incomplete picture. Therefore, sharing the right information early leads to better responses and usually saves several rounds of clarification later.

Business Context

The brief should explain the company's stage, funding position, development objectives, strategic priorities and target milestone. This does not require disclosure of unnecessary commercial detail; it should simply help the laboratory judge the appropriate level of rigour, pace and flexibility.

Programme Context

Programme context should cover the product type and modality, route of administration, development phase, existing control strategy and relevant regulatory history. Together, these points allow the provider to distinguish an early exploratory requirement from work that must withstand later-stage or commercial scrutiny.

For example, the programme may involve a small molecule, monoclonal antibody, peptide, oligonucleotide, cell or gene therapy, vaccine or another advanced therapy medicinal product (ATMP). Stating this clearly helps providers identify relevant platform experience rather than relying on broad capability claims.

Analytical Context

Describe the existing analytical methods and their validation status, the availability of reference standards and historical data, any technology-transfer requirements and the regulatory standard the work is expected to meet. Where methods have known limitations, sharing those early is more useful than presenting them as transfer-ready.

Microbiological Context
Where microbiological support is relevant, explain the sterility and bioburden expectations, environmental monitoring requirements, water-system details, endotoxin limits and the status of existing microbiological methods. These details are particularly important where sample handling, containment or method suitability could affect the proposed approach.

Scope of Support Required
Define the activities required, the expected deliverables, the respective internal and external responsibilities, and the criteria by which the work will be judged successful. Clear boundaries are especially valuable where more than one laboratory, manufacturer or internal team contributes to the same programme.

Known Challenges
Be realistic and transparent.

Known constraints might include limited sample availability, product instability, concerns about method robustness, aggressive timelines, budget limits or regulatory uncertainty. A good provider should be able to explain how these constraints affect feasibility, sequencing and cost, rather than simply accepting them without challenge.

How a laboratory responds to uncertainty can often be one of the strongest indicators of future performance.

4. What to send out? An RFI-first approach
For most analytical and microbiological work, an RFI is a sensible place to start.

It lets you check capability, capacity, relevant experience, availability and overall fit before asking several providers to spend time producing a full proposal.

The purpose at this stage is not to appoint a supplier, but to create a credible shortlist of laboratories worth taking into a more detailed discussion.

When an RFI adds value
An RFI is most useful when requirements are not fully defined, several providers are being screened, specialist expertise is under review, or the development and analytical strategy is still evolving. It is also appropriate where the sponsor's internal understanding is incomplete and informed challenge from the market would help shape the eventual scope.

In practice, the RFI should reveal more than a list of services. It should provide evidence of relevant product experience and inspection history, show whether the laboratory understands the technical problem, and give an early indication of cultural fit and working style. It also gives the analytical service provider the opportunity to decline to quote if the work doesn't fit their capability/capacity or cost base.

When should a proposal be requested?
A detailed proposal should be requested once the scope is clear, deliverables are understood, timelines are defined and the principal risks have been identified. At that point, providers are more likely to price and resource the same requirement, making their responses genuinely comparable.

Shortlisted laboratories can then be asked for a detailed proposal or statement of work that sets out the delivery model, resources, assumptions and pricing basis. Requiring the same response structure from each provider makes gaps and differences easier to identify.

For many testing projects, a focused proposal or statement of work is sufficient.

A formal procurement-style RFP is generally justified only for multi-year contracts, global testing programmes, virtual development organisations, commercial supply support or other large outsourcing initiatives. For a discrete work package, the additional process may add time without improving the decision.

A common mistake is requesting detailed proposals before the scope is mature. This typically results in assumptions, clarification cycles and proposals that are difficult to compare meaningfully.

5. Structuring your laboratory brief
Keep the request simple and easy to follow.

You are not trying to prove how much technical detail you know. Instead, you are giving laboratories enough context to decide whether they can help and to explain how they would tackle the work.

A good laboratory brief should include:

Company Overview
Begin with a short company overview covering the organisation's background, its development stage and the milestone the work is intended to support. This gives context without turning the brief into a corporate presentation.

Product Overview
The product overview should identify the product type, modality and development phase, together with any feature that materially affects testing, handling or regulatory expectations.

Scope
Set out the activities and tests required, expected sample types and quantities, and any stability requirements. Explain when samples will be available and identify any handling, storage or containment constraints that affect the work. State what is excluded and which inputs the sponsor or another provider must supply, so laboratories can identify dependencies when planning and pricing the scope.

Deliverables
Specify whether the required outputs include analytical, validation or stability reports, certificates of analysis, investigation reports, datasets or other documentation. The expected review and approval status of each deliverable should also be stated where it affects timing or price.

Timelines
Include submission dates, clinical milestones, regulatory deadlines and testing deadlines, but distinguish fixed dates from planning assumptions. Providers should be asked to identify dependencies and the latest dates on which samples, methods or decisions must be available.

What the laboratory should address
Ask each laboratory to explain its proposed technical approach, including the main stages of work and any assumptions that influence the design. The response should identify the people who will perform, review and oversee the work, rather than naming only the commercial or business-development contacts.

The proposal should define achievable lead times and state whether turnaround ends at test completion, data review or delivery of approved data. Show how these commitments depend on sample availability, method readiness, review cycles and decision points. Specify the format in which data will be supplied and how it will be accessed. Identify technical, quality, capacity and regulatory concerns, with proportionate mitigations rather than generic assurances.

Commercial assumptions should be explicit, particularly where pricing depends on method performance, the number of runs, repeat testing, storage duration, investigation effort or changes to the agreed scope. This makes later comparison and change control considerably more straightforward.

Try not to design the solution for the laboratory before it has had a chance to look at the problem.

Sometimes the best response is the one that suggests a simpler, faster or more scientifically sound approach than the one you first had in mind.

Leave room for providers to explain how they would solve the problem.

COMPARING

6. Comparing laboratories
Once the responses come back, do not let price dominate the discussion, unless one of your key drivers of your tendering process.

The aim is to find the laboratory most likely to help you reach the milestone, not simply the one with the lowest quote.

Before assessing responses, agree which requirements are essential and which involve trade-offs. Check essential technical and quality requirements first, then compare the remaining providers using the same criteria and a weighting that reflects your programme's priorities. Record the evidence, assumptions and unresolved questions behind each assessment. A low price should not compensate for a failure to meet an essential requirement.

Technical Capability

Technical capability should be judged across instrumentation, method expertise, scientific depth and reputation. Equipment alone is not evidence of capability; the more useful question is whether the team can select, develop and troubleshoot methods appropriate to the product and stage.

Relevant platforms may include HPLC or UHPLC, LC-MS/MS, GC-MS, ICP-MS, FTIR, TOC, DSC, NGS and flow cytometry. The assessment should focus on the configuration, capacity and operator experience needed for the actual work, rather than counting instruments on a capability list.

Relevant Experience

Relevant experience means more than having worked in the same broad sector. Establish whether the laboratory has supported comparable products, solved similar analytical problems, understands the current development stage and can accommodate likely future requirements without avoidable re-transfer.

Microbiological Capability

Assess microbiological capability against the actual testing requirements. Depending on the scope, this may include sterility and endotoxin testing, anaerobic capabilities, environmental monitoring, water testing and organism identification. For the methods required, pay particular attention to suitability, contamination controls and the laboratory's ability to investigate atypical results.

Quality Systems

Review GMP compliance and inspection history alongside the systems used to protect data integrity, manage CAPA and control change. Strong quality systems should be visible in routine behaviours and records, not only in policy documents prepared for audit.

Good quality systems make day-to-day delivery easier and reduce both operational and regulatory risk.

The data produced are the output of the relationship, so assess how the quality system supports their smooth and timely delivery. Confirm how data are supplied, accessed and controlled, and how review and approval fit the agreed delivery schedule.

Capacity & Turnaround

Capacity should be tested against the laboratory's existing workload, expected sample throughput, stability-chamber availability, instrument access and stated turnaround commitments. Ask what capacity is genuinely reserved and what happens if demand increases, an instrument fails or an investigation extends the schedule.

Capacity problems are a very common reason for avoidable delays, so it is worth pressing for a realistic answer.

Project Management

Project-management capability is reflected in practical governance, clear communication, workable escalation routes and useful reporting. Confirm who owns day-to-day delivery, how technical and quality decisions are made, and how emerging risks will be communicated before they become delays. Ensure clear routes of escalation are understood and reporting expectations outside of data supply are transparent.

In many cases, good project management is what turns a technically capable laboratory into a genuinely good partner.

Commercial Fit

Commercial comparison should cover pricing

transparency, underlying assumptions, additional and storage charges, the treatment of changes and the likely long-term value. A lower headline price can be misleading if routine repeats, investigations, project management or method changes are charged separately.

The cheapest option on paper is not always the cheapest, or easiest, once the work is under way.

DUE DILIGENCE

7. What to check during due diligence

Once you have a preferred provider, take the time to check that the reality matches the proposal.

This is not about trying to catch the laboratory out. It is about making sure the promises made during the selection process can be delivered consistently in day-to-day work.

Quality & Compliance
Review GMP certifications, inspection outcomes, relevant audit reports and quality metrics. Look for evidence that commitments arising from inspections or audits have been closed effectively and that performance is stable over time.

Facilities
Assess whether the laboratories, environmental controls, storage arrangements and stability infrastructure are suitable for the product and volume of work you intend to place. The facility tour should confirm that the operating environment matches the written description.

Equipment
Confirm equipment qualification and calibration status, preventive-maintenance arrangements and the availability of suitable backup instrumentation. For critical methods, understand how quickly work can resume after a failure and whether software versions and configurations are controlled.

Personnel
Understand the technical expertise and structure of the proposed team, current resource availability and the level of senior oversight. It is useful to distinguish the people involved in winning the work from those who will actually perform, review and approve it. Try to identify any current bottlenecks and request an insight into the operational metrics for on time in full (OTIF) delivery.

Data Integrity
Evaluate the electronic systems, audit trails, access controls and data-review procedures used for the work. The review should establish how original data are created, changed, reviewed, retained and retrieved, including the controls applied when manual steps are unavoidable.

Business Continuity
Determine the laboratory's disaster-recovery capability, access to backup facilities and wider continuity planning. The important question is not simply whether a plan exists, but whether it has been tested and can protect samples, data and critical timelines during a realistic disruption.

Where work will be subcontracted, confirm which laboratory will perform each activity and verify how its quality systems, capacity and data controls will be overseen. Check that client consent and quality-agreement requirements have been addressed, and that responsibilities for data review, investigations, reporting and escalation are consistent across the provider relationships.

References
If you can, speak to previous clients about delivery, communication and responsiveness. The most useful references come from programmes that are similar to yours in scale, stage or technical complexity.

Before appointment, document the selection rationale, resolve any critical due diligence findings and agree how remaining actions will be closed. Confirm that the statement of work and any required quality agreement align on scope, deliverables, responsibilities, timelines, data access and change control. Work should begin on a shared understanding of what will be delivered and how it will be governed.

Summary
Choosing a testing partner is not about finding the biggest laboratory or the lowest price.

It is about finding a provider you can trust to produce reliable data and meet the required regulatory standard. For sponsors, that means helping move the programme forward. For service providers relying on third-party support, it means supporting business delivery and meeting their own clients' expectations.

Successful partnerships combine technical expertise and scientific judgement with regulatory understanding, strong quality systems, reliable delivery and open communication. No single attribute is sufficient: the value comes from how consistently these capabilities work together across the life of the programme.

A little more time spent preparing, comparing providers properly and checking the detail up front can save a great deal of time and risk later.

Use Pharma Services Hub to identify and compare analytical and microbiological testing partners with the right technical expertise, quality standards and capacity for your programme. Start your search and connect with suitable providers at **www.pharmaserviceshub.com**