Beyond the RFP: Key Selection Criteria for Cell & Gene Therapy CDMOs

Minaris Advanced Therapies

White Paper

Introduction

In the complex and rapidly evolving landscape of cell and gene therapy, selecting a Contract Development and Manufacturing Organization (CDMO) is one of the most consequential relationships an innovator will establish. No two drug manufacturing journeys are the same; the path from bench to bedside may contain unforeseen scientific nuances, regulatory hurdles, or operational constraints. Consequently, the task of identifying an honest, reliable partner is of the utmost importance.

This selection process is less about procuring a service and more about aligning with an organization to act as an extension of your own team. The right partner does more than execute a scope of work; they share your program's specific intent, understand the stakes of your milestones, and commit to the patient outcomes you are driving toward. When a sponsor and CDMO operate from a foundation of shared trust and open communication, the dynamic shifts from a vendor relationship to a strategic alliance for navigating the unpredictable nature of drug development.

A structured decision-making process will help you begin this journey. By methodically setting criteria, communicating with transparency, assessing options beyond the surface level, and committing with intention, you ensure that your selected partner has the expertise and experience to advance your product to the finish line.

Phase 1:

Set Your Conditions for Partnership

The selection process begins long before you send a Request for Proposal (RFP). It starts internally, with a rigorous, honest assessment of your program's current reality and its future trajectory. Determining your priorities depends significantly on your product's clinical stage and your long-term commercial goals.

To navigate this early phase, sponsors can ground their search by asking three fundamental questions. First, is the CDMO technically capable of executing exactly what you need? Second, does the CDMO have the flexibility and agility to match the pace of your team? Ideally, a partner functions as a seamless extension of your own workforce, so their operational rhythm will sync with yours. Third, who will be on the other side of the table? You will want the assurance of a dedicated advocate who will drive your program forward.

Beyond these basics, consider how size may affect operations. For example, an organization with the largest capacity may not always translate this to dedicated attention to your program, or may have corporate red tape that slows decision-making. Ask yourself how trading greater capacity for potentially reduced attention may play out, both now and in the future.

As your program grows, your needs will likely become more complex. In the future, do you anticipate selling in additional geographies, compared to today? Will you need to navigate different regulatory frameworks? Will you eventually need access to different technologies, specific cell types, or viral vector production? What's the best way to integrate release testing to reduce cycle time and risk? Is the efficiency of vendor consolidation a priority? Will transferring to meet future requirements introduce unnecessary friction and risk? You will likely want a partner that combines the scale you need, the prioritization and agility required to solve problems at your cadence, and the willingness to meet your tolerance for risk.

Finally, evaluate not only your changing needs, but also if the CDMO is growing in the right direction to meet your needs as they may evolve. Cell and gene therapy is a dynamic, rapidly changing field; your partner should be evolving alongside it. Are they adding technologies and positioning themselves for future industry needs? Crucially, are they actively looking at ways to address the high cost of these therapies—a major issue for the entire sector? A partner who is proactive about such macro challenges, one who often brings new approaches and platforms to your attention, is more likely to future-proof your trajectory.

Decision Guide: The 3-Point Partner Evaluation

Use this framework to evaluate potential CDMOs against your program's specific trajectory.

Evaluate	By Asking	Listen for This Strategic Signal
1. Technical Capability	Can they do it? Assess current capacity, specific technologies (viral vectors, cell types), and future scalability.	The CDMO demonstrates they can handle your process today and has the infrastructure (technologies, clean rooms, integrated testing) to support your growth without forcing a change in partners.
2. Operational Agility	Will they prioritize it? Assess their flexibility, speed of decision-making, and organizational structure (red tape vs. agility).	The CDMO combines global reach with a flexible, high-touch service model. They treat your timelines with urgency.
3. Project Advocacy	Who is accountable? Consider the Project Management structure and the specific team members who may be assigned to your account.	The CDMO assigns a dedicated point person who acts as an extension of your team and advocates for your needs internally.

Phase 2:

Communicate Openly and Transparently

A true partnership relies on speaking plainly to align on the realities of your program. For the sponsor, this means providing context beyond technical specifications. Here, it is very helpful to be candid about your program's resources and any specific milestones required to unlock the next stage of your growth. Clarify your key priorities and share your technical, manufacturing, regulatory or timeline risks and uncertainties. When a CDMO understands these dynamics, they can structure the relationship to fit your situation—perhaps by modulating contract structures, focusing on immediate proof-of-concept goals, or identifying where platform technologies can be leveraged to maximize efficiency. This alignment ensures that the CDMO's strategy supports your business trajectory rather than straining it.

On the CDMO side, transparency means proactive honesty. For example, a partner invested in your success will not blindly accept an RFP that contains gaps that carry a significant risk to the successful execution of your program. They will challenge assumptions before submitting a proposal, and incorporate periodic project milestones assessing program readiness to advance. If there are ambiguities regarding analytics, starting materials, or timelines, a trustworthy partner will flag them immediately. Such conversations are early indicators of operational maturity.

Assess Your Options—and What's Behind Them

Once proposals are in hand, the goal is not simply to compare prices, but to interpret the strategy, assumptions, and commitments contained within. Pricing, scope, and timelines must be normalized as much as possible so that differences are meaningful rather than cosmetic. Outliers, such as whether a proposal is unusually fast or surprisingly inexpensive, deserve scrutiny, as they often rely on assumptions that may surface later as unforeseen risks.

Meet directly with each CDMO to walk through their proposal in detail. Ask how timelines were constructed, what assumptions underpin cost estimates, and where operational flexibility exists. A CDMO that has engaged deeply with your program will be able to explain trade-offs, constraints, and options with specificity. Generic answers usually reflect a generic understanding, which may be due to inexperience. Can your program afford the uncertainty resulting from this inexperience?

A CDMO that is clearly prepared to grow with you will show it in their investments. For instance, a strategic partner will have integrated capacity for multiple modalities, such as the ability to work with different types of cell therapies, viral vector production, and advanced in-house release testing. This kind of comprehensive infrastructure may prevent the need for costly and risky program transfers down the line.

Furthermore, evaluate the CDMO's global capabilities as part of an overall picture. At Minaris, for example, we have facilities in North America, Europe, and Asia. This presence enables a "global yet local" support model—providing the high-touch service of a regional partner with regulatory compliance across regions and a global quality system. This differentiation is critical for balancing reach with the high degree of focus your program will require.

Assess Strategic Signals Beyond the Proposal

Use this assessment during evaluation to uncover the operational philosophy and true commitment of a prospective CDMO.

Evaluation Area	The Generic Response (Warning Signal)	The Strategic Partner Response (Success Signal)
Depth of Engagement	"We responded strictly to the details provided in the RFP."	Actively challenges assumptions, proposes alternatives, and refines scope to better fit your resources/milestones.
Operational Priority	"We have massive global capacity across all sites."	Clearly articulates how your specific program will maintain high visibility and priority against the broader portfolio.
Growth & Investment	"We can service your needs today."	Demonstrates ongoing investment in diverse technologies (e (digital infrastructure, advanced manufacturing solutions, automation, etc.) to support your future growth and market expansion.
Regulatory Reach	"We have European (or US) compliant facilities."	Provides a clear strategy for global access, detailing how your product can be supplied across multiple regulatory frameworks (e.g., US, EU, Asia) without needing a transfer.
Cost Mindset	"Our pricing is standard for the industry."	Actively discusses structural cost drivers and demonstrates a proactive mindset toward optimizing cost-of-goods to align with industry needs.

Make a Commitment

A successful CDMO relationship culminates in shared esponsibility and collaboration. Once a partner is chosen, success depends on whether both teams can function as a single, aligned unit, working from a common understanding of objectives, constraints, and trade-offs. This final phase validates the deep trust that is, ideally, established during the evaluation process.

As the innovator has committed to being transparent about their resource landscape, the CDMO now commits to optimizing that landscape. The high Cost of Goods Sold (COGS) remains one of the most significant barriers to broader access for cell and gene therapies. A committed partner views this as a shared problem. For example, Minaris recently partnered with a client who sought to comprehensively reevaluate the long-term commercial viability of their program, resulting in a significant reduction in cost per batch.

Furthermore, sustaining commitment requires fostering a shared culture and sense of mission. One way Minaris reinforces this commitment is by holding regular seminars with our clients. This creates engagement at every level of our organization, ensuring that everyone—from process development scientists to quality control technicians—is continuously reminded that the work is more than just a project. It is part of a greater mission to advance cell and gene therapies for people in need. Ultimately, the most successful programs are those where the sponsor chooses a CDMO whose operational philosophy, investments, and level of engagement match their own strategic needs. Trust is built through consistency, accountability, and openness over time. When those elements are in place, the CDMO is positioned not simply to execute a scope of work, but to help strategically advance the program.

Learn More About Minaris Advanced Therapies

Minaris Advanced Therapies has over 25 years of experience in developing, manufacturing and testing therapies as a specialized CDMO focusing on cell and gene therapy. We support innovators from preclinical development through commercial production. Our technical expertise, global infrastructure and end-to-end services ensure consistent delivery, efficient tech transfer and scalable manufacturing solutions. Our facilities in North America, Europe, and Asia allow us to supply patients globally. We are committed to helping clients advance their programs and increase patient access worldwide.

Minaris Advanced Therapies

CONTACT US

Get in Touch With Our Team Today

minaris.com/contact

WP-C-261035-1