How to Choose The Right Manufacturing Partner to Meet Your Goals

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As drug sponsors begin the journey of developing clinical or commercial manufacturing strategies for cell or gene therapies, the task of identifying honest, reliable partners to meet their needs is of the utmost importance. This selection process should first start early and internally, prior to meeting with prospective manufacturers. To launch a successful search, begin by outlining the scope of your project, defining its goals and mandatory Contract Development and Manufacturing Organization (CDMO) requirements. From that vantage point, your team will be in a much better position to assess potential partners.

Ultimately, no two drug manufacturing journeys are the same; as such, it is vital to ensure that both sponsor and CDMO are committed to open communication around challenges, flexible solutions, and patient-centricity. By building trust into your dynamics, you are far more likely to develop a mutually beneficial, long-term relationship that you can depend on throughout your drug's life cycle. Before you embark on this journey, consider the best ways to ensure that your selected CDMO partner has the expertise and experience to manufacture your product safely and efficiently, guaranteeing that a high-quality drug is delivered to patients in need.

Set Your Criteria

Determining your priorities depends on a product's clinical stage and long-term goals. To start, define what CDMO offers are non-negotiable for your therapy. This entails setting expectations for product quality, timeline, and cost. Define what you want your partner to offer in terms of capacity, materials, equipment, and project management. Decide the type of relationship you are looking to form – it may be a long-term strategic partnership or a quick, one-time contract. Are you seeking a development partner or a partner to bring you to the commercial market? These distinctions affect the type of CDMO that is best suited. However, think beyond your current needs and make sure the CDMO can meet later requirements such as phase 3 production or commercial manufacturing. Changing manufacturing partners later will be time-consuming and costly. If your project is targeting small manufacturing volumes, make sure the CDMO will not de-prioritize you, thus include prioritization questions into your CDMO selection process.

Importantly, define your internal decision-making process and your internal roles. The decisions you make during the selection process should be recorded for later reference and used to structure a thorough RFP (request for proposal) with all the information a CDMO would need to build their proposal. The greater the effort that you put into your RFP, the more likely you are to receive high-quality proposals in response. Provide a clear cost structure to ensure that the CDMOs will develop comparable metrics. One way to help guarantee that the proposals are comparable is to supply CDMOs with a proposal template or set of guidelines. During the criteria defining stage, you might also consider working with a CDMO consultant to help you design a realistic timeline and project plan for GMP manufacturing.

Communicate Openly and Transparently

Ideally, a CDMO is more than a vendor; at Minaris, we strive to serve as a partner who can provide reassurance throughout the process. There are several ways to bolster this relationship, but first and foremost, we communicate openly and transparently from day one. In the beginning, that means a sponsor must be straightforward about their expectations, capacity needs, and any assumptions they are under. Similarly, a trustworthy CDMO partner will be honest and forthcoming about timelines, costs, and any foreseeable challenges that could arise. Minaris will proactively contact potential clients to discuss gaps in their RFP before submitting our proposal. We might ask for further clarification on the process, analytics, starting materials, or other technical details, as well as any potential milestones a startup may need to reach for added funding. A CDMO needs to have clarity around the long-term goals of a project, including whether a sponsor is only looking for proof of concept or a full scale-up plan. The better a CDMO understands a sponsor's goals for their program, the better support they will provide.

We also ask potential clients to determine which components of the process are fixed and which could potentially be replaced by our platform technology. Leveraging CDMO platform processes, if possible, saves sponsors a significant amount of money and increases efficiency. In some scenarios, a client may try to rush a timeline at the risk of compromising quality. In this situation, we have a very frank conversation about how a timeline can be customized with creative solutions as well as the potential risks associated with prioritizing speed over quality. To ensure that this phase goes as smoothly as possible, both the sponsor and the CDMO would be wise to designate a point person to guide the process and act as a resource for any questions that arise.

Assess Your Options and Their Strengths

Once CDMO proposals are in-house, start by comparing your different options, including the scope of each. Harmonize the pricing structures as best as possible to ensure that they are truly comparable. Flag the outliers – i.e., lowest and highest cost as well as fastest and slowest timelines. It is important to remain cautious; if a pricing proposal or timeline seems too good to be true, there is a

chance that it is. Meet with each of the CDMOs to discuss their proposals and ask for the rationale behind their calculations; if something doesn't make sense, ask them about it. If a CDMO has truly done the research to customize the proposal towards your individual goals, they will have thorough, educated responses to your questions. Alternatively, if the proposal is generic, the lack of understanding around your product will be apparent.

During these meetings, we highly recommend requesting an on-site tour of the facilities to get to know the staff you would be working with, as well as the facilities, platforms, and caliber of equipment. This affords you the opportunity to ask questions freely and gauge compatibility. Determine which countries you'd like your product to be accessible in and ensure that a CDMO has the necessary accreditation in those regions. To assess their quality system, ask about the number of audits they have conducted, potential audit findings, the number of products that have been manufactured on-site, and if possible, third-party references. Discuss their experience developing chemistry, manufacturing, and controls (CMC) packages and if they might provide example templates; from there, ensure that their capabilities will accommodate your regulatory filing prerequisites. When it comes to the tech transfer, ask the CDMOs to describe their tech transfer process and any major milestones along the way. Additionally, you might ask for examples of previous tech transfers and their average timeline. Ideally, all deliverables will be integrated into the tech transfer strategy.

In terms of materials, an experienced CDMO will have a set of standard operating procedures (SOPs) in place to guide their procurement strategy. Touch base to verify whether they offer off-the-shelf, GMP material from a warehouse or conduct just-in-time manufacturing. At Minaris, we use a risk-based approach to procurement that is rooted in supplier management and communication. The sponsor will need to provide appropriate context for whether the materials need to be qualified, which is generally determined by the product's clinical stage. If you are hoping to form a long-term partnership, do due diligence to assess whether a CDMO has the long-term capacity and financial sustainability to accommodate your project. Be direct and communicate about your long-term goals, priorities, and how they expect their business to grow and change in the coming years.

Make a Commitment

Once you identify the partner that is best suited to meet your needs, guide the relationship towards becoming mutually beneficial. Crucially, this requires developing a structured project approach together and trusting the advice of your CDMO when they recommend certain strategies, timelines, and regulatory interactions. Throughout the process, both sponsor and CDMO should have project teams with subject matter experts dedicated to discussing budget, what is in and out of scope (including runs, quantity, quality control, batch record review, additional experiments, etc.), and any obstacles that come up along the way. Defining what is in scope and out of scope sets clear expectations for both parties and helps avoid potential misunderstandings. At Minaris, we strive to highlight any risks for our clients that may come up as we move through the process; this allows both teams to have honest discussions and adaptable mindsets as we go. CDMO selection is a highly individualized process that is specific to the needs of your cell or gene therapy; there is no one-size-fits-all approach.

Rather than committing to the first CDMO you meet with, take the time to clearly define your must-have features and the qualities that will make the experience ideal for your team. When you ultimately find the CDMO that can fulfill your goals, commit to creative and patient-centric collaboration. By emphasizing trust between all stakeholders, you ensure that a better product will reach your patients.

Learn More

Minaris Regenerative Medicine is a global contract development and manufacturing organization (CDMO) for cell and gene therapies. We offer our clients high value clinical and commercial manufacturing services, development solutions, and technologies. We are pioneers in the field with more than 20 years' experience providing outstanding quality and reliability. Our facilities in North America, Europe, and Asia allow us to supply patients globally with life-changing therapies.

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