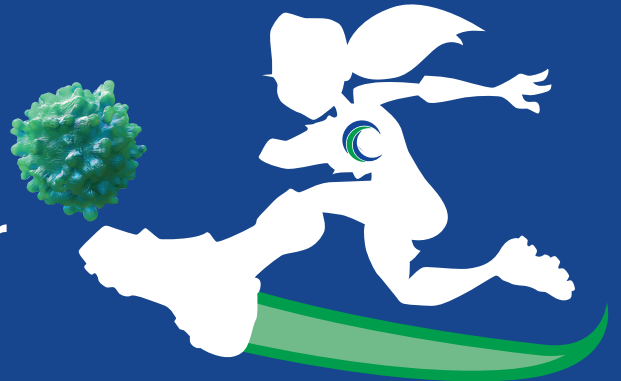


Scoring the Goal

10 Questions To Ask Your External Manufacturing Partner

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If you're a striker (playing forward position) on a soccer team, you know that your primary role is to score a goal. But what makes you confident in your ability to accomplish that task? It is really about confidence in the team around you.

No player is an island, no matter how talented, and the communication, cooperation, and aligned interests of other teammates – whom you know have trained hard and have the skill and passion needed to win the game – cannot be understated. If your team members are each out for personal glory rather than the good of the group, if they're lackluster, or if they haven't together come up with a strategy for success, playing the game is much more risky and winning is much less of a sure thing, especially at a high competitive level.

Entering into a partnership with a cell therapy manufacturer is a lot like making sure you have a great set of team members beside you on the pitch when the referee blows the whistle to begin the match. You have the passion, the experience, and the skill to get your cell therapy to commercialization, but you want teammates whose goals are aligned with yours – ones who are prepared to communicate well, anticipate what is needed in each situation, work hard, and give it their 100 percent. You need a goalie and defenders who can mitigate risk, and midfielders who can maintain momentum and deliver high quality crosses, time after time. You need a team that has your back as you go for the goal.

To help you find the right team players, here are 10 questions you should ask your potential external manufacturing partner before you even set foot on the field:

1 Do you have experience with my specific cell type?

The ideal manufacturing partner will have not just years of expertise in cell therapy manufacturing, but years of direct experience with your specific cell type or manufacturing platform.

2 Do you offer a broad range of technology solutions?

A manufacturer that offers only one-size-fits-all technology might not be able to offer customized solutions, thus locking you in to certain equipment or processes. It's your process, it's your future.

3 What manufacturing challenges have you overcome for clients?

Even with an optimized and customized approach to commercial manufacturing, the road ahead is never without risk and potential roadblocks. The question is not whether your potential manufacturing partner can ensure that there will be no obstacles, but rather, whether they have the expertise and experience to offer a recovery plan when setbacks happen.

Cost Versus Value

Importantly for cell therapy, the value proposition associated with working with the ideal manufacturing partner will include direct experience with your specific cell type or manufacturing platform. Ranking last should be cost. But at the moment of decision, invariably cost becomes a real and present force in that critical decision. All we can say is be wary of choosing a 'product life-cycle partner' based on cost, as one way for a potential partner to seem appealing is to appear to be giving something away. Your first question should be "Why is the cost so low?" and right after that, "What am I sacrificing?" The decision comes down to a straight analysis concerning cost vs. a nuanced analysis concerning value. The old adage, "**You get what you pay for,**" comes to mind.

4 Do you know how to strengthen my manufacturing process to maximize the potential for commercial deliverability?

If your manufacturing partner's goal is simply to get you to commercialization, they are aiming too low. Your manufacturer should help you address the key elements of deliverability from the earliest stages of clinical development all the way through commercialization. This approach will help to ensure a robust, scalable process, reasonable cost of goods, and a process that is sustainable over the commercial life of the therapeutic.

5 Are you willing to be flexible?

It is important that your manufacturing partner be flexible both in its willingness to learn and adapt to the needs of your program rather than force your process into a templated approach, and in its ability to offer engagement that is appropriate and offers maximum impact at each stage of development.

6 Is there a two-way flow of communication?

Communication between organizations is critical, but we find that communication and alignment within each organization is equally critical in keeping a healthy and productive relationship. It is crucial that your manufacturing partner be willing to work with you to identify which communication and project management models work best for the relationship, to agree on frequency and nature of communication, and to establish the most effective communication resources, information exchange platforms, progress/decision tracking mechanisms, and effective mechanisms for issue escalation. Both parties must feel comfortable sharing ideas and concerns at every stage in the process and at each management level within each organization.

7 What are your policies and procedures to protect confidentiality around my cell therapy and my IP?

Be sure that your prospective partner has a spotless track record of preserving the confidentiality of clients and their intellectual property. Careful attention to electronic records keeping is integral in this regard.

8 Do you have both the experience and facilities required to meet all FDA regulatory standards?

Your manufacturing partner should have a sophisticated understanding of regulatory requirements for all stages of clinical development, along with cGMP compliant facilities. Manufacturing facilities should be compliant with both EU and US regulations so that you preserve flexibility for the future.

9 What is your process for identifying and mitigating risk?

Your manufacturing partner should have a proactive, structured approach to identifying sources of risk and minimizing your exposure. Considering automation, process changes, optimizations, and potential pitfalls at the very beginning of clinical development reduces the chance that costly, time-consuming changes or troubleshooting will be needed in later stages. Importantly, it's about a great deal more than meeting release requirements. It's about having a deep understanding of process capability. That's how you mitigate risk - by first identifying where it lies, qualifying it, and prioritizing how to address it wherever it rears its head in the process.

10 Are you innovators?

More than a manufacturer that can meet your basic needs on paper, what you really want in a partner is an organization willing to think outside the box, offer custom solutions, and find new ways to make your process more efficient, more cost effective, and more sustainable. You and your cell therapy manufacturer should share the goal of bringing your cell-based therapy to market using an approach that best positions you and your product for long-term commercial success. Your manufacturing partner is the key to positioning your cell therapy for success - today and tomorrow.

With these ideas in mind, you and your manufacturing team are on the way to the world cup of cell therapy manufacturing - a cell therapy product with a reasonable cost of goods that is scalable and sustainable over the commercial life of the product. **Gooooooal!**



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