partner perspective

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Why early, honest CDMO partnerships win

AGC Biologics discusses what separates lasting CDMO partnerships from purely transactional ones



Ahmed **Yahia**
Director,
Business Development,
Cell and Gene
Technologies Division

AGC Biologics

At what stage should sponsors begin engaging CDMOs?

Naturally, the earlier sponsors engage a CDMO, the better. Discussions should start during late discovery or the early preclinical stages before IND-enabling studies.

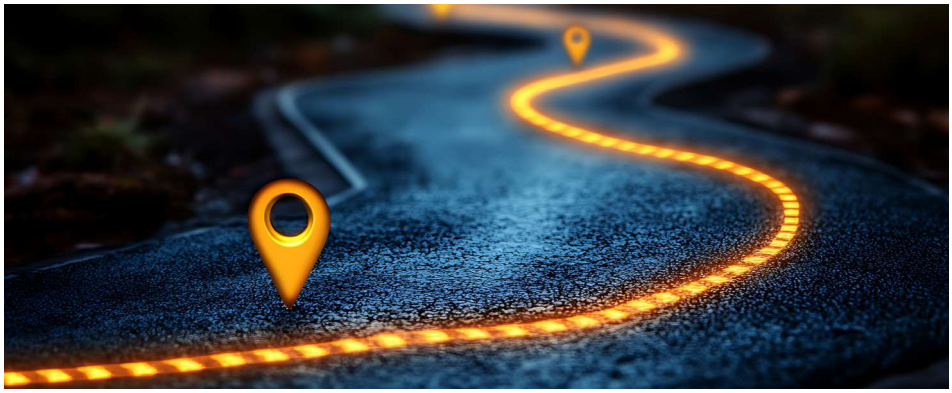
Early engagement enables better development decisions while there is still room to adapt. Choices around process design, analytics, raw materials or scalability may seem purely technical at first, but they can have a major impact on timelines, costs and regulatory strategy later on.

When manufacturing experts are involved early, potential issues are identified before they become expensive problems. It also allows everyone to think ahead about technology transfer, facility fit and supply chain readiness.

The programs that tend to move most smoothly are those where CMC and manufacturing are part of the conversation from the very beginning, rather than being considered once the process is already established.

Some argue that CGT timelines are often driven more by aspirations than manufacturing reality. How can sponsors and CDMOs better align expectations?

Most timeline issues don't come from a lack of commitment—they come from optimism. Sponsors understandably want to move as quickly as possible, while manufacturing progresses at the pace allowed by the science and the data.



The best way to stay aligned is through transparency from both sides. As CDMOs, we have a responsibility to be honest about technical risks, critical assumptions and realistic timelines, even when those conversations are difficult. At the same time, sponsors should openly discuss their clinical objectives, funding constraints and key decision points.

Rather than building a plan around the best-case scenario, it's much more valuable to agree upfront on technical milestones, contingency plans and clear go/no-go decisions. That creates a partnership where everyone is working toward the same objective with realistic expectations.

How can CDMOs balance sponsor demand for customization with the operational advantages of standardized platforms?

Standardization and customization aren't mutually exclusive and the best projects usually combine both.

Whenever possible, sponsors should leverage standardized platforms because they improve robustness, simplify technology transfer and ultimately reduce both timelines and risk. That said, cell and gene therapies are incredibly diverse, and there are always situations where adapting the process is the right scientific decision.

A good balance is to customize only where it genuinely adds value for the product or the patient, while standardizing everything else that benefits quality, consistency and execution.

For example, in many cases with cell therapy products, the core process is initially developed by the sponsor, while the CDMO contributes its expertise in scale-up, process performance, and quality improvement. This can include applying equipment, reagents, and materials already used successfully in other programs. This allows the sponsor to benefit from existing platform data and manufacturing know-how already present within the CDMO.

Finding that balance gives sponsors the flexibility they need without introducing unnecessary complexity.

What must CDMOs do to be true strategic partners?

Being a strategic partner means contributing much more than manufacturing capacity.

Sponsors expect a CDMO to bring experience, challenge assumptions when needed and share practical lessons learned from previous programs. Sometimes that means proposing a different technical approach or highlighting a risk before it becomes a problem.

Every company has different priorities. Some are focused on speed, others on preserving cash or preparing for commercial manufacturing. A true partner understands those priorities and adapts its approach while never compromising on quality or compliance.

What characteristics differentiate the strongest sponsor/CDMO partnerships from the weakest?

The strongest partnerships all have one thing in common: both teams behave as if they're working for the same project rather than for separate organizations.

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A cohesive team openly discusses risks and technical challenges instead of waiting until problems become critical. Decisions are made collaboratively, with regular communication between project management, technical and quality teams.

By contrast, weaker partnerships often become purely transactional. Communication is limited to contractual obligations, and each side focuses on protecting its own position rather than solving problems together.

Cell and gene therapy is too complex for that approach to work. The most successful collaborations are those where sponsors and CDMOs work as one integrated team, sharing the same objective of delivering therapies to patients as efficiently and safely as possible.

Ahmed Yahia *is a former scientist turned business development leader with 15+ years supporting pharma and biotech companies. Ahmed focuses on advancing cell & gene therapies, building strategic partnerships across AAV, lentivirus, oncolytic viruses, and cell therapies — turning great science into real solutions for patients. He is passionate about collaboration, optimizing strategy, and bringing energy (and good coffee) to every deal.*

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