

Build vs. Buy: The CDMO Decision That Could Make or Break Your Cell Therapy

When is outsourcing to a CDMO the right move?

Process decisions have far-reaching consequences. Partnering with a contract development and manufacturing organization (CDMO) can accelerate your path to clinic but requires careful evaluation to ensure it's the right choice for your cell therapy.

The Strategic Value of CDMO Partnerships

CDMOs offer immediate access to manufacturing expertise, regulatory knowledge, and established infrastructure. This partnership allows you to leverage existing systems while focusing on your core strength: advancing breakthrough science.

The most successful cell therapy companies recognize that manufacturing decisions made today will shape their business outcomes tomorrow. Partnering with the right CDMO isn't just about outsourcing production, it's about accelerating your path to patients while minimizing risk.

- Joe Sinclair, VP & Head of Commercial

A strong CDMO relationship serves multiple strategic purposes:

- Accelerated timeline to clinic through established infrastructure and operational experience
- Resource optimization that enables your team to concentrate on therapeutic development
- Risk mitigation by drawing on specialized manufacturing expertise
- Strategic positioning for potential acquisition, as larger players value well-established manufacturing pathways

Many successful early-stage companies have recognized that dividing focus between scientific innovation and GMP manufacturing creates unnecessary complexity. By partnering with the right CDMO, you gain access to quality systems and manufacturing capabilities without diluting your scientific focus.

Building a Successful CDMO Partnership

A successful CDMO partnership is built on true collaboration, not just a transactional relationship. Long-term success relies on mutual engagement, transparent communication, and the alignment of shared goals. The most effective partnerships capitalize on complementary strengths to drive progress.

CDMOs, with their experience across multiple clients and therapeutic modalities, offer valuable cross-disciplinary expertise that can significantly enhance your development process. However, without consistent alignment and communication, you risk undermining the GMP-readiness essential for bringing your therapy to market.

Navigating Contract Expectations

One of the most common challenges in partnerships arises from misaligned expectations during the contract phase. Given the inherent unpredictability of biology, it's essential that agreements clearly define the responsibilities of both parties. Equally important is establishing well-defined procedures for managing the inevitable obstacles that may emerge throughout the partnership.

Strategic partnerships thrive on transparent communication and aligned expectations. The strongest CDMO relationships are built on mutual trust, clear accountability frameworks, and shared commitment to navigating the challenges that inevitably arise in cell therapy manufacturing.

- Adam Haskett, Sr. Director & Head of Strategic Alliances and Partnership

Effective contracts should explicitly outline:

- Process repetition parameters and change order management if initial runs don't meet specifications

- Project stage-gates and clear decision frameworks for unexpected challenges
- Communication protocols for timeline adjustments
- Resource allocation responsibilities when process modifications become necessary

Open, honest discussions about potential challenges before committing to a contract help establish realistic expectations and create the foundation for successful collaboration.

Setting The Stage For Success



Acknowledge knowledge gaps and actively seek external expertise.



Question assumptions to build deeper understanding of process requirements.



Maintain flexibility as clinical manufacturing invariably presents unforeseen challenges.



Define SMART goals with realistic timelines and outcomes.



Prepare for the unexpected by establishing contingency plans.



Assemble the right team with complementary skills and experience.

Selecting Your Ideal CDMO Partner

Finding the right manufacturing partner requires thorough due diligence. The ideal CDMO acts as a true partner, seamlessly integrating with your team while remaining flexible, committed, and aligned with your therapeutic's vision and clinical objectives. When assessing potential CDMO partners, prioritize those who demonstrate:

- **Proven Experience Across Development Stages:** A strong history of supporting innovative therapeutics from preclinical through early- and late-stage clinical development.
- **Respect for Internal Technical Expertise:** A collaborative mindset that values your team's scientific contributions and seeks to complement, not override, internal knowledge.
- **Complementary and Differentiated Capabilities:** Technical expertise, processes, and infrastructure that strategically enhance your existing capabilities rather than duplicate them.
- **Alignment with Your Manufacturing Strategy:** The operational capacity and flexibility to adapt to your specific process development and GMP manufacturing requirements.
- **Technology and Equipment Fit:** Access to the right process technologies and analytical instrumentation needed for your modality and scale, ensuring smooth tech transfer and efficient execution.
- **Proven Regulatory Track Record:** Demonstrated success navigating global regulatory pathways, with experience in regulatory submissions, audits, and compliance standards across various regions and modalities.

- **Operational Agility:** A flexible approach to timelines, scope changes, and unforeseen challenges, critical for managing the dynamic nature of therapeutic development.

For earlier-stage CDMOs without extensive late-phase and commercial history, evaluate their talent depth, technical resources, and operational foundation. The right partner should enhance your capabilities while providing the manufacturing expertise necessary to advance your therapeutic toward patients.

Is Made Scientific the Right Fit for Your Cell Therapy?

Scientific breakthroughs hold immense promise but turning them into real-world therapies requires more than innovation alone. At Made Scientific, we exist to drive life-saving cell therapies from development to delivery.

Our comprehensive facilities provide the ideal environment for cell therapy production with state-of-the-art development, GMP manufacturing, quality control testing, and warehousing and cold storage management.

Our partnership model is built on four key drivers that ensure successful therapy advancement:

- **Precision:** We never compromise on quality, compliance, or scientific rigor
- **Speed:** We accelerate timelines without sacrificing excellence
- **Scale:** Our infrastructure enables seamless transition from concept to widespread impact
- **Cost-Efficiency:** Smart economics ensure therapies remain accessible and commercially viable

From early development through commercial manufacturing, Made Scientific is ready to transform your scientific breakthrough into a treatment that changes lives

About Made Scientific

Made Scientific is a leading cell therapy contract development and manufacturing organization (CDMO) dedicated to advancing the field of cell therapy. Since 2019, the company has specialized in developing, manufacturing, and releasing autologous and allogeneic cell therapy products for early- to mid-stage clinical trials, and has evolved into an end-to-end clinical-to-commercial service provider. Operating from two U.S.-based manufacturing facilities, Made Scientific combines the flexibility and entrepreneurial spirit of a specialist CDMO with the global expertise and resources of GC Corporation of South Korea, a global leader in the pharmaceutical and biotechnology sectors.

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Defy Limits.
Deliver Results.