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Scale Decisions for MSC Manufacturing: Build In-house or Partner with a CDMO

The decision to build in-house or partner with a CDMO is less philosophical than it appears. At its core, it is a question of where manufacturing risk will live over the next 24 to 48 months.

Most teams believe they are choosing a manufacturing location. In reality, they are choosing how much operational, regulatory, and execution risk their organization can absorb while advancing the clinical program.

When Building In-house Is Rational

In-house manufacturing can make sense when:

- The MSC process is already stable and well-characterized
- There is a clear commercial strategy that justifies capital investment
- GMP operators, quality leadership, and technical staff can be recruited and retained
- The organization can absorb the cost of future process changes and comparability work

The limiting factor is rarely scientific talent. It is the presence of a functioning quality system, validated aseptic behaviors, and sustained operational discipline.

When Partnering Is Rational

Partnering often wins when:

- Speed to clinic outweighs facility ownership
- The process is still evolving and requires experienced process development support
- Access to closed or semi-closed platforms is needed without long lead times
- Integrated QC testing and stability programs are required from the start
- An inspection-ready GMP facility is needed immediately
- The need for flexible capacity and ability to rapidly scale from clinical to commercial manufacturing

Made Scientific's model is designed around this integration, combining process and analytical development, GMP and non-GMP manufacturing, aseptic fill & finish, QC testing, and regulatory support within a single operational framework.

The Hybrid Option Many Teams Overlook
A third option exists: hybrid client-in-plant models that preserve internal oversight while leveraging an established GMP environment.

For many programs, this approach provides a practical bridge between early outsourcing and long-term internal manufacturing without assuming full facility risk upfront.

A Decision Framework Holds Under Pressure

- **Patient delivery risk**

If reliable product delivery is at risk, process optimization becomes mandatory regardless of who manufactures.

- **Comparability exposure**

Early, phase-appropriate optimization reduces future regulatory and comparability burden.

- **Capability fit**

Ensure alignment between process needs and available platforms, particularly for harvest, wash, formulation, and fill & finish.

- **Operating model realism**

Assess whether the team can truly operate GMP manufacturing while advancing clinical research and fundraising. Many early-stage organizations cannot, and that constraint is structural, not a failure of ambition.

Ready to discuss this topic further with our Subject Matter Experts? Let's talk.

About Made Scientific

Made Scientific is a leading U.S.-based cell therapy contract development and manufacturing organization (CDMO) specializing in the development, manufacturing, and release of autologous and allogeneic cell therapy products for clinical- and commercial-supply. Operating from two state-of-the-art manufacturing facilities in New Jersey, Made Scientific combines the agility 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. For more information, visit www.madescientific.com.

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