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Eleven Manufacturing Considerations for Your MSC Program

When is outsourcing to a CDMO the right move?

Below are eleven key considerations that determine whether MSC manufacturing remains consistent and scalable.

1. Source strategy and donor variability
Define controls for biological variability, especially when scaling across donors or tissue sources.

2. Cell bank strategy and lifecycle
An MSC cell bank is not inventory. It is a control strategy for comparability, long-term supply, and regulatory continuity.

3. 2D versus 3D expansion pathway
Two-dimensional systems are often appropriate early. At scale, automated bioreactor platforms and, in some cases, 3D microcarrier-based expansion can improve consistency, provided comparability planning begins early.

4. Defined media exchange strategy
Align media changes to growth behavior using measurable signals. In-process metabolite monitoring helps detect drift before it becomes batch-limiting.

5. Predictive critical quality attributes (CQAs)
Surface markers alone do not define potency. CQAs must align with mechanism of action and clinical intent.

6. Harvest is a process, not a moment
Harvest and wash should be engineered unit operations with defined, controllable parameters.

7. Agglomeration control
Agglomeration drives downstream risk. In-line filtration and optimized wash design improve robustness and handling.

8. Automation aligned to development phase
Automate what reduces immediate risk, such as cell washing, while maintaining a roadmap for higher-throughput automation.

9. Cryopreservation and formulation fundamentals
Formulation directly impacts post-thaw viability and function. This is a frequent point of GMP translation failure if not addressed early.

10. DP container and fill strategy
Select phase-appropriate fill and finish early to avoid costly changes and comparability work later.

11. QC testing and stability for living products
MSC programs require tailored identity, potency, sterility, and stability strategies that support shelf-life claims.

These are not optional enhancements. They are the levers that determine reproducibility, release reliability, and whether scale feels controlled or chaotic.

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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