MADE SCIENTIFIC

From Scientists to (Smooth) Operators: Key Strategies for a Successful Tech Transfer

Tech transfers can feel akin to mastering the telephone game. Find out how to achieve scalability, repeatability, and overall GMP readiness for your cell therapy product.

Ensuring that your cell therapy can be repeatedly produced by manufacturing operators – not just the scientists who developed it – requires adaptive planning and execution. Think of it like the "telephone game," where in order to avoid miscommunication (and costly delays), you must close the loop on the process as much as possible to achieve the desired results. Readiness indications, such as successful toxicology tests and animal studies, provide a strong foundation, but there are additional factors to consider for a smooth transition to clinical manufacturing.

Contract development and manufacturing organizations (CDMOs) bring extensive knowledge in evaluating good manufacturing practices (GMP) readiness. This article will highlight what to expect when partnering with a collaborative CDMO, and how you can assess your own process for potential gaps before moving to clinical manufacturing.

The Three P's: Plan, Process, People

Accelerating your cell therapy to market requires a compelling approach. The three P's —Plan, Process, and People—offer a proven framework to set your program up for success.

A successful tech transfer comes down to teamwork. When development, MSAT, and manufacturing are on the same page, we catch issues early, keep things moving, and avoid expensive delays. It's all about building a process that's not just theoretically sound, but actually works in the real world.

- Sun Ra Bullins, VP & Head of Technical Operations

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1. Plan: Asking the Right Questions

A dynamic plan considers the full product lifecycle while keeping the end goal in focus. Key considerations should include the patient population, regulatory domain, and the commercial landscape. Questions you should be asking include:

- How will cost-of-goods (COGs) be factored into your framework?
- Is your technology scalable and aligned with industry standards?
- How does your cell therapy product fit into tomorrow's competitive market?

Rather than forcing a technology into a market that isn't ready for it, your approach should be shaped by real-world demand. A comprehensive plan with these considerations in mind will serve as your north star throughout development and manufacturing.

2. Process: Testing Scalability & GMP Readiness

Your process must be scalable—not just in theory, but in the live manufacturing environment. Keeping the end goal in mind, the preferred way to test this is through pilot production and engineering runs using patient or donor material, and GMP-grade materials. Critical actions to improve process resilience include:

- Close as much of the process as you can;
- Ensure the tools and technologies play well throughout the entire process;
- Test scalability on real patient or donor materials.

The goal here is to think of this not as a series of independent steps your product must advance through, but as a methodical process by which your chemistry, manufacturing, and controls (CMC) team — as well as your manufacturing, science, and technology team (MSAT) — can help you continuously refine and pivot until, ideally, you achieve a fully characterized process.

3. People: Assembling the Right Team for Clinical Success

Having the right people in place is critical to having confidence in the clinical program. It is important to have industry veterans — whether they are from your own team or provided by a perceptive CDMO — who have experience with bringing products through to market including:

- Engineers, manufacturing, and quality control specialists who know what at-scale manufacturing looks like and where common pitfalls lie in clinical manufacturing and product release;
- Experts in regulatory and CMC environments that understand the nuances involved in tech transfers and how they stand up to regulatory guidances;
- Specialists with insight into various technologies and equipment who can evaluate the impact of migrating to newer, potentially more efficient tools.

When you have the right team in place, you can trust that your manufacturing process is set up to successfully transition to clinical and commercial readiness.

Demonstrating Process Reliability

When you transfer from a process development lab to a GMP manufacturing suite, you need to go through a range of

activities that demonstrate the reliability of your process. This includes water runs, training runs, feasibility runs, and multiple pilot or engineering runs. If you can demonstrate that your process can be run using a batch record while consistently meeting in-process and release specifications, you're in a strong position to take the next step into clinical manufacturing.

All of this, like everything else in clinical manufacturing, is a journey toward ensuring your product can be produced by personnel who are not scientists who spent years developing your process, but instead operators who will be relying on batch records for explicit instructions and procedures. Providing operators with sufficient time for training and familiarization with the unit operations included in your process is crucial for success.

Engaging MSAT for a Smooth Transition from Process Development to GMP

Achieving the results you have been working so hard for is thrilling. As you look toward the next stage, the repeatability and scalability of those results should be at the forefront of your mind. That is why the knowledge transfer stage is so momentous, and that is exactly where the work the MSAT team does to translate the results of process development into the approach for clinical manufacturing comes into play.

Cell therapy manufacturing isn't just about science – it's about execution. MSAT ensures that a process developed in the lab can succeed in a GMP environment, without compromising scientific integrity.

- David Smith, VP & Head of Development

The MSAT team helps bridge the gap between process development and GMP production. In the initial process development stage, your team is composed of highly specialized personnel performing a process they have spent years developing. Transitioning that process over to your manufacturing team comes with obstacles. A prime obstacle is that this new team who will be manufacturing your product is, inevitably and by design, less familiar with the science behind your process. They may also be less skilled with the unique unit operations associated with your process.

To work through this challenge, it is necessary to create a multi-way dialogue that focuses on how you can make the process appropriate for the GMP environment without changing the cell journey, i.e., producing the desired outcomes in a different environment.

For knowledge transfer to be successful, subject matter experts from both R&D and MSAT (or CDMO) teams will need to discuss the work completed during process development; scale-up considerations and process modifications; and documentation, training, and material readiness. This effort will ensure the MSAT team, who is responsible for helping you transition the process to a GMP manufacturing setting, has a clear understanding of your current state.

The MSAT team will identify any gaps that need to be closed before you can move into clinical manufacturing. They can then convert that gap analysis into a GMP-readiness plan, which will include improvements to documentation, training programs required for operators, and updates to materials and tools. Additionally, knowing any outstanding risks is vital to ensure a proactive and successful journey to GMP manufacturing.

At Made Scientific, our MSAT team serves as a hands-on liaison between our partners and our own process development and manufacturing teams, working to consistently improve how therapies are advanced from bench to bedside.

Our team works closely with a variety of cell therapy developers, including startups, large pharma companies, academic medical centers, and biotech companies who have autologous and/or allogeneic cell therapy products. Our expertise spans across multiple modalities, and our customizable approach is designed to ensure successful tech transfer of products in any clinical phase to commercial enablement.

Need expert guidance on your tech transfer strategy? Let's talk.

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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