

CASE STUDY



DiscGenics Collaboration Successfully Develops Allogeneic Therapy to Enable Efficient Manufacturing

DiscGenics is a biopharmaceutical company that develops regenerative cell-based therapies to alleviate low back pain and restore function in patients with degenerative diseases of the spine.

CHALLENGE

DiscGenics had established a novel process to generate cells for their allogeneic therapy, but knew they needed to improve the efficiency of the process as well as lower the cost of manufacturing. They wanted to develop a new technology to address this, but with a small team of ten employees they did not have the necessary expertise in-house. They also were not ready to invest in more equipment until they knew exactly what their process would require.

DiscGenics is building their own manufacturing facility and needed to limit their contract engagement to process development only. They were looking for scientists and engineers who could essentially work as an extension of their team in the areas where they had limited staff and resources.

However, DiscGenics found that many contract development and manufacturing organizations (CDMOs) that they approached for assistance in developing the new technology were not interested in a standalone process development project.

SOLUTION

The Centre for Advanced Therapeutic Cell Technologies (CATCT), operated by CCRM and Cytiva, with its state-of-the-art equipment and process development expertise, was a perfect fit.

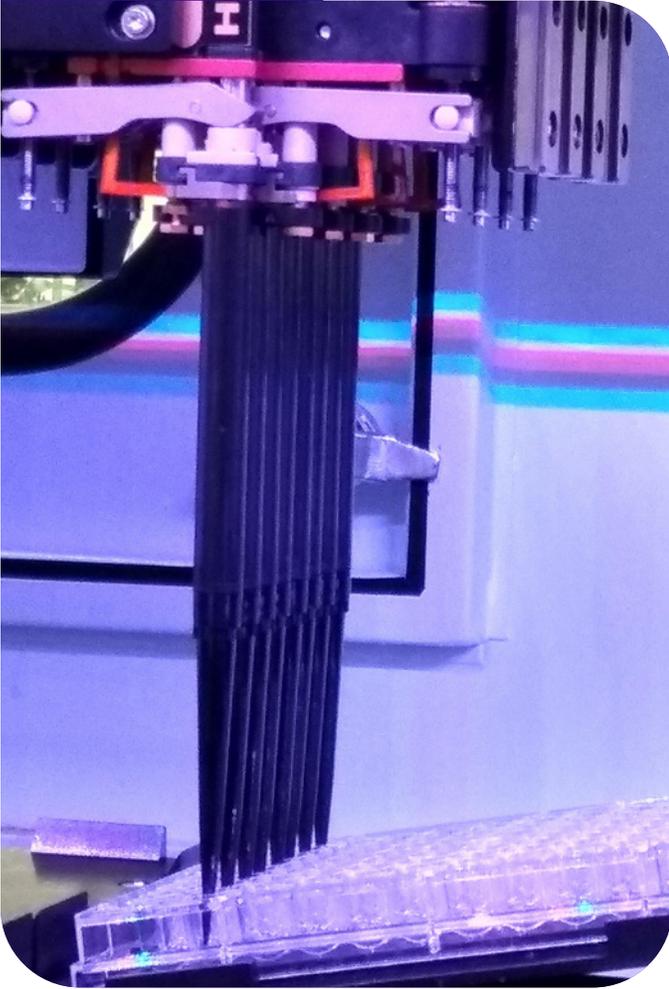
After only a brief introduction with members of the CCRM and Cytiva team, DiscGenics learned that these individuals had experience with the type of equipment DiscGenics intended to use. Following some preliminary development work, CCRM and Cytiva were able to make progress on the areas that DiscGenics had tasked them with addressing. This gave DiscGenics the confidence that the CATCT team could help them reach their next milestone.

“One of the things we noticed right away is that the people we were working with were good scientists,” says Lara Ionescu Silverman, PhD, Senior Director, Research and Development, DiscGenics. “These were experts with a lot of experience in the science, as well as in managing customers and clients. It felt very much like they were

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comfortable with doing quite complicated research that we couldn't necessarily provide all the input on. We were looking to them to help us craft the scope of work and help us get to the end."

Throughout this long-term relationship, frequent change requests and various statements of work were handled so that DiscGenics always had the flexibility they needed.

"When issues arose due to budgeting or an experiment producing unexpected results, CCRM and Cytiva were able to pivot quickly and make it work for us," Dr. Silverman said. "The CCRM and Cytiva team was very collaborative, and when we provided input, they were always willing to listen and hear our perspective because each cell therapy is so different and unique."

Importantly, the technology transfer was efficient and seamless, showcasing CCRM and Cytiva's experience in

cell therapy process development activities. The team initially worked side-by-side, and then executed the project with minimal input for several years, almost acting as an extension to DiscGenics' R&D team. This wasn't a traditional technology transfer that went directly into the Good Manufacturing Practices (GMP) environment, but rather was returned to the development environment at DiscGenics so that they could gain further in-house experience and training prior to commencement of manufacturing.

RESULTS

Having access to CATCT's equipment and expertise, without direct capital investment, was a great advantage to DiscGenics so they could focus on their clinical roadmap rather than day-to-day operations of the development program. In fact, DiscGenics found the lab at CCRM so organized and well maintained that they used it as a model for their own facilities.

"There were a number of reports and standard operating procedures that were generated by CCRM and Cytiva, so we have all that for historical record," says Dr. Silverman.

"It was a very collaborative relationship and it was a little sad when we finished working together," says Dr. Silverman. "[The team] really helped us get to where we are today. Because of the successful experiments, we ended up investing in a lot of that equipment ourselves. We ended up hiring people with similar backgrounds and now we're able to work independently and move really quickly internally. We've come a really long way in a few short years and I think a lot of that is thanks to the relationship we had with CCRM and Cytiva. They were the launching pad to get us from the clinical stage to our future commercial process."

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