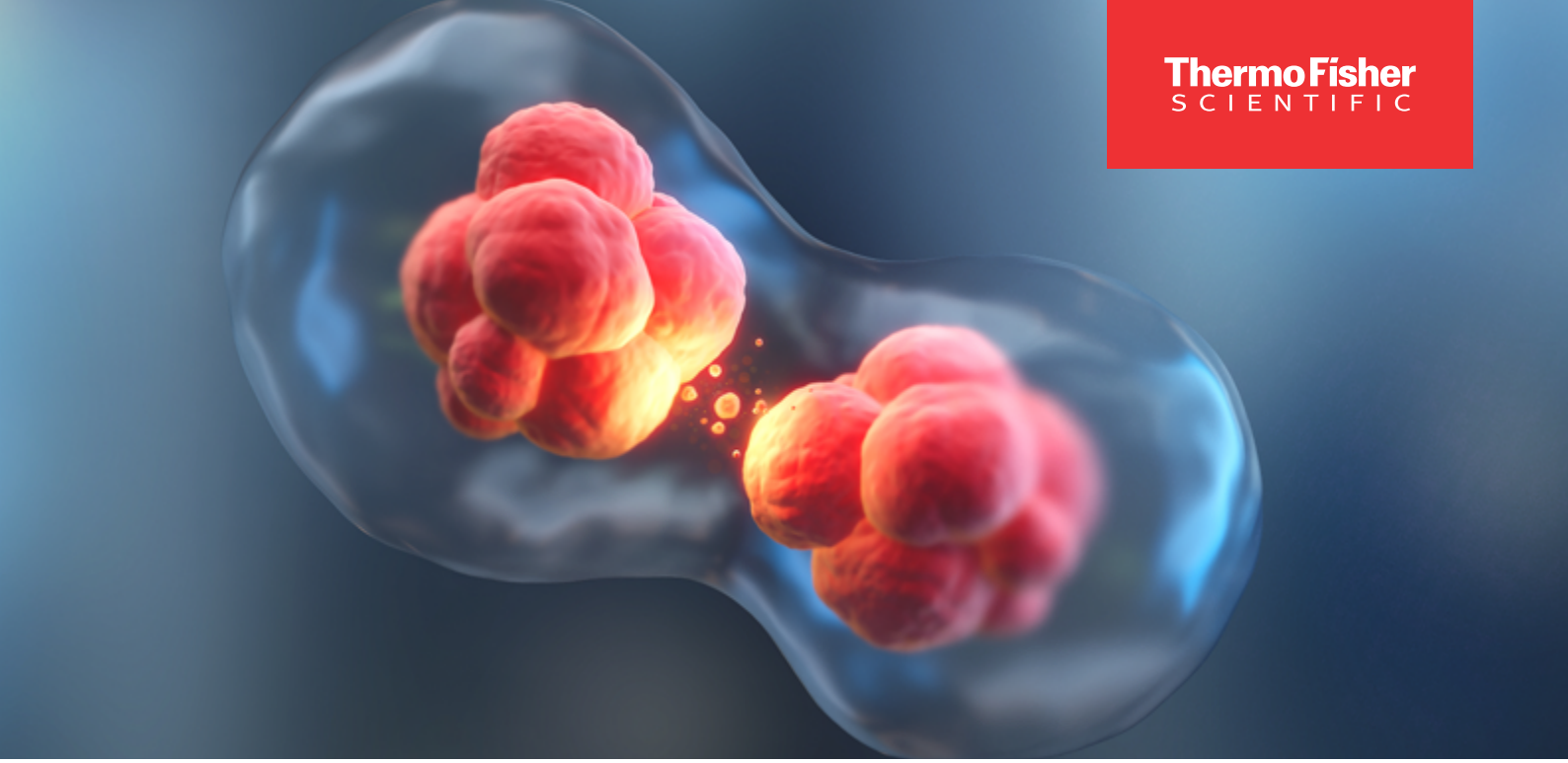

Case Study

Scaling up for the largest CAR T production facility in South Korea

The Challenge

Building the largest CAR T-cell therapy manufacturing facility to scale-up operations

	Specialized and sophisticated manufacturing processes for CAR T-cell therapy
	Strict regulatory guidelines for compliance as a Good Manufacturing Practice (GMP) facility
	Quick and agile scale-up of operations that enable operational efficiency

CAR T-cell therapy—an individualized form of treatment that harnesses the power of the immune system to fight cancer—requires specialized and sophisticated manufacturing processes to help ensure timely delivery and the highest standards of treatment for patients.

Based in Daejeon, South Korea, Curocell, a clinical-stage biotechnology company that specializes in chimeric antigen receptor (CAR) T-cell therapy, also develops the OVIS™ (Overcome Immune Suppression) technology to improve the clinical efficacy and safety of CAR T-cell therapies by improving the immune cells' ability to attack cancerous cells.

In 2021, the company began the construction of a new premise to provide contract manufacturing services, where it was to also include a GMP facility to enable the commercial manufacturing of CAR T-cell therapies and an R&D center for further cell therapy pipeline development.

Building a GMP facility is no easy feat. There are strict and highly regulated requirements to meet which include following evolving standards according to new information and improved methods of risk reduction, as well as the challenge to maintain consistency and accuracy of product integrity. The manufacturing process must ensure adequate safety levels to protect investments, operational staff, and the public health.

The Solution

A partner with expertise and experience in setting up GMP facility

	Expertise in cell therapy manufacturing process and GMP standards validation
	Documents for inspection and certification prepared in advance for GMP validation
	Procedural guidelines and training for operational staff

Leveraging our know-how from our previous partnership in 2018 for Curocell's first GMP facility, we too successfully assisted them in meeting GMP standards for this second facility. Our experience in GMP compliance lent success to the setup of this center where we ensured that the provided equipment and solutions contributed to the prerequisite process qualification, continued process verification and quality assurance protocols for each phase of the manufacturing process.

Procedural guidelines and operational training were also provided for the staff to help ensure operations are consistent with the first GMP facility. Our team was able to pre-empt potential roadblocks and prepare necessary documentation for inspection and certification quickly, resulting in streamlining the validation process. An exhaustive list of equipment and solutions was prepared in advance, enabling Curocell easy access to documented evidence and to verify that the production equipment is:

- correctly installed;
- operating according to requirements;
- performing safely and;
- consistently producing conforming products.

The Impact

Largest CAR T-cell therapy manufacturing site that is GMP compliant for commercial manufacturing leading to global business expansion

	Scaled up operations with more than 500% increase in manufacturing throughput
	Complete GMP validation and standards compliance
	Largest CAR T-cell therapy manufacturing site in South Korea

With this new GMP facility which meets all regulatory standards for CAR T-cell therapy manufacturing and is now the largest in South Korea, Curocell managed to scale up its operations, resulting in more than 500% increase in manufacturing throughput. This helped lend Curocell success in effective commercial manufacturing and its global business expansion.

"We're excited to be partnering with Thermo Fisher Scientific once again for the building of the first CAR T commercial manufacturing facility in South Korea, that is also the largest in the country. Our previous partnership with them has paved the way for this second collaboration where we are pleased with the expertise, know-how and experience that they have brought to the table. Thermo Fisher Scientific has always met our high expectations and provided us with seamless collaboration, and the best experience."

Mr. Jeon Donghyuk
Head of GMP Center, Curocell Inc., South Korea

Learn more at **thermofisher.com/celltherapy**

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