Minaris Regenerative Medicine
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Minaris Regenerative Medicine: creating cell therapy solutions

With vast experience in cell-based therapies, Minaris Regenerative Medicine has become a trusted global partner for clinical and commercial manufacturing of cell therapies.

Producing cell-based therapeutics is extremely complex, but Minaris Regenerative Medicine, the principal global contract development and manufacturing organization (CDMO) in cell and gene therapies, is leading the way. Minaris—derived from the Japanese word 'mirai' (meaning future) and the English word 'miracle'—stands for the company's commitment to constantly push the boundaries of what is possible.

Delivering cell-based therapies to patients globally

The company has more than two decades of cell-therapy manufacturing experience, including a wide range of cell types, manufacturing technologies and procedures, analytical methods and processes, and regulatory expertise—with demonstrated success. Minaris has led the field for many years, including advancing one of the first cell and gene therapies through clinical development, and being one of the first CDMOs to manufacture a commercial cell therapy.

Minaris Regenerative Medicine, a global organization owned by Showa Denko Materials Co. Ltd., has a global footprint of over 200,000 square feet, with six state-of-the-art facilities across the United States, Germany, and Japan. This allows its clients to supply patients in all three major markets: North America, Europe, and Asia, explained Kazuchika Furuishi, General Manager of Showa Denko Materials Regenerative Medicine Business Sector. The highest quality control and safety standards form an integral part of its processes, ensuring complete traceability, highly consistent batch-to-batch quality, and full regulatory/GMP compliance. Moreover, Minaris is significantly expanding its production sites in all three regions, aiming to more than double capacity by 2023.

"We have vast experience working with human cells in multiple therapeutic applications, including allogeneic and autologous settings, as well as native and genetically modified cells," said Dusan Kosijer, CEO of Minaris Regenerative Medicine GmbH (Germany). "Combining state-of-the-art capabilities, infrastructure, and systems with current GMP manufacturing practices enables us to provide late-stage clinical testing and the seamless transition into commercial production."

Consulting and development

In addition to delivering cell-based therapies to patients, Minaris harnesses its expertise and extensive experience to develop integrated manufacturing solutions, helping clients design efficient and robust manufacturing processes and analytical development methods, improving the commercial viability of products.

Process development for cell and gene therapies is highly complex, requiring custom-developed solutions from the very beginning of defining a product's attributes to establishing a commercialization plan. Whether it is optimizing input materials and unit processes, improving process efficiency and product comparability, conducting stability studies, designing cryopreservation protocols, upscaling bioreactors or optimizing product storage and transportation, Minaris can achieve it, pro-actively navigating pathways for approval and commercial production.

Key to success is the company's multifaceted team, which is able to draw on diverse backgrounds to both anticipate and overcome challenges, accelerating gene and cell therapy projects while reducing their overall cost and minimizing the risk of setbacks.

"Each project has specific needs and unique challenges, and we take a quality-by-design and risk-based approach, personalizing guidance based on the size, scope, and clinical stage of a product," explained Jacqueline Veivia-Panter, Global Head of Quality. "We identify issues that impact the four critical drivers of commercial success—namely quality, scalability, sustainability and cost—and provide advice to overcome them."

Partnering

With an international reputation for transparency, quality and reliability, it is no surprise that Minaris has built strong relationships with a number of international clients, ranging from big pharmaceutical companies to small- and medium-size biotechnology firms and academia—an international client base that is rapidly expanding. In May 2020, for example, the company further expanded its well-established relationship with bluebird bio, agreeing the long-term clinical and commercial supply of gene therapies for sickle cell disease, transfusion-dependent β-thalassemia, and cerebral adrenoleukodystrophy.

"Minaris provides comprehensive clinical and commercial manufacturing services, development solutions, and technologies for cell and gene therapies," said Furuishi. "Our expert services and operational capabilities, coupled with our reputation for outstanding quality and reliability, enable the successful development of clinical and commercial cell and gene therapy products for the benefit of patients worldwide."

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