Minaris Regenerative Medicine
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Bringing down barriers to cell and gene therapy

Minaris Regenerative Medicine is developing large-scale 3D cell-production processes and optimizing its culture parameters, as well as enabling in-house batch certification, to enable its partners to realize the huge potential of cell therapies.

Minaris Regenerative Medicine is tackling barriers to the development and commercialization of cell and gene therapies. As a global contract development and manufacturing organization (CDMO) with more than 20 years of experience, the company is at the leading edge of efforts to realize the life-changing potential of these therapies, including through the creation of efficient large-scale cell-production processes.

With experience spanning a wide range of cell types, manufacturing technologies, procedures, analytical methods and processes, as well as regulatory expertise, Minaris can support companies as they move through clinical development and on to commercial manufacturing. The company provides this support from six state-of-the-art facilities across the United States, Germany and Japan, giving it a global footprint of more than 30 clean rooms.

Minaris plans to significantly increase its capacity in the coming months. A new manufacturing building in Germany, close to the Minaris facility near Munich, is under construction and will give the company extra clean rooms, quality-control laboratories, warehousing and cryo-storage. With its modular design, the facility allows Minaris to go from single rooms to a ballroom design. In the United States, Minaris is doubling its capacity in New Jersey for phase 3 trials and commercial projects. Minaris is also setting up its facilities to welcome more allogeneic projects, and there is potential to add capacity at sites in Japan to meet the requirements of its clients.

All the sites adhere to high quality-control and safety standards, ensuring traceability, highly consistent batch-to-batch quality, and regulatory compliance. As a global, full-service CDMO, Minaris offers a range of development services, including upscaling to 3D bioreactors.

Enabling efficient, large-scale cell production

Bioreactors set the limitations of current approaches to the production of allogeneic cell therapies. Although off-the-shelf treatments have the potential to industrialize cell therapy, the 2D culture of adherent cells in T-flasks or cell stacks is inefficient and both cost- and labour-intensive. Long-term expansion of human mesenchymal stem cells (MSC) results in limited proliferation and loss of differentiation capacity.

Minaris is solving these problems by developing efficient, large-scale cell-production processes using 3D bioreactors. Notably, the CDMO developed a serial subculture process towards the 50-liter culture of adherent cells in bioreactors, and optimized the culture parameters, medium composition, microcarriers and stirring profiles.

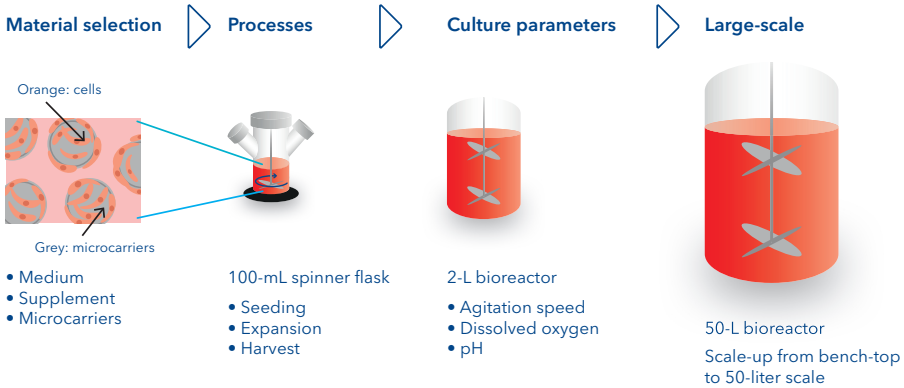

Fig. 1 | Creating efficient large-scale cell-production processes for cell and gene therapies.

In the Minaris process, nucleoside supplementation maintains MSC surface-marker expression and enables faster proliferation in prolonged culture. Minaris has found a simple bead-to-bead cell-transfer method to be faster, and less prone to contamination, than the conventional method of cell harvest and re-inoculation, which is labour intensive and risks compromising the integrity of the cells.

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Using this process, Minaris can smoothly scale up MSC cultures from 4 liters to 20 liters and even 50-liter single-use stirred-tank bioreactors, supporting a 242-fold increase in the number of cells with yields of 1.45×10^{10} cells. The harvested cells maintain the desired characteristics of MSCs, such as their proliferation ability, surface markers, tri-lineage differentiation potential, and immunomodulatory properties (Fig. 1).

The company has also applied its expertise to non-adherent cells in suspension culture to support the production of T cells. Using a closed platform with a scalable, unit-automated process and single-use technologies, the CDMO has achieved 1.0×10^{10} T cells in a 2-liter bioreactor culture.

Providing EU certification by a qualified person

Minaris offers batch certification by a qualified person (QP) for advanced therapy medicinal products manufactured outside the European Union. QPs have sole responsibility for ensuring that each batch of a therapy is manufactured and checked in compliance with the laws in force in the European country where certification takes place, as per the requirements of the clinical trial application or marketing authorization, and in compliance with good manufacturing practice (GMP).

Manufacturers importing into the region therefore need access to a QP. To meet that need, Minaris has established a team of QPs that can perform certification for both clinical and commercial products, enabling it to offer efficient, timely batch certification.

The introduction of the QP service by Minaris and the development of its 3D bioreactor processes are testament to the company's commitment to adapting to the changing needs of the cell-therapy industry. By continuing to invest in its operation, this global CDMO has kept ahead of the rapid evolution of the sector, and cemented its status as a partner that can help realize the life-changing potential of cell therapies.

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