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Sartorius and Stanford Extend Their Collaboration to Develop a Scalable Platform for Large-Scale Human iPSC Production

A research paper featured on the cover of the *Advanced Healthcare Materials* journal in December 2022 describes how scientific collaborators from Sartorius and Stanford developed a scalable platform for large-scale human induced pluripotent stem cell (iPSC) production.

While the promise of biomanufactured autologous tissues and organs has been a long-standing challenge, recent and rapid progress in 3D bioprinting technologies unlocks the third dimension of tissue biofabrication. Despite the revolution in the field of stem cells in the past decade, bioengineers are critically limited by the need for cellular material and a solid, automated process to generate reproducible batches of cells at large-scale with the aim of bioprinting.

During a two-year research collaboration project, scientists at Sartorius and Stanford successfully utilized a design of experiment (DoE) approach to optimize process parameters for generating high yields of human induced pluripotent stem cells (iPSCs) in 250 mL. In the second phase of this project, they developed a comprehensive platform for large-scale expansion and differentiation of iPSCs at a 2 L scale. The final scale-up platform combines the Sartorius Ambr® 250 Modular multi-parallel bioreactor, Biostat® B-DCU, Univessel® Glass (2 L), MODDE®, BioWelder® Total Containment, and NutriStem® hPSC cell culture medium.

“One of the biggest challenges in the field of cell therapy and tissue engineering is the difficulty of scaling up cell production to meet the needs of large-scale biomanufacturing. Through our collaboration with Stanford, we developed a scalable platform for iPSC production to improve process robustness, decrease batch-to-batch variability, and reduce cost. This platform accelerates the time to market of these promising therapeutics.” says Maya Fuerstenau-Sharp, Head of Marketing, Cell Culture Technologies at Sartorius.

“We are delighted with the results of our collaborative work with Sartorius. We were able to reliably produce billions of high-quality pluripotent stem cells, which is of utmost importance for fueling our organ engineering pipeline. These pluripotent stem cells underwent efficient differentiation into organoids and could be used for bioprinting vascular and cortical structures.” said Mark A. Skylar-Scott, Assistant Professor in Bioengineering at Stanford University.

In the next phase of the collaboration, the researchers aim to further scale up iPSC production and investigate large-scale production of iPSC-derived cardiomyocytes at 10 L scale.

A profile of Sartorius

The Sartorius Group is a leading international partner of life sciences research and the biopharmaceutical industry. With innovative laboratory instruments and consumables, the Group's Lab Products & Services division focuses on laboratories performing research and quality control at pharmaceutical and biopharmaceutical companies as well as academic research institutes. The Bioprocess Solutions division, with its broad product portfolio focusing on single-use solutions, helps customers manufacture biotech medications and vaccines safely, rapidly, and economically. The company based in Goettingen, Germany, has a strong global reach with around 60 production and sales sites worldwide. Sartorius delivers significant organic growth and regularly expands its portfolio through the acquisition of complementary technologies. In fiscal 2022, the company generated sales revenue of around 4.2 billion euros. At the end of 2022, around 16,000 employees were working for customers around the globe. www.sartorius.com

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