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## Bio-Engineering on Stem Cell Bioprocessing and Manufacturing

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## **Editorial Note**

The next healthcare revolution will apply regenerative medicines using human cells and tissues. Regenerative medicine aims to make biological therapies or in vitro substitutes for the replacement or restoration of tissue function in vivo lost thanks to failure or disease. However, whilst science has revealed the biomedical potential of this approach, and early products have demonstrated the facility of such therapies, there's a requirement for the event of bioprocess technology for the successful transfer of the laboratory-based practice of somatic cell and tissue culture to the clinic as therapeutics through the appliance of engineering principles and practices.

This Special Issue of Bioengineering on "Stem Cell Bioprocessing and Manufacturing" addresses the central role in defining the engineering sciences of cell-based therapies by bringing together contributions from worldwide experts on somatic cell science and engineering, bioreactor design and bioprocess development, scale-up, and therefore the manufacturing of stem cell-based therapies.

In the previous couple of years, Human Pluripotent Somatic Cell (HPSC) derivatives have emerged as promising allogeneic cell therapy products, with amazing potential to treat a good sort of diseases and a huge number of patients globally. Brian Lee and coauthors addressed various challenges associated with the manufacturing of PSCs in large quantities for commercialization,

which include bioreactor process development-namely, scalable bioreactor technology for the large-scale manufacturing of high-quality therapeutic PSCs derivatives.

Among the foremost promising hPSC derivatives, hepatic cell lineages represent a possible cell source, holding great potential for biomedical applications, like in liver cell therapy, disease modeling, and drug discovery. João Octavio and Tiago Fernandes assessed the assembly of various hepatic cell lineages from PSCs, including hepatocytes, also because the emerging strategies to get hPSC-derived liver or ganoids, highlighting their current biomedical applications.

Alongside the event of novel bioreactor configurations for cell therapy manufacturing, efforts have also been undertaken to optimize bioreactor operating conditions. In their study focused on the manufacturing of Mesenchyme Stem/Stromal Cell (MSC) therapies, Josephine Lambing and colleagues developed a fed-batch, micro carrier-based process during a Vertical-Wheel system, which enhanced media productivity while driving an economical and fewer laborintensive cell expansion process. As another strategy to enhance the cost-effectiveness of cell manufacturing processes, Kathleen Van Beylen and colleagues developed a lactate-based model predictive control strategy for cell growth monitoring and therefore the control of cell proliferation, by adapting the feeding strategy supported lactate measurements, while envisaging the reduction in unnecessary costs, a very relevant issue in large-scale cell manufacturing.

An additional key aspect towards the successful translation of cell therapy products is that the got to use animal origin-free products (i.e., xeno (generic)-free) for the derivation, expansion, and differentiation of stem cells so as to attenuate the risks of animal-transmitted diseases and immune reactions to foreign proteins. during this context, Valentin Josser and colleagues developed a bioprocess approach for the expansion of Adipose-Derived Stem Cells (ASC), targeting autologous therapies by employing xeno- and serum-free culture conditions and testing static, planar (2D), and dynamically mixed (3D) cultivation systems. To the present end, the authors compared the donor variability in both culture systems and developed a mathematical growth model to explain cell growth, nutrient consumption, and metabolite production.

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