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Short Commentery

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Induced pluripotent stem cells

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Introduction

Stem cell-based technologies are one of the most promising approaches in further advancement of cell therapy and regenerative medicine. With great hopes are linked to using stem cells as a tool for drug discovery. In order to make progress towards commercialization, researchers in field are evaluating standardization of their cultivation and efficient scale-up. Mesenchymal Stem Cells (MSCs) are multipotent cells derived from bone marrow, from adipose tissue, cord blood or other tissues related to embryonic mesoderm. They are relatively easy to obtain and have potential for cell therapy and drug screening.

Widely established in traditional cell culture, controlled bioreactors have potential to establish reproducible expansion of stem cells. They provide extensive options for monitoring and control of key parameters such as pH and dissolved oxygen in real-time and facilitate a controlled differentiation of cells. Through scalable bioreactor design, results obtained in small scale can be transferred to larger working volumes while maintaining optimum mass transfer.

Since the pioneering development of cell reprogramming by Shinya Yamanaka in 2006, Induced Pluripotent Stem Cells (iPSCs) have risen to be the most promising alternative to ethically problematic embryonic stem cells. Controlled cultivation and scale-up in clinical grade as well as ways to control their differentiation towards their final destiny will be key steps towards commercial use of these cells.

Human Pluripotent Stem Cells (hPSCs), Comprising Human Embryonic Stem Cells (hESC) and Induced Pluripotent Stem Cells (hiPSC), and their derivatives are considered promising cell sources for novel regenerative therapies. Cell therapies aim at replacement of cell or tissue loss induced by degenerative disorders such as cardiovascular and neurodegenerative diseases, diabetes and many others, which cannot be healed by currently established, conventional treatments. Specific human cell types derived from hPSCs by differentiation can be utilized for the development of yet unavailable in vitro disease models, novel drug discovery strategies and more predictive drug safety assays.

Development and implementation of bioprocessing technologies will require collaborations between academic institutions and a rapidly growing global industry seeking to commercialize stem cell products, as well as interactions with regulatory agencies providing oversight of these processes. It will highlight the most common current approaches and remaining challenges facing development of bioprocessing technologies necessary for scalable and robust manufacturing of stem cells and stem cell-derived products.

Novel monitoring modality that allows systematic development of clinically relevant culture system- methodologies, which control and regulate stem cell self-renewal, expansion, differentiation as well death. Ultimately, such a breakthrough will lead to the engineering of reproducible, well-characterised, regenerated "designer" tissues and organs that meet strict regulatory criteria for clinical applications. Engineering challenge involved in fabrication of proposed modality can only be met by cross-fertilisation and amalgamation of expertise of cell biologists, engineers, scientists, and clinicians.

Fundamental bottleneck of any bioprocess is the lack of real-time, on-line, in-situ, quantitative information with respect to cellular behaviour in culture. As result, control, optimisation, and scale-up of bioprocesses are essentially manual (empirical), which results in sub-optimal productivity (i.e., inadequate cell expansion) and product quality (i.e., inconsistent cell phenotypes). To harness immense potential of stem cells (SCS) in terms of their plasticity and expansion capabilities, physiological activity in relation to the culture parameters (local) such as pH, dissolved oxygen, nutrients/metabolite concentrations and growth factor concentrations needs to be recorded quantitatively with needed level of accuracy and subsequently evaluated in biologically meaningful manner.

Stem cell-derived products have potential to represent promising therapeutic approaches for treatment of wide range of conditions. Neurodegenerative diseases, like Parkinson's disease or Huntington's disease, neurological disorders, cardiac failure, and blood disorders, among others, may one day be treated using cellular therapies and regenerative medicine approaches based on stem cells.

Experimental culture conditions are critical for ex vivo expansion and differentiation of stem cells. In fact, variables such as culture supplements, purity of initial cell population, initial cell concentration, and duration of culture affect outcome of stem cell cultures and, consequently, regenerative potential of ex vivo cultured stem cell-derived products.

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