

## **ENABLING STEM CELL BASED THERAPIES: ADAPTABLE AND SCALABLE MANUFACTURING OF HUMAN PLURIPOTENT STEM CELLS**

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Enabling stem cell-base therapies requires innovative solutions to close the gaps which exist between research and commercialization. Allogeneic cell therapy indications that target large patient populations will necessitate the use of flexible cell production platforms to meet required cell quantities. Here we will show how moving away from conventional 2D culture platforms and developing a truly scalable, controlled bioreactor platforms for cell expansion enables meeting cell quantity demand for clinical applications while allowing comparability between the various scales. Likewise, it enhances process automation and allows integration of online monitoring systems. These bioreactor platforms are flexible cell production platforms, applicable to various cell types. Utilizing many common components, such as bioreactor controllers and centralized up-stream and down-stream hardware, while being able to quickly and easily change components such as vessels, media and microcarriers. The capability of effectively culturing adherent stem cells, namely pluripotent stem cells, will be presented. Cells are expanded in suspension, in a controlled bioreactor, obtaining high fold expansion without compromising cell quality, and the capacity to be further differentiated. This achieved through avoiding 2D cell culture steps, reduces footprint, labor and cost, while enhancing process control and cell product quality.