TRANSITIONING CELL-BASED PROCESSES TOWARDS SCALABLE PRODUCTION

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Scalable insulin-producing cell replacement has the potential to offer a long-term functional cure to treat type 1 diabetes patients. Transitioning a research-grade process into a cell manufacturing process for eventual pivotal trial / commercialization requires a progressive increase in scale-up and cryopreservation capabilities. We review progress made at ViaCyte towards the development of a cell aggregate-based production pipeline, including moving from a 2D to a 3D cell culture platform for hESC expansion, and to a closed bioreactor system for the directed differentiation process. Identification of process parameters and determination of their optimal ranges are required to maximize cell growth rate and yield while maintaining the therapeutic aspects of the cell product. We will explore the manner in which impeller speed, cell concentration, aggregate diameter, and media pH impact hESC passaging and differentiation processes. In addition, we will present strategies for media formulation, cell separation, and semi-automation to support the requirements of a scaled-up process to meet late stage clinical and commercial demand.