

## **CONTINUOUS BIOMANUFACTURING CONCEPTS FOR CELL THERAPY PROCESSES**

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Cell therapy targets the treatment of some of the most widespread and difficult diseases, many of them representing unmet medical needs. To date, there are several promising cell therapy treatments in Phase III of clinical trials, which once proven effective for the treatment of their target indication, will not only be a significant medical breakthrough but also result in very high global demand. If the manufacturing costs of these therapies are too expensive, many patients will not have access to them. Therefore, the commercialization of many, if not all, cell therapy processes will require novel approaches to manufacturing which are cost effective, robust, and efficient.

Continuous bioprocessing streamlines manufacturing resource requirements such as labor, equipment, and consumables in a cost-effective manner while increasing throughput and productivity. An appropriate cell therapy platform should be scalable, robust, and maximize final product yield while keeping both costs low and the final product quality at a high standard. While the focus of allogeneic cell therapies is to “scale up” production for the treatment of large numbers of individuals per lot and autologous cell therapies focus on “scale out” production for maximized number of individualized patient cell lot production, there are overlapping best practices and technologies used in both types of cell therapy processes, as well as in current continuous protein biomanufacturing, utilized for scalable, continuous, end-to-end processing in a completely closed and disposable platforms.

This presentation will highlight current cell therapy end-to-end platform solutions which are scalable, robust, automated, and maximize final product yield while keeping both costs low and the final product quality at a high standard. We will also identify common bottlenecks and challenges in cell therapy manufacturing, including facility designs, and explore potential solutions utilizing modified continuous mAb/protein/viral bioprocessing methods and technologies for the optimization of cell based therapy products.