

## **PROCESS SCALE-UP AND CHARACTERIZATION FOR A CARDIAC DERIVED CELL THERAPY**

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Cardiac cells are increasingly being investigated to treat the symptoms of heart failure and repair damaged heart tissue. As cell therapies move from early clinical trials towards late stage development, scale-up of cell manufacturing processes to commercially feasible scales is needed. Key goals from process scale-up include meeting the demands of production capacity, ensuring product quality and maintaining product comparability to that produced in earlier clinical trials. The process scale-up and characterization approach for a novel cardiac cell therapy is described. Different scale-up technologies were investigated and were able deliver the required production capacity, however the ultimate choice of scale-up technology was determined by product comparability considerations.