EXPERIMENTAL AND ECONOMIC EVALUATION OF DIFFERENT CULTURE SYSTEMS FOR MESENCHYMAL STROMAL/STEM CELL EXPANSION FOR CLINICAL APPLICATIONS

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The translation of cell therapies into clinical practice requires a scalable, efficient and cost-effective manufacturing process. This study presents an integrated experimental and cost analysis of different cell culture technologies for commercial manufacture of a novel umbilical cord-derived cell therapy, currently in early phase clinical trials for the treatment of acute graft-versus-host disease (aGvHD). The experimental analysis assessed the expansion and harvest potential of mesenchymal stromal cells (MSCs), derived from umbilical cord matrix (UCM-MSCs), in different scalable cell culture technologies: a multi-layer vessel (ML), a stirred tank bioreactor with microcarrriers (STR), a hollow fiber bioreactor (HF) and a packed-bed bioreactor (PB). The presentation will highlight differences in cell proliferation rate, expansion fold and harvesting efficiency across the technologies. The cells retained their functional properties post culture in all the technologies evaluated. The experimental results were incorporated into a bioprocess economics tool comprising a stochastic cost of goods (COG) and sizing model to evaluate the commercial economic feasibility and robustness of the technologies. The financial and risk rank orders predicted by the tool will be presented, as well as their sensitivity to the reimbursement scenario selected. The model determined industrially relevant scenarios for which no technology will yield a satisfactory gross margin, indicating that many studies are still needed to establish an optimized manufacturing process.