

ECONOMICS AND QUALITY ATTRIBUTES OF hMSC PRODUCTION IN XENO-FREE BIOPROCESSING MEDIA

Lye Theng Lock, RoosterBio Inc., 4539 Metropolitan Ct., Frederick, MD 21701
lye@roosterbio.com

Iain K. Farrance, RoosterBio Inc., 4539 Metropolitan Ct., Frederick, MD 21701
Jon A. Rowley, RoosterBio Inc., 4539 Metropolitan Ct., Frederick, MD 21701

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Human Mesenchymal Stem Cells (hMSCs) are key raw material in Regenerative Medicine and are widely used for therapeutics, engineered tissues, and medical devices. Yet, achieving an economical bioprocess for hMSC production remains a significant challenge for industry. Bioprocess economic modeling highlights media as a major cost driver in cell manufacturing. Hence, the availability of efficient and robust xeno-free bioprocessing media will not only reduce manufacturing cost, but also decrease regulatory burden associated with bovine serum components found in traditional culture media. Here, we evaluated and compared hMSCs quality parameters in bovine serum-containing and xeno-free bioprocess media formulations and assessed quality parameters such as cell identity, potency and functionality. Cells in xeno-free media maintained critical hMSC functional properties including angiogenic cytokine (FGF, HGF, IL8, TIMP1, TIMP2, and VEGF) secretion, trilineage differentiation, and immunomodulatory potential. In addition, hMSCs cultured in xeno-free media expanded rapidly and achieved confluency within 4-5 days of culture without media exchange. The economics of hMSC expansion in this xeno-free media were modeled and compared to other competitive hMSC cell or media systems where it consistently outperformed traditional hMSC systems by more than 8 fold on the critical productivity metric of Million cells per Liter, making it ideal for industrial-scale manufacturing of hMSCs.