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# A successful approach to rapidly scale up microcarrier-based expansions of human mesenchymal stem cells for allogeneic cell therapies

**Valentin Jossen[1], Stephan Kaiser[1], Ann Siehoff[2], Christian van den Bos[2], Dieter Eibl[1] and Regine Eibl[1]**
[1]Zurich University of Applied Sciences, Switzerland
[2]Lonza Cologne GmbH, Germany

Human mesenchymal stem cells (hMSCs) isolated from adipose tissue and bone marrow represent often used cell types in many pre- and clinical studies running today. This can be explained by their high therapeutic potential resulting from their differentiation capability, immunosuppressive, immune regulating, migrating and trophic properties. In the majority of clinical studies with adipose tissue- and bone marrow-derived hMSCs the treatment of orthopaedic and cardiac diseases is focused on autologous and in special cases on allogeneic cell therapies. However, the required number of therapeutic hMSCs for such allogeneic treatments is in the range of trillions per year. Due to the high cell quantities, alternatives to the 2-dimensional planar cultivation systems (stacked plate systems) typically being applied to propagate hMSCs and suitable scale-up strategies of the expansion procedure are stringently required.

The talk will present a successful scale-up Approach based on microcarriers and stirred cultivation systems with cultivation containers intended for one-time usage. This approach, combining knowledge in bioengineering and cell biology allowed direct transfer of process and cultivation conditions from 100 mL upto 35L and 50L culture volume as shown for adipose tissue- and bone marrow-derived hMSCs. It presupposes extensive screening studies performed in spinner flasks in order to establish the optimal culture medium-microcarrier type-combination, the optimal medium composition and the optimal operational conditions. For rapid process scale-up, experimental and numerical investigations have to be realized in order to predict the optimum stirrer speed and fluid flow pattern, the suspension criteria (NS1 and NS1U), and to keep the shear stress low. In so doing, we achieved one of the highest peak cell densities (0.7-0.8•·106 cells mL-1) reported to date for hMSCs expanded on microcarriersat L-scale under low-serum conditions.

valentin.jossen@zhaw.ch