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## Upstream expansion solutions for stem cells

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The long-term view of regenerative medicine therapies predicts an increased need for expansion solutions that ease scalability, utilize animal origin-free materials and are compatible with limited downstream processing steps. As more stem cell therapeutics progress through clinical testing, current *in vitro* culture methods in 2D vessels are proving cumbersome to scale. Moreover, the concurrent decreased demands for serum from the recombinant protein and vaccines markets may result in a shortage of serum as clinical cell therapy programs are successful. Currently available technologies and challenges in the upstream bioprocessing space, focusing on expansion of allogeneic mesenchymal stromal/stem cells (MSCs) will be reviewed within the context of specific case studies. First, we have developed an approach for selecting media and microcarriers, using adipose-derived MSCs as a model cell line. Next, an evaluation of animal-free media supplementation and cellular detachment solutions was performed. Because cellular therapeutic manufacturing processes are further complicated by the requirement to separate cells from microcarriers whilst retaining cell yield, viability and target phenotypic and functional characteristics, the importance of considering downstream challenges while establishing upstream parameters will be highlighted.

## **Biography**

Julie R Murrell is a Senior R&D Manager for Stem Cell Biology and Collaborations at EMD Millipore. She led an early technology assessment group for the past 7 years and has been part of the Stem Cell group for 3 years. Through that time, she has led the efforts to establish robust assays and identify new targets as key quality attributes for large scale stem cell manufacturing, with a special focus on hMSCs. Her background is in Cell and Molecular Biology. Her multi-disciplinary background has led to innovative team-driven approaches in the field of stem cell production.

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## The organization of stage-by-stage, consistent medical assistance for patients with wounds and wound infections

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A district out-patient centre was set up in the 2012 at the SBFEHC City Clinical Hospital No. 13 of the Department of Health of Moscow to treat wounds and wound infections, which has a properly equipped bandage unit and full-time personnel working 6 days a week and counseling patients, referring them for surgery, as well as providing post-hospital monitoring and out-patient management of patients with chronic wounds. We used a multi-disciplinary approach and standardization of approaches to the diagnosis and treatment of these patients. The Formularies are revised once every 2 years. In the treatment of wounds and wound infections, we employ methods and technologies that can be used both in in-patients and in out-patients in accordance with the principles of the TIME system and according to the phases of wound healing: combined enzymatic preparations, state-of-the-art antiseptics, interactive bandage materials, polymeric wound dressings, compression knitwear, and multi-layer compression bandages applied for a few days, electrical impulse muscle stimulation, ozone therapy, wound oxygenation, hyperbaric oxygen therapy, quantum therapy, air plasma flows and NO-therapy, biologicals and cell technologies, as well as a modified local negative pressure method etc. This has allowed, on one hand, to use the aforementioned methods in an out-patient setting and, on the other hand, to reduce hospital stays in the contaminated surgery department. In particular, the average hospital stay was 17.0 days in the 2011, 14.8 days in the 2012, and 14.7 days in 2013. The average number of out-patient centre visits has been about 400-500 a month since the centre was launched. Our experience is a matter of discussion for health care professionals and managers.

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