SCALE-UP AEROBIC BIOREACTORS

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Abstract

In general, scale-up of a microbial process comprises the transfer of a new or an improved process from laboratory scale to production scale. Apart from bubble columns, processes at larger scale are often carried out in stirred tank reactors with one or more Rushton type turbines, although new fermenter concepts are developed. The trend to improve microbial processes asks for reliable rules for scale translation. The success of a new or improved process depends on the performance of the process at production scale and therefore good simulation of the production conditions at laboratory scale is necessary. However, in practice, when new strains are selected or when a new process is developed, the scale-up of the process is more or less considered as a necessary evil and is not always set-up properly. This results in production yields which are generally lower than expected from laboratory experiments, or the production reactor is overdesigned. In both cases this means higher production costs, than for a good optimized and scaled process.

The scale-up of fermentation processes is critical to the success of industrial fermentation for the production of biologicals in the biopharmaceutical market. Bioreactor scalability is critical to streamlining the adaptation of culture volumes during process development and manufacturing. Single-Use Vessels are of geometrically similar stirred-tank design. We analyzed engineering parameters critical for scale-up (tip speed, mixing times, k_La-values, Power numbers). Scaling up CHO cell culture processes confirmed the scalability among the Single-Use Vessel portfolio. For the routine application of adult stem cells in cell-based therapy and drug discovery large numbers of cells have to be produced with consistently high quality. Besides providing the needed cell quantities, stem cell production must also comply with the manufacturing process regulations required of a fully controlled production system. Stem cell expansion in stirred-tank bioreactors can be monitored and is scalable, and hence can fulfill these requirements from experimental quantities to production. In the development of any pharmaceutical production process, decisions on the best process parameters and methods are made based on cost, time, and titer comparisons. Flexible bioprocess control station ease comparing the performance of batch, fed-batch, and perfusion processes.

***Keywords**: Bioreactor scale-up, Oxygen transfer rate, Scalability, engineering parameters*