

A SCALABLE SINGLE-USE PERFUSION SYSTEM: ARE SINGLE-USE BIOREACTORS SUITABLE & SCALABLE?

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Key Words: Plug-play 2mL fully automated, integrated, single-use device; process development.

Although the scalability of large-scale bioreactors has been well characterized for perfusion processes, it presents several challenges. For a filtration-based retention device, scale-up depends on cell retention efficiency, preventing filter fouling, and the similarity of various scale-up perfusion systems. In recent years, many smaller volume single-use bioreactors have been developed based on mass transfer and mixing principles. In our current processes, we have utilized various scale-down perfusion models ranging from 2 mL to manufacturing scale. The 2 mL working volume bioreactor has an embedded filtration-based cell retention 1.1 μm pore size and the manufacturing scale bioreactors use a separate device - alternating tangential flow (ATF) filtration - for retaining cells. We addressed the impact of protein retention, the impact of gassing and agitation on shear, stress and showed the scalability between the single-use and larger scale systems. Here, our study reveals a simple and scalable perfusion system that predicts the current perfusion process. We demonstrated that single-use is an alternative platform to increase process efficiency covering a wide range of applications including cell line development, medium optimization, and cost reduction.