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Scalability of the Mobius® single-use bioreactor from bench to clinical scale: Examination of key engineering parameters and robustness.

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To successfully implement a large scale single-use bioreactor platform, equivalent performance, i.e. scalability, with smaller sized bioreactors across the platform must be demonstrated. With the recent development of a single-use clinical scale (2000 L) bioreactor, the EMD Millipore bioreactor portfolio now spans from the bench-scale (3 L), through the small-scale (50 L) and pilot-scale (200 L) up to the manufacturing process volume range. The performance design space of the entire Mobius® Single-use Bioreactor platform was characterized using several key engineering parameters including oxygen mass transfer coefficient (kLa), power per unit volume, Reynolds number (Re), mixing time and tip speed. Based on a detailed understanding of the dynamic performance capabilities of each bioreactor across the platform, appropriate process parameters can be selected to achieve scalable performance. This presentation will highlight how a detailed understanding of the performance design space of each sized bioreactor can enable the selection of process parameters at each scale that will enable scalable performance across the platform.