

## CELL CULTURE SCALE-UP IN BIOBLU® C RIGID-WALL, SINGLE-USE BIOREACTORS

Steffen Ostermann, Eppendorf AG Bioprocess Center, Juelich, Germany  
ostermann.s@eppendorf.com  
Xiaofeng Han, Eppendorf Inc., Enfield, USA  
Stacey Willard, Eppendorf Inc., Enfield, USA  
Ma Sha, Eppendorf Inc., Enfield, USA

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For cultivation of mammalian cells in biopharmaceutical research and manufacturing, single-use technology possesses several advantages to autoclavable material. Bioreactor scalability is critical to streamlining the adaptation of culture volumes during process development and manufacturing. We analyzed BioBLU Single-Use Vessels of different sizes (maximum working volumes of 0.25 L, 3.75 L, and 40 L) that are of geometrically similar stirred-tank design. We identified a scalable tip speed zone and an overlapping range of  $k_{La}$  values, which cover most mammalian cell culture needs.

Using computational fluid dynamics simulations we determined the power numbers of the BioBLU bioreactors. Based on these data we scaled up a mAb production process in CHO cells from 250 mL to 3.75 L to 40 L by keeping constant  $P/V$  values (impeller power consumption per liquid volume) among the differently sized vessels. Similar cell growth curves and mAb production profiles were achieved at all three scales. In summary, this study demonstrates the excellent scalability of the single-use bioreactors tested.