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# CHALLENGES OF SCALE DOWN MODEL FOR DISPOSABLE BIOREACTORS: CASE STUDIES ON GROWTH & PRODUCT QUALITY IMPACTS

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Despite wide-spread use of disposable bioreactors, there is a lack of well-established scale-down model for larger scale SUBs. Here we report a case of NS0 cell culture process transfer from 2000L stainless steel bioreactor (SST) to 2000L disposable bioreactor (SUB). Initial attempts in trying to grow the NS0 cells in the small scale 2D bags yielded non-satisfactory results, as growth was impacted by bag material type as well as by suppliers of the same bag material type. However, 3D bags of 50L and above proved to be supportive of the NS0 cell line growth.

Even for cell lines that do not have growth issues in SUBs, surprising product quality difference between SUBs and traditional bench top glass bioreactors are still being observed, thus making the bench top glass bioreactors non-ideal as scale down models. We report two cases where glycan profiles of the expressed antibody products show such dramatic differences. In one case, extensive testing of glass bioreactors from various suppliers led to a particular type being able to mimic the glycan profiles from the SUB, whereas in the other case, alternative scale down model had to be identified and the process had to be modified to maintain the glycan profiles when scaling up to the 200L SUB.