SMALL VOLUME SINGLE USE FACILITY STRATEGY – HARVEST CASE STUDY

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Single use technology is not new; the innovative element lies in how to use, evolve, and integrate its applications into a new or existing facility (continuous, end-to-end single-use or hybrid with Stainless-Steel, connected) to enable cost effective, flexible, and faster biopharmaceutical manufacturing. As industry advances towards more intensified processes with higher titers and cell densities, there is significant opportunity to improve the unit operations downstream including harvest and purification. This poster focuses on two case studies for evaluating a suitable single use technology to replace the conventional stainless steel disc-stacked centrifuge for the harvest unit operation. One such technology is the Cadence Acoustic Separator (CAS) from Pall Life Sciences, which is marketed as a single-use first-stage clarification alternative to accommodate intensified processes and enable continuous bioprocessing. Small scale CAS experiments were conducted to gain an understanding of the technology and establish scale-up criteria for future pilot scale CAS runs. Another technology is the alternating tangential filtration (ATF) device from Repligen. Although the ATF is more commonly used for perfusion, the case study on this poster presents the ATF as a feasible single use option for harvest. The CAS and ATF harvest case studies are used as examples to discuss the key performance indicators monitored during the harvest, challenges encountered in-process, and acceptance criteria for evaluating the feasibility of new single use harvest technologies for a small volume (2kL) single use facility.