

PROCESS SUSTAINABILITY THROUGH NEW TECHNOLOGIES: SINGLE-USE CENTRIFUGE IMPLICATIONS ON PROCESS AND PRODUCT EFFICIENCY

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Background:

Single-use technologies (SUTs) have enabled flexible, modular, and often closed-system processes for process development and pilot/clinical scale. More recently, SUTs have made their way into commercial production for the ability to scale-out at pace with the products demands without substantial sunk-cost risk in capital traditionally associated with stainless facilities.

Each piece of the bioproduction workflow has had SUTs emerge over time and become established to varying degrees and technical excellent, from upstream, harvest/separations, downstream, formulation, and eventually fill/finish.

Harvest – the process of preliminary clarification and separations of solids and debris from supernatant typically containing product – traditionally was accomplished in stainless facilities with continuous-flow stainless steel centrifuges and stainless SIP depth filter (DF) housings. For SU-facilities, the SU-centrifuges were not available and expanded SU-DF became a standard. Cell culture processes have intensified, with more solids and higher volumes in SU formats than ever before, driving expanding count of SU-DF required for harvest.

Harvest Sustainability through SU-Centrifugation:

As processes intensify in SU-formats and SU-DF cartridge count rises per batch, the solids and liquid wastes generated by SU-DF can exceed 400 kg and thousands of liters of buffer and caustics. In an efficient facility, a single bioreactor process suite could generate 6,000 to 8,000 kgs of SU-DF solid waste annually.

New SU-centrifuges are coming available that mimic the benefits of the traditional stainless continuous flow centrifuges, reducing required filtration areas and enabling large-scale processing, with additional benefits of single-use, closed-system processing – are a promising step to make intensifying harvest processes more sustainable. Through empirical testing and bioeconomic modelling, we evaluated the potential impact of SU-centrifuge on the ability to provide a more sustainable single-use harvest solution, projecting a 50-70% reduction in solid's waste and >45% reduction in liquid's waste using a SU-centrifuge. In addition, we evaluated the impact on of the change on labor and suite time, shipping and warehousing, and comparative cost of operation. Overall, the (re)introduction of (single-use)centrifuges into the bioprocess promises to enable intensified bioprocesses that are simultaneously more sustainable that traditional single-use processes.

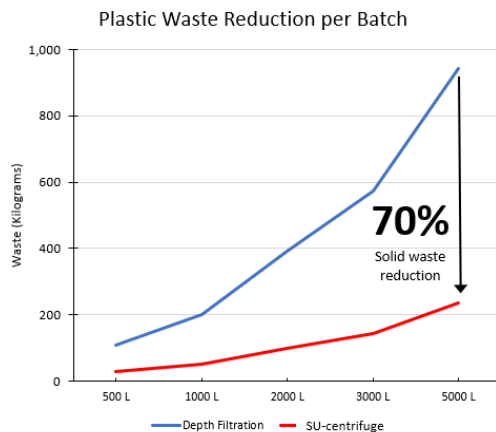


Figure 1 – Example reduction of solids waste of per batch from use of single-use depth filtration vs single-use centrifugation and filtration across different reactor batch volumes.