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3M™ Harvest RC Establishing Value of Single Stage Harvesting

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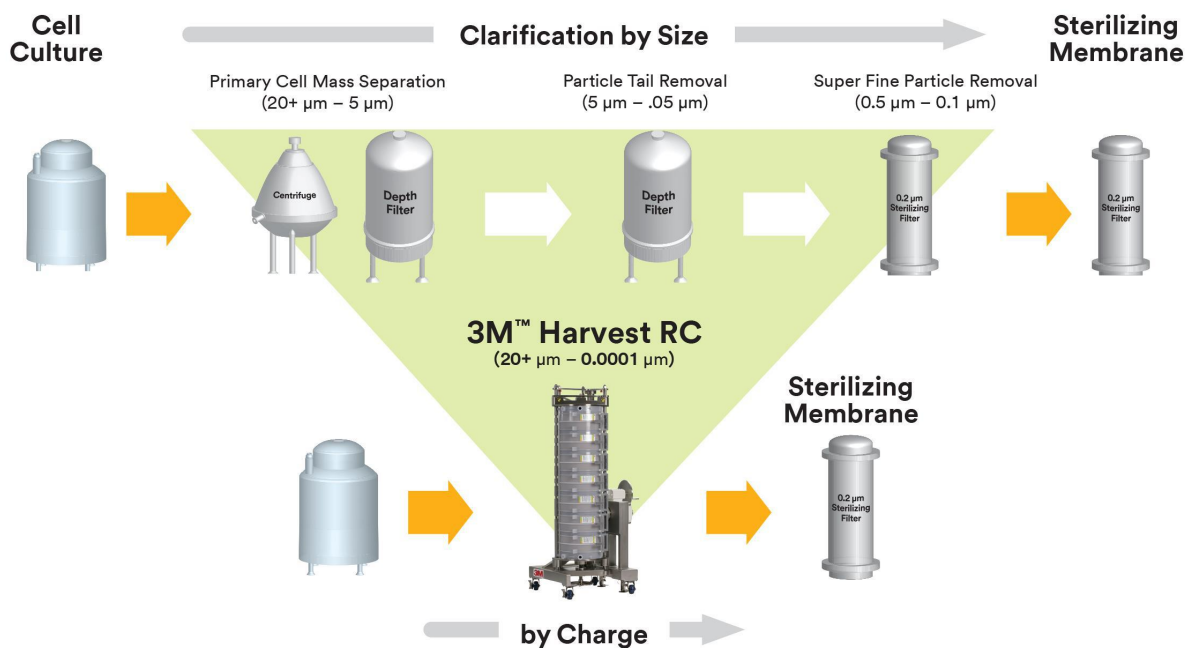


Producing mAbs consistently at commercial scale is both a complex and expensive process with sales per gram ranging from \$1,000 to \$50,000 depending on the dosage. High costs and variability has put biopharmaceutical companies under pressure to improve manufacturing plant productivity by increasing titer (5–10 g/L) and cell densities $>20 \times 10^6$ cells/mL. Limitations around scaling capacity and higher densities necessitate more sophisticated purification steps using advanced materials.

3M™ Harvest RC: Establishing Value of Single Stage Harvesting

3M™ Harvest RC is a chromatography-based clarification technology using 3M's proprietary fibrous (synthetic) material that is truly scalable ranging from discovery phase all the way to manufacturing. This technology will have separation capabilities that have never been seen before; not only for small particles but also larger particles from several microns to ten and twenty microns for capture of whole cells and cell debris.

Figure 1: 3M™ Harvest RC – Simple Single Stage Harvesting



Source: 3M



3M™ Harvest RC will not have to operate as an island, but as a component of a much larger connected bioprocessing system. On a day-to-day basis, the most immediate effects of 3M™ Harvest RC will be noticed in its ability to achieve chromatographic separation of large particles.

With the capacity to support single stage clarification spanning across a wide range of cultures with different cell densities, packed cell volumes and cell culture characteristics, this technology will be able to achieve predictable performance, without operators/scientists having to program every step.

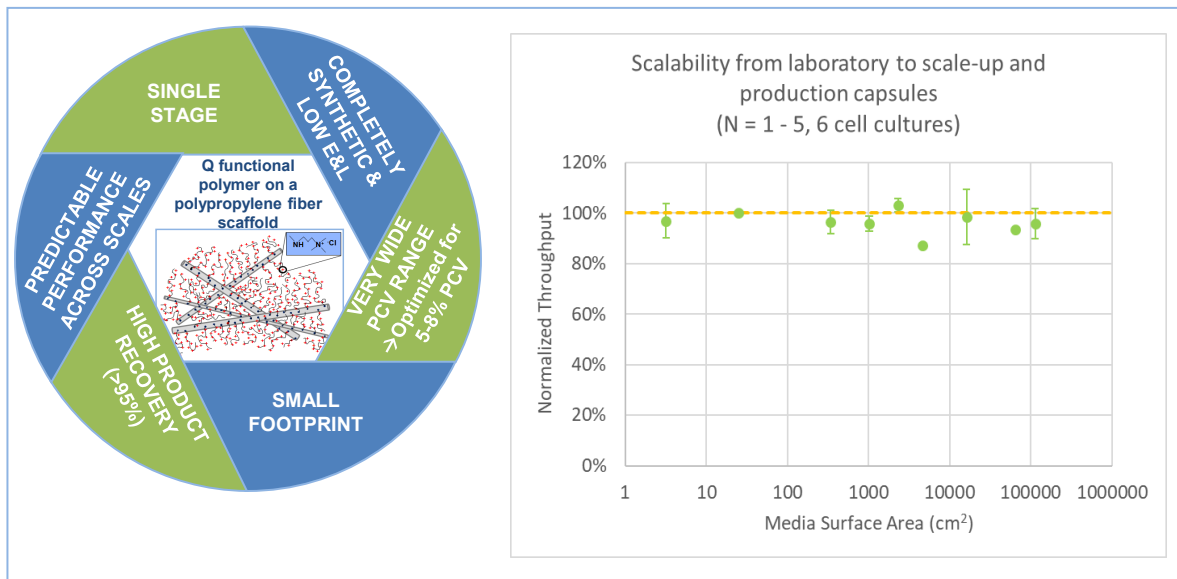
3M™ Harvest RC offers a sand box approach; providing the ability to purify both large and small contaminants and soluble and insoluble particulates, which are both imperative to improve yield in biopharmaceutical manufacturing.

Based on several advantages listed in Figure 5, 3M™ Harvest RC was able to get a very high yield and product recovery with almost greater than 95% product yield across the board with several different mAb cell cultures at high packed cell volume (PCV) of 5 – 8 %. This is an impressive result as it is almost unimaginable to attain recovery close to 85 to 95% with other traditional clarification technologies such as centrifugation and depth filtration.

Figure 2: Why this technology will be a game changer?

<p>3M™ Harvest RC BC16000 Capsule Media surface area : 1.6 m² Clarification capacity : ~ 8 L of solid</p> 	<p>3M™ Encapsulated System Holder Capacity : 7 BC16000 capsules Media surface area : 11.2 m² Clarification capacity : ~1000 L @ 5-6% PCV Clarification time : <1 hour</p> 
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Source: 3M



Source: 3M

It may sound like 3M™ Harvest RC is just another iteration of improved traditional clarification technologies such as single use centrifugation systems or synthetic depth filters. However, past improvements from traditional clarification technologies have not moved the needle enough to compress purification timelines or increase product recovery rates compared to what 3M™ Harvest RC has demonstrated.

3M™ Harvest RC's potential goes beyond increasing yield limits and product recovery rates. The other consideration and probably more significant benefit is the technology's ability to be seamlessly deployed in a predictable manner at any scale (small and large).

As shown in Figure 5, 3M™ Harvest RC technology's one large scale capsule would have 1.6 square meter of filter area which corresponds to about 8-9 L of solid capacity. This basic unit architecture will then allow 7 capsules to be put together, allowing operators/scientists enough solid capacity to clarify 1000 L with around 6% PCV.

3M™ Harvest RC solution scales linearly across lab, pilot, and manufacturing scales. Fibrous chromatographic clarification assures scalable performance from discovery to manufacturing. Performance is consistent from lab capsules (BC4 and BC25), to pilot capsules (BC340 and BC1020), to manufacturing capsules (BC2300 and BC16000) within $\pm 20\%$ of BC25 throughput. This significant leap to extract the same performance and throughput whether it is at bench scale, one capsule scale or multiple capsules for one fully loaded holder, is nothing short of revolutionary.

Based on differential test results (factors listed in Figure 5) it is clear that 3M™ Harvest RC technology will eventually replace DFs by 2030 due to its ability to support single stage clarification spanning across a wide range of cultures with different cell densities, packed cell volumes, and cell culture characteristics. These results will have profound implications for operators/scientists, who can now take advantage of 3M™ Harvest RC technology and set ambitious goals in terms of scalability, fidelity, and predictability.

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