

# 3M™ Harvest RC Chromatographic Clarifier—Powering Single-Stage Clarification

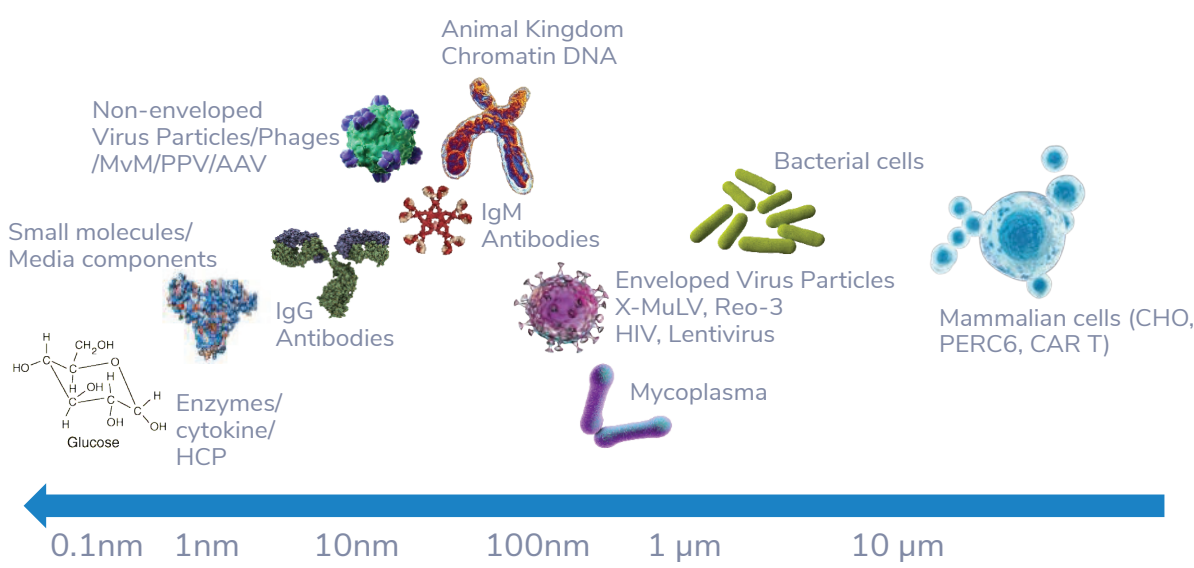
A major drawback with current clarification strategies is that no single approach can scale from discovery to manufacturing. As a result, companies must explore using chromatography platforms to get further separation during the harvest and clarification steps to truly increase monoclonal antibody (mAb) yields while streamlining the upstream process.

## Data Points:

1. The intensification of cell culture processes has led to an increase in cell densities and product concentrations. Biopharmaceutical companies can now culture high cell densities of up to 50 million cells per mL, which poses a huge challenge to conventional harvest technology.



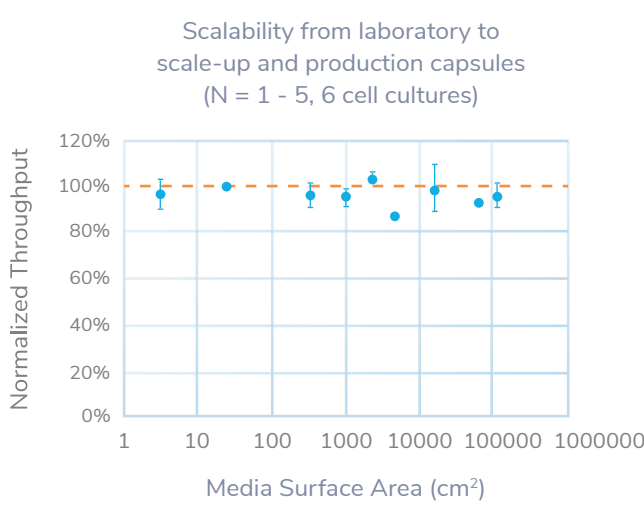
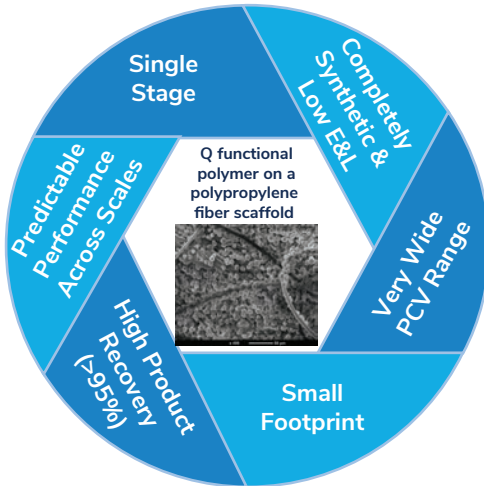
2. High cell density processes are accompanied by more impurities, which can burden the downstream process. Impurities can range from the host cells to cell debris (0.1-10 µm) to much smaller particulates such as DNA, viruses and proteins (100 nm to 0.1nm). Traditional filtration technologies are inadequate to provide a platform approach that is able to purify both large and small contaminants and soluble and insoluble particulates, especially for high cell density cultures (>50 million cells/mL), which is imperative to improve yield.



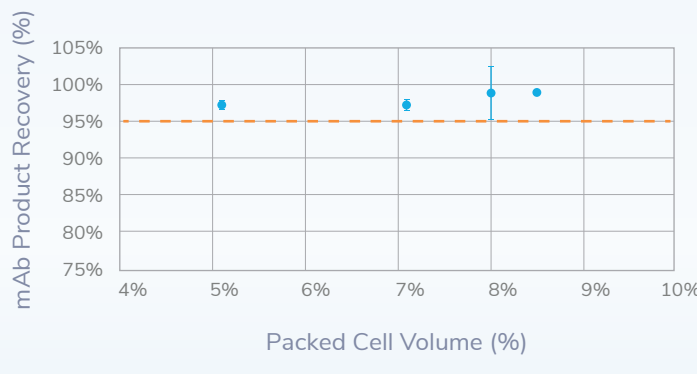
3. It is critical to choose a technology that complements the specifications of the upstream process and type of biologic products. Currently, the onus is on operators/scientists to work with a combination of different clarification technologies to arrive at the downstream purification steps. The ability to support single-stage clarification spanning a wide range of cultures with different cell densities, packed cell volumes and cell culture characteristics will enable a predictable performance.



4. 3M™ Harvest RC offers a revolutionary approach that brings chromatography into the clarification space, enabling high yield, scalability, and manufacturing flexibility. This unique fiber chromatographic technology enables the purification of both large and small contaminants and soluble and insoluble particulates, which are imperative to improve yield in biopharmaceutical manufacturing.



5. 3M™ Harvest RC can get a high yield and product recovery with almost a 95% product yield across the board with several different mAb cell cultures at high packed cell volume (PCV) of 5%-8%. This is impressive as operators/scientists struggle to attain consistent and high product recovery with legacy approaches such as centrifugation and depth filtration.



6. 3M™ Harvest RC goes beyond pushing boundaries to increase product recovery. One production capsule of 3M™ Harvest RC corresponds to about 8 L of solid capacity. This basic unit architecture will allow seven capsules to be put together, allowing operators/scientists enough solid capacity to clarify 1,000 L with about 6% PCV. The other significant benefit is the technology's ability to be seamlessly deployed at any scale (from discovery to manufacturing).

### 3M™ Harvest RC



BC16000 Capsule  
Media surface area: 1.6 m<sup>2</sup>  
Media bed volume: ~11- 12 L

7. Direct experience using an industry-standard process modeling platform (BioSolve™) enabled 3M to model the impact of the inclusion of 3M™ Harvest RC technology on bioprocessing costs of goods sold (COGS). In scenarios that reduced steps and replaced them with 3M™ Harvest RC, there was an increase in the yield accompanied by an overall cost of goods reduction of about 15%.



8. 3M™ Harvest RC is being tested in different upstream clarification mAb process train layouts. Customers have benefited from the technology's ability to be optimized across molecules and sites for a range of higher cell densities. The clinical to commercial scalability benefits have been great, and the impact on yields is even better. This is an excellent investment for biopharmaceutical companies seeking to simplify their process and improve plant productivity.

### 3M™ Encapsulated System Holder



Capacity: 7 BC16000 capsules  
Media surface area: 11.2 m<sup>2</sup>  
Clarification capacity: ~1000 L @ 6-7% PCV  
Clarification time: <1 hour

For more information on 3M™ Harvest RC, visit [3M.com/Harvest](http://3M.com/Harvest).

3M is a trademark of 3M Company. All other trademarks are the property of their respective owners.