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A Frost & Sullivan White Paper

3M™ Harvest RC Process Economic Analysis

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The biopharmaceutical industry faced with challenges to meet demand for intensified bioprocessing of mAbs must embrace operational excellence strategies. First and foremost is a pivot that embraces “single-product or multi-product” capacity management as a catalyst for better utilization on manufacturing footprint, which requires facility flexibility. In order to achieve this, biopharmaceutical industry’s priorities must lie in shortening product changeovers or downstream processing times and look at every step in the process to reduce manufacturing costs.

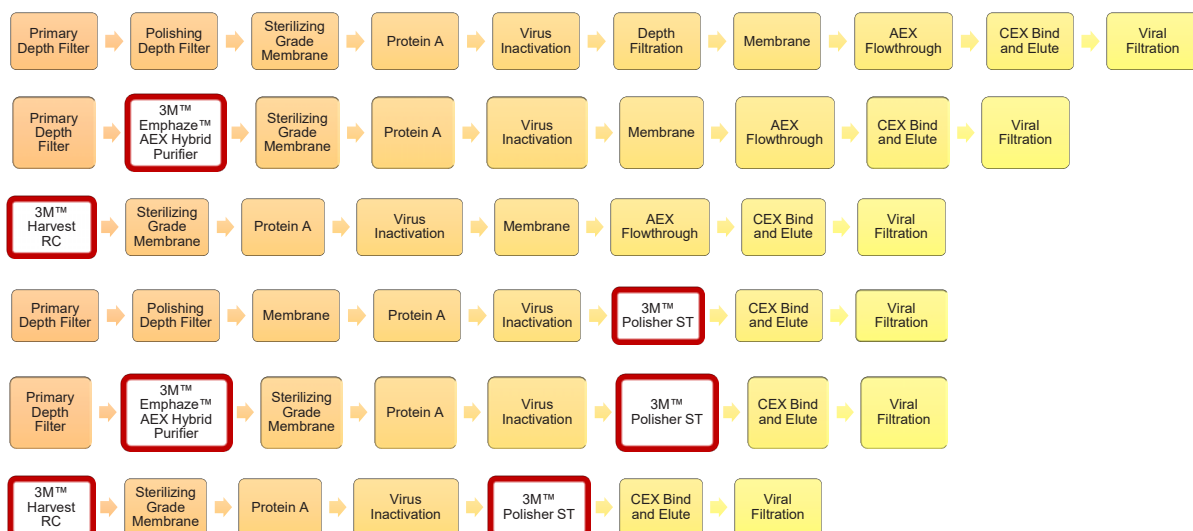
3M™ Harvest RC: Process Economic Analysis

Biopharmaceutical companies looking to future-proof their clarification strategies from discovery to manufacturing stages, must recognize the potential of 3M™ Harvest RC. Its scalable, high yield quality, and ease of deployment across discovery to manufacturing are set to revolutionize the bioprocessing world. Let’s examine the cost benefits of 3M™ Harvest RC and how this promising technology will supercharge single use clarification and polishing trains.

Direct experience using an industry standard platform (BioSolve™) enabled 3M to model the impact of inclusion of 3M™ Harvest RC technology on bioprocessing costs of goods sold (COGS). 3M investigated a total of six processes (Figure 1).

The first process is a typical mAb purification process. The sixth process is the next generation process that includes 3M™ Harvest RC technology & 3M™ Polisher ST technology. It is evident that the practical impact of the changes from first to sixth process by introduction of these two technologies has made the process simpler. In these model scenarios that show gradual reduction in steps by intensifying the anion-exchange chromatography (AEX) polishing step and then the harvest step, there was an increase in the yield accompanied by an overall cost of good reduction of about 30%.

Figure 1: Impact of 3M™ Harvest RC & 3M™ Polisher ST on Bioprocessing



Source: 3M

3M further analyzed impact on mAb COGS and capacity across the six processes (Figure 7a & 7b).

Figure 7 (a): Impact on mAb COGS

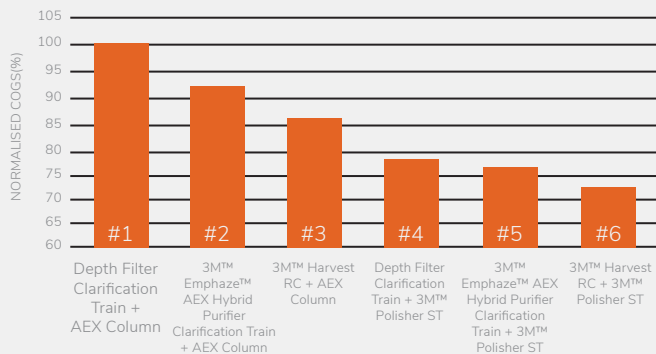
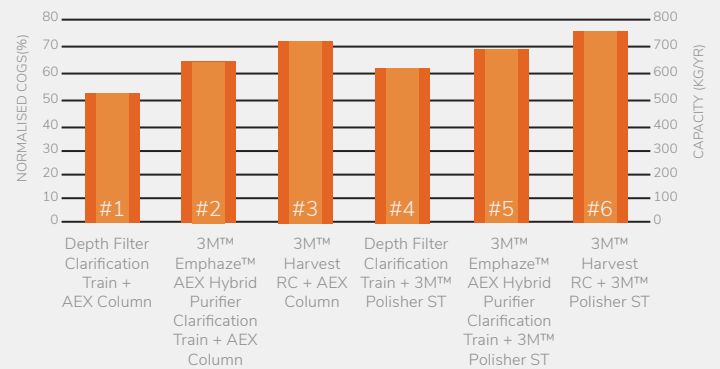


Figure 7 (b): Impact on mAb Capacity



Source: 3M

Figure 7 (a) shows the (normalized) cost per gram of manufacturing for mAb product and measures relative changes between the different process iterations. It is clear that as unit operations get smaller, the process becomes more efficient. There is reduction in COGS through the different process iterations and overall the difference in COGS between process one and process six is approximately 30%.

Figure 7 (b) shows the capacity to manufacture mAb product (kilograms per year) and which is plotted for each of six processes. The results show that there is an upward trend in mAb manufacturing capacity. This indicates that with each iteration, it is feasible to produce more mAb in the process, driven by increased yield in downstream processing.

In conclusion, it is important to note that the overall cost of the process is decreased when high performance single use technologies are implemented. Yield is also important in terms of reduced cost of goods resulting from implementing the high performance solution and combining multiple steps, and also in terms of increasing facility flexibility.

3M brings a world class approach and a suite of technologies to fulfill these growth opportunities. 3M™ Harvest RC is being tested in different mAb clarification trains and will be on target to eventually replace centrifugation, tangential flow filtration (TFF), depth filtration, and microfiltration in many mAb process trains. This is an excellent opportunity for biopharmaceutical companies to clear the bar on investments in new clarification technologies and demonstrate a significant increase in return on assets/investment (RoA/Rol) and plant productivity.

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