



**Developing Next Generation mAb
Process Using 3M™ Zeta Plus™ Depth
Filter, 3M™ Emphaze™ AEX Hybrid
Purifier and 3M™ Polisher ST**

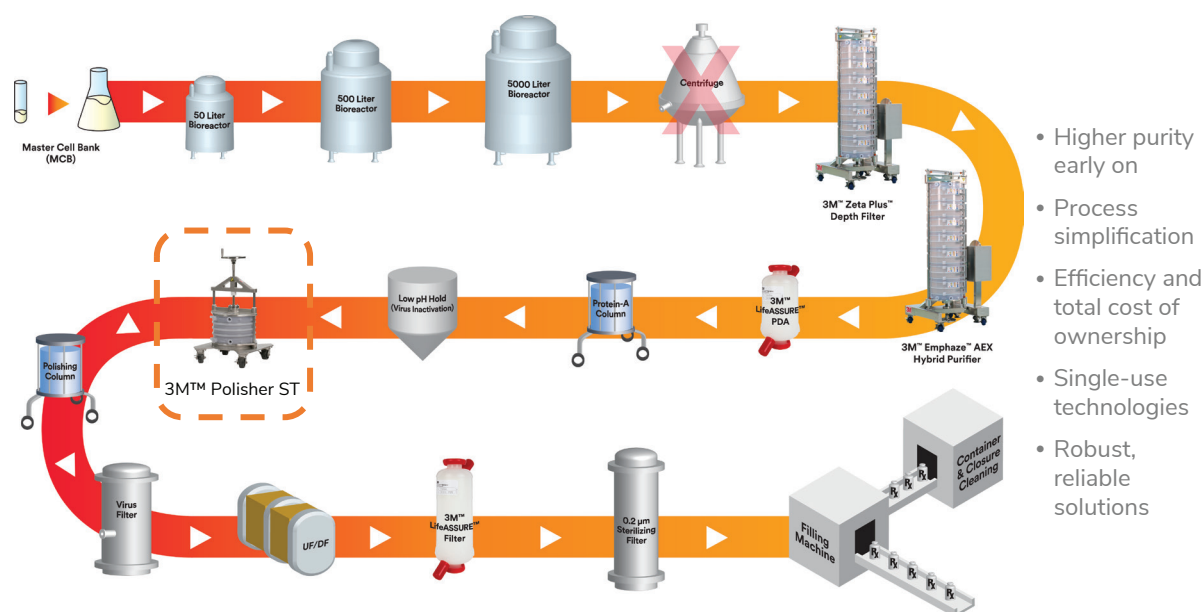
Powering clients to a future shaped by growth

Biopharmaceutical companies are now riding the wave for extensive Single Use Technology (SUT) integration to design flexible facility layouts. With the implementation of these SUTs, the optimization of downstream processing workflows will continue to accelerate over the next 3 years.

While upstream processing has led to increasing yields, downstream processing has remained a costly bottleneck: advances in titers over the past two-decade shift the main manufacturing costs from USP towards DSP. There is a lot space for improvement in DSP by leveraging process intensification techniques that allow replacing multi-use steps with high regulatory burden by single use solutions.

3M has put together several platforms relating to each other in unique ways which stand to revolutionize bio-pharmaceutical manufacturing.

Figure 1: Enabling Robust Viral Clearance-Introduction of Single Use AEX step



Open grades of 3M™ ZetaPlus™ depth filters with high capacity, allow for a direct harvest, without the need for centrifugation. 3M™ Emphaze™ AEX Hybrid Purifier can replace the second depth filtration stage for removing small cell debris thereby enabling higher purity earlier on in the DSP. This chromatographic clarification unit removes 4 to 5 logs of impurities like DNA and chromatin based on charge. This is a big step in process intensification as it can drive improved performance of capture columns, which will also result in >10 fold lower host cell protein levels than are normally seen in elution pools.

When 3M™ Emphaze™ AEX Hybrid Purifier is used in the clarification, turbidity after viral inactivation and neutralization will be much lower and as a direct result of that, there is no longer a need for a depth filter step to deal with this turbidity.

Finally, 3M™ Polisher ST can replace the anion exchange polishing column and it does not need a depth filter or a membrane for protection, thereby combining multiple steps into one. The 3M™ Polisher ST will have 100 times the capacity of a traditional Q resin with a recommended target loading of 10 kg of mAb per m². The increased capacity means that a capsule can be used which is much smaller than the traditional column.

Bioprocess engineers are challenged to make early-on commitments to specifications on different unit operations. Access to 3M's disruptive technologies will change the traditional project execution model leading to sharing responsibilities between engineers and equipment suppliers to ensure that downstream processing needs are met. Combining these 3M matched component solutions allows significant process simplification and compression.



NEXT STEPS

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- ② Interested in learning more about the topics covered in this white paper? Call us at 877.GoFrost and reference the paper you're interested in. We'll have an analyst get in touch with you.
- ③ Visit our **Digital Transformation** web page.
- ④ Attend one of our **Growth Innovation & Leadership (GIL)** events to unearth hidden growth opportunities.

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