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A Frost & Sullivan Virtual Think Tank

3M™ Polisher ST Beta Testing Series

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Frost & Sullivan recently invited a panel of pharmaceutical bioprocessing industry leaders and key opinion leaders to participate in a new and unique thought leadership forum, our Virtual Think Tank (VTT) Early Access series. Each VTT panel, comprised of professionals from top pharmaceutical companies, contract development and manufacturing organizations (CDMOs), and 3M Company, discussed the new 3M™ Polisher ST technology following participation in a beta test program.

Panelists:

- ▶ **HENDRI TJANDRA,**
Director of Isolation and Purification,
Bayer Healthcare
- ▶ **MARK CHIBOROSKI,**
Senior Staff Engineer,
Regeneron
- ▶ **KRUNAL MEHTA,**
Sr. Scientist,
Amgen
- ▶ **JILL KUBLBECK,**
Scientist,
Pfizer
- ▶ **ANDREW DETZEL,**
Investigator,
GSK
- ▶ **JONATHAN RHEUBEN,**
Senior Manager, Downstream Process,
MabPlex USA
- ▶ **JOHN ALEXOPOULOS,**
Functional Lead DSP, Senior Scientist,
Novartis
- ▶ **LESLIE WOLFE,**
Senior Director, Process Development,
KBI Biopharma

Introduction

Manufacturing biopharmaceuticals at a commercial scale is a costly, complex, and lengthy process due to their unique properties and the variations of monoclonal antibodies (mAbs). Despite this, biopharmaceutical companies continually face pressures to commercialize and manufacture therapies faster and at lower costs. Consequently, technology developers like 3M™ are heeding their demands and developing innovative new technologies to improve the tedious and expensive biologics manufacturing workflow. As part of their process intensification strategies, biopharmaceutical companies and CDMOs are turning to innovations like single-use technologies that condense process steps, drive efficiency, and reduce the total cost of ownership. One such technology launched by 3M™ is their 3M™ Polisher ST—a single-use AEX chromatography device that uses a guanidinium-functionalized polyamide membrane protected by a Q-functionalized non-woven material. 3M™ Polisher ST replaces the traditional resin-based columns in the biopharmaceutical manufacturing process while simplifying the workflow. The ST stands for its functional membrane's salt tolerance capability, which allows it to function at a wide range of conductivity.

Benefits of Adopting 3M™ Polisher ST

The major benefits hailed by expert panelists during the 3M™ Polisher ST beta test included:

- The disposability, speed, ease-of-use, modularity, and configuration of the product
- The improved viral clearance ability and flexibility to work with various conditions (pH 5.5 to 7.5) and conductivity of 3 to 20 mS/cm
- The single-use aspect, which drives the volume adaptability
- The capsule capacity of 100 times that of a traditional Q resin, which allows for easy commercial scalability

3M™ Polisher ST's superior performance across all tested process conditions is one of its key benefits. The initial panelist response to 3M™ Polisher ST was generally positive because the technology met their high expectations.

Hendri Tjandra, Director of Isolation and Purification at Bayer Healthcare, said, "Viral clearance seems to be better or higher when we use a much higher amount of conductivity."

The broader range of conductivities means less process dilution, smaller containers, and much less risk during the manufacturing process. This adaptable aspect benefits an organization whose pipeline consists of a wide variety of molecules. Fluctuations in workflow often hold true for CDMOs, as **Jonathan Rheuben, Sr. Manager of Downstream Process at MabPlex USA**, explained. "I've worked with molecules that don't particularly care to be at pH from 7 to 8, so being able to look at lower ranges of pH 6, and even to 5.5 or 5, will give you flexibility [for molecules] that may not necessarily all fit on the same platform...Not everything is going to be well behaved, IG-1, IG-2, fusion proteins, and all kinds of constructs that require a lot more flexibility of thought. Being able to apply it in different ways and not have to totally redevelop everything is a plus."

Investing in disposable single-use technology as opposed to Anion Exchange (AEX) columns makes economic sense, especially for early-stage production. Rheuben explained, "If you're only doing one run, there's really not much in the way of a driving goal to use columns. I can sanitize and reuse and store them, but if you're just doing one run, especially for a CDMO, it saves a lot of trouble [to use 3M™ Polisher ST]." On the other end of the spectrum, in a continuous manufacturing setting, the product can simplify processes because the single-use filter offers 10 kg of mAb per m² as target loading while eliminating steps. This enhanced capacity demonstrates its endurance to tackle larger scales and enables reduced cycling, resulting in cost savings. It also eliminates validation efforts and cleaning protocols, resulting in time savings and procedural efficiency.

A panelist shared seeing tighter binding and lower recoveries when trying to elute HCPs off 3M™ Polisher ST after flowthrough even within loading 4 to 10 kgs per liter. This demonstrates the superior ligand chemistry of the filter absorber, potentially leading to capacity improvements in the process. **Rheuben** stated, "So far, it has performed as well, or better, than the other capsule devices I've been using." In addition, the robust viral clearance in the presence of turbidity adds significantly increased yields to the process. **Andrew Detzel, Sr. Scientist at GSK**, said, "The HCP clearance is much better than I expected."

Adoption of 3M™ Polisher ST in Production Processes

The adoption of 3M™ Polisher ST brings implementational benefits that have an overall effect on the production process:

- It replaces AEX columns and combines multiple steps into one
- It simplifies the downstream chromatography step
- Provides reliable and robust performance



3M™ Polisher ST provides the ability to replace AEX flow-through columns in any downstream process layout regardless of where the column is positioned in polishing train layouts. It combines the AEX column, the depth filter, and the membrane into one step, resulting in time and cost savings. The elimination of the chromatography step has economic benefits while also simplifying the process and reducing opportunities for contamination. **Krunal Mehta, Sr. Scientist at Amgen**, explained, "It does widen our range a bit. We have to rely on multimode chromatography. But yes, compared to purely AEX, it offers benefits. It offers more flexibility during the process development itself, and also, from a manufacturing standpoint, less conditioning and less pH adjustment are required post the polishing step."

Any organizational hesitance to implementing new commercial and clinical processes using 3M™ Polisher ST can be readily overcome by understanding the data regarding its reliability and robustness. The technology's utilization metrics, implementation techniques, and success cases are self-evident and go a long way in overcoming the resistance to change. **Rheuben** explains, "The more data, the better, the stronger your case is when you go forth and change things."

Conclusion

The major challenges associated with traditional downstream polishing trains are that the process is laborious, time-intensive, and costly. There is limited flexibility to work in varying conditions and conductivity, making it hard to deal with fluctuating volume needs or commercial scalability. During this Virtual Think Tank (VTT) Early Access series, the compelling feedback from the respondents made it evident that adopting the 3M™ Polisher ST in commercial manufacturing will largely overcome and eliminate these challenges.

Ultimately, adoption of 3M™ Polisher ST allows for higher purity earlier on in the process train, simplifies the very complex biomanufacturing process by eliminating steps, and creates an overall robust manufacturing package that can be applied across a range of process conditions. As the biopharmaceutical industry drives towards bringing therapies to market faster and cheaper, 3M™ Polisher ST shines as a major tool in the growing toolbox of innovative single-use technologies.

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