

Powering clients to a future shaped by growth

Polishing

column 2

Bio manufacturing is being transformed by rapid adoption of single use technologies (SUTs). Process intensification strategies have leveraged this dramatic shift to displace multi-use unit operations with SUTs that drive efficiency and reduce the total cost of ownership.

Biopharmaceutical companies are approaching the limits of manufacturing productivity and scalability, and innovative downstream bioprocessing (DSP) solutions are required to address these challenging issues. The bottleneck in process-scale chromatography negates any advantages of scaling up earlier process units, since bind-and-elute chromatography steps are driven by mass rather than volume.

This means that savings made upstream do not translate into increased productivity during purification. Larger columns also impact directly on facility layouts, costs and infrastructure because the space and buffer volumes for all steps also increase. As a consequence, pool and buffer volumes act as serious limitations when it comes to the introduction of high-titer processes into existing facilities.

Traditional process

Protein A

Virus

Virus

inactivation

Polishing

column 1

Polishing

column 2

Polishing

column 2

Protein A

Virus

Virus

inactivation

Protein A

Virus

Vir

Virus inactivation

Figure 1: Transition to Single-use Monolithic Systems

3MTM Polisher ST offers not only economic benefits and versatility, but it also has specific functional advantages over equivalent packed-bed columns. These are:

- 1. Convenience There is no cleaning or validation, no packing, re-packing and recycling.
- 2. Small footprint A production scale capsule of 1.6m² can replace a packed column of 80 liters. Capsules can be stacked for even higher loadings.
- 3. Economics Use of one fifth (80%) of the buffer volume compared to a column of equal capacity, saving time and money. Lower buffer volumes in the purification process drive down wastewater that needs to be handled for disposal.

It is exciting for bioprocess engineers to explore novel technologies such as 3M™ Polisher ST to replace the AEX column. The platform has strong potential to outperform AEX columns by achieving high purity, high recovery and driving process simplification and flexibility.



NEXT STEPS

- Schedule a meeting with our global team to experience our thought leadership and to integrate your ideas, opportunities and challenges into the discussion.
- 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.
- Visit our <u>Digital Transformation</u> web page.
- Attend one of our <u>Growth Innovation & Leadership (GIL)</u> events to unearth hidden growth opportunities.

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