



3M™ Polisher ST Replacing Column Performance Across all Process Conditions

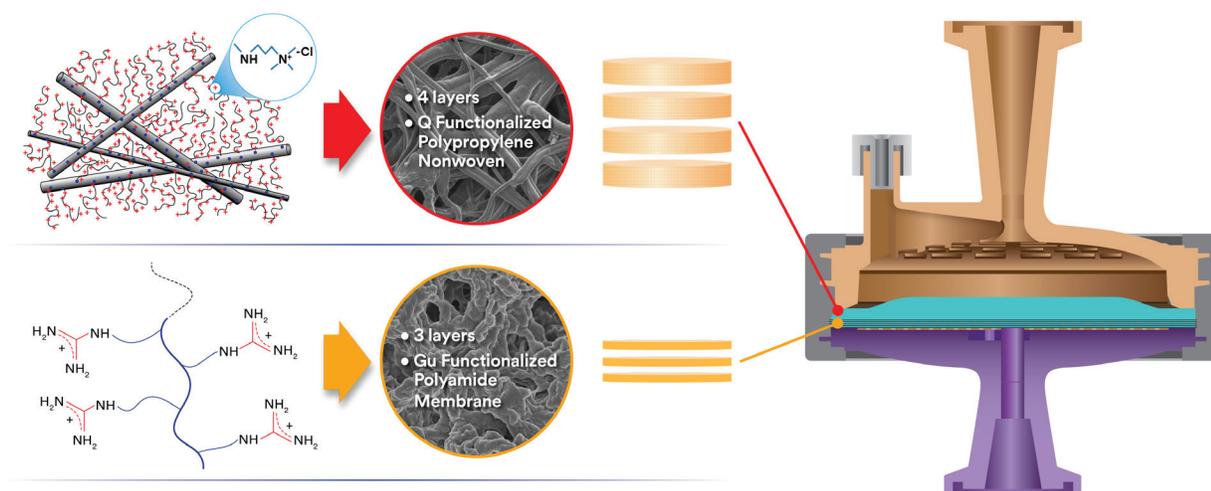
Powering clients to a future shaped by growth

While the growth in Monoclonal Antibodies (mAbs) market has been incredible, challenges in downstream manufacturing persist. The typical mAb manufacturing process has several steps, including multiple clarification stages and one or more polishing columns. The steps if not properly designed impact yield, impurity and cost. Biopharmaceutical companies are limited on process design choices based on their product pipelines and platforming requirements.

The need to launch innovative therapies faster and at lower costs has increasingly pushed biopharmaceutical companies to focus on improvements in manufacturing technologies. Downstream process development and manufacturing has become a strategic pivot for most companies to ensure the drug's safety, quality, identity, purity, and efficacy (SQIPE) meet regulatory requirements for clinical trials and commercialization.

3M™ Polisher ST technology, which utilizes a guanidinium-functionalized polyamide membrane protected by a Q functionalized polypropylene material (Figure 1), has demonstrated the viability of replacing the depth filtration and anion exchange chromatography (AEX) steps to achieve a simplified and cost-effective process. The platform is designed to reduce process and product related impurities, and offer robust performance across a wide range of process conditions.

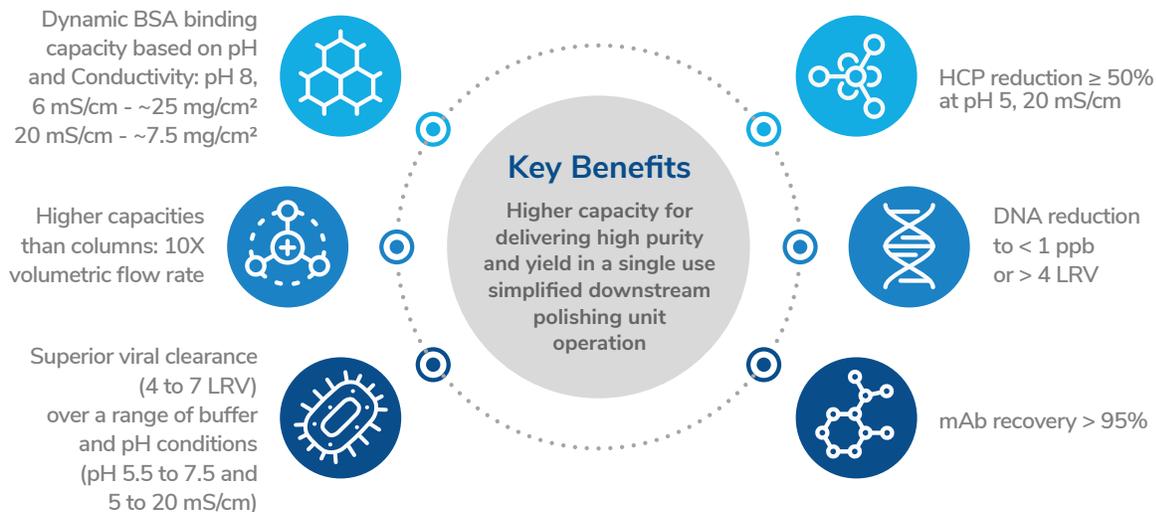
Figure 1: New chemistry design enabling true process potential: 3M™ Polisher ST (2020)



Monoclonal Antibodies (mAbs) are complex biologic molecules in their nature, including size (e.g., 150 kDa IgG–900 kDa IgM), heterogeneity (e.g., glycosylation, deamidation, oxidation), structure (e.g., monomer, dimer, trimer, hexamer), charge (e.g., pI of 5.0–9.0), hydrophobicity, and genetic source (e.g., rodent, human). This intrinsic complexity mandates biopharmaceutical companies to adopt a new growth mindset to utilize new, innovative technologies and solutions.

3M™ Polisher ST technology offers a sand box approach (Figure 2); providing both cost savings and greater efficiency which are both imperative to biopharmaceutical manufacturing.

Figure 2: Why this platform will be a game changer?



It offers several advantages including the ability to anticipate process yield, product purity and quality:

- >100 X mAb loading of typical Q resin (10+ kg/m² target loading)
- Scalability from lab to manufacturing scale
- High salt and low pH tolerance
- Robust viral clearance across very wide range of conditions
- Viral nano-filter protection

Based on differential tests results (factors listed above) in comparison to Adsorptive Depth Filters (ADF) and in particular 3M™ Polisher ST technology's capability to remove HCP, DNA and high molecular weight (HMW) aggregate, it is clear the this technology will eventually replace AEX by 2030.

Successful replacement of reusable AEX columns by single use solutions has proven to be challenging, mainly due to scalability constraints and sensitivity of current technologies to subsets of the typical process conditions. Supercharged with increased capacity, scalable from the laboratory to commercial scales, eliminating the need for column packing along with cleaning, validation costs and high buffer usage associated with a traditional column, 3M™ Polisher ST technology has all the great indicators of how it can actually achieve this feat.

NEXT STEPS

- ① **Schedule a meeting with our global team** to experience our thought leadership and to integrate your ideas, opportunities and challenges into the discussion.
- 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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