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Article: A Frost & Sullivan Webinar Summary

Next-Generation Biopharmaceutical Manufacturing Platforms

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This article was derived from a recent webinar

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Biopharmaceutical Industry Ready for its Close-up Shot: Following > 900 Biologics Heading into Clinic

Biopharmaceutical products (biologics) are transforming the treatment of many diseases like cancer, rheumatoid arthritis (RA), Hepatitis C, and Multiple Sclerosis (MS). Monoclonal antibodies (mAbs) and recombinant therapeutic proteins are the two largest biologics segments, comprising nearly 86.0% of the total biologics market in 2020. Producing these molecules consistently at a commercial scale is both complex and costly.

The complexity is demonstrated by the variety of modifications on the molecule, including post-translational modifications, such as glycosylation, and degradation products, such as oxidation and hydrolysis, which affect the efficacy and safety of the drug. Similarly, progress in the mammalian cell culture process has resulted in significantly increased product titers, but also a substantial increase in process- and product-related impurities.

The need to launch innovative therapies, such as combination therapies, and new constructs, such as multi-valent antibodies, faster and at lower cost has increasingly pushed biopharmaceutical companies to focus on improvements in manufacturing technologies.

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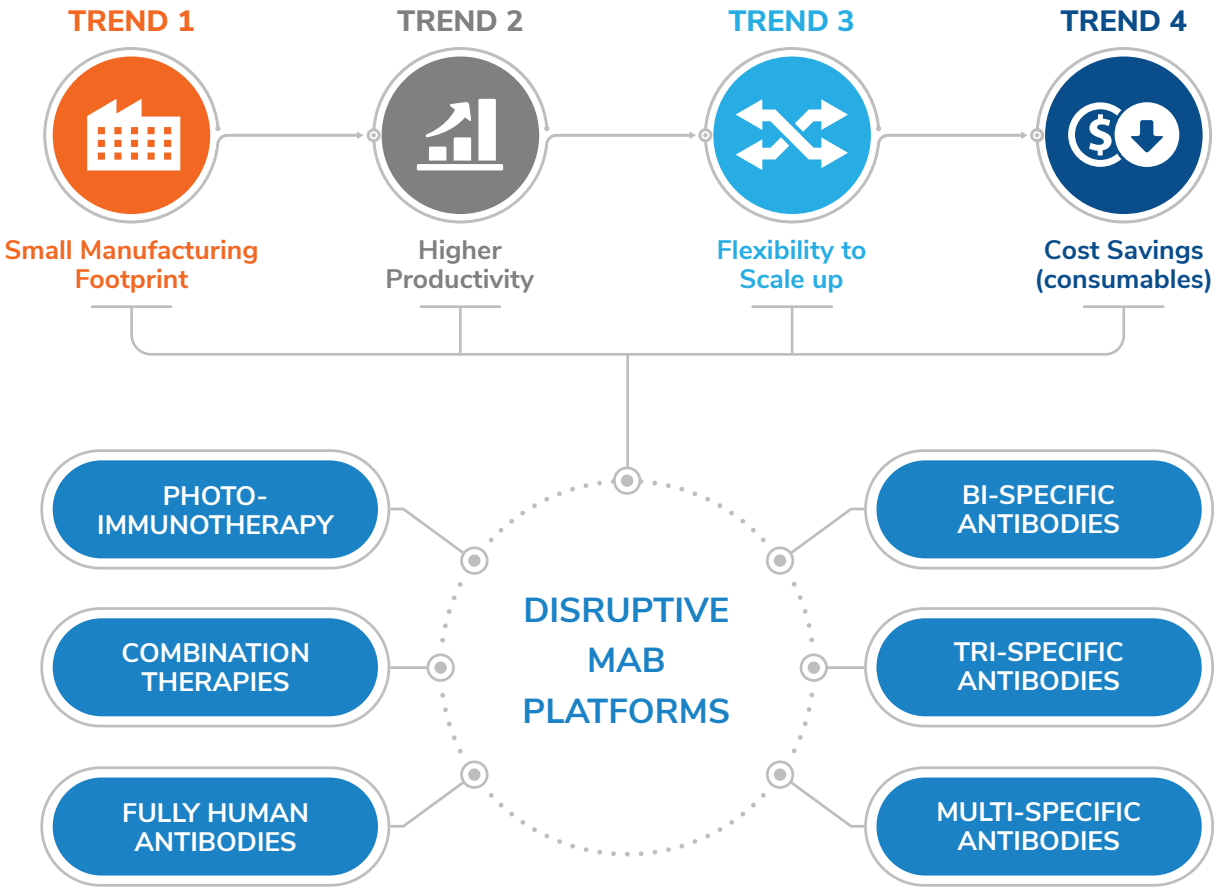
Frost & Sullivan has identified four key trends driving biopharmaceutical companies to adopt a sandbox approach for development of next-generation biopharmaceutical manufacturing platforms:

Figure 1: Booming Monoclonal Antibody Clinical Development Demands Novel Bioprocessing Solutions



Source: Frost & Sullivan

By harnessing the power of these different trends, biopharmaceutical companies can truly project that downstream process development, and manufacturing will become a strategic pivot for the different companies to commercialize next-generation therapeutics.

These trends will not only support the ever-expanding biopharma pipelines, but also improve the ability to intensify the facility footprint in terms of its productivity and ability to both scale and very quickly transfer processes—not only within one organization, but also between different organizations around the world.

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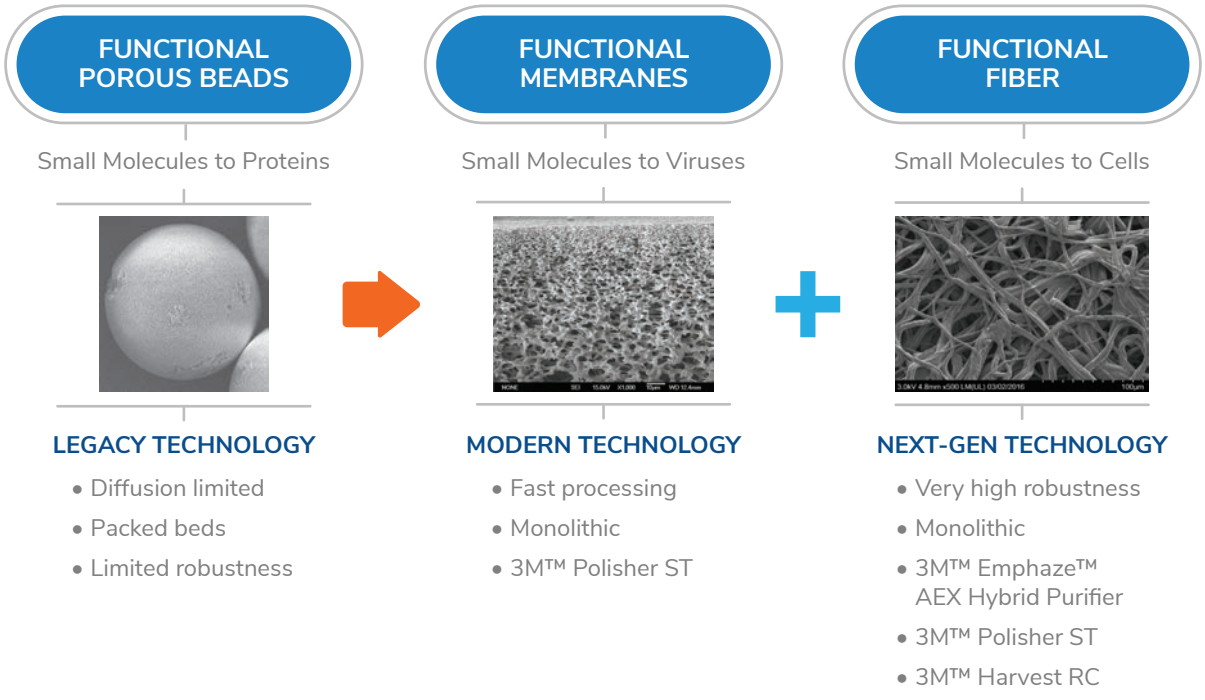
Promising Innovations in Material Science and Related Applications Define Future of Bioprocessing

By investing in next-generation manufacturing platforms, biopharmaceutical companies maximize their ability to make the same amount of products, or more in smaller systems, through process compression and intensification. The platforms are designed around flexible, single use, portable systems that can both scale up and scale out, depending on the requirements of a particular drug.

Perhaps the most significant advantage of these platforms is the access to sophisticated separation technology as well as chemistry. The bioprocessing industry has witnessed a rapid move from packed chromatography beds utilizing porous beads that are diffusion-limited, less robust, difficult to both scale up and scale out to much faster systems based on functional membranes and, much more recently, based on functional fiber materials. New functional chemistries have greatly improved fidelity of separation for both processes as well as product-related contaminants over a much larger field of operating conditions.

Alexei Voloshin, Global Manager Biopharma Application Development, 3M, pointed out that these trends have created a paradigm shift for the overall process strategy (Figure 2).

Figure 2: Advanced Materials Enable "Chromatography of Everything"



Source: 3M

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He further commented that as the process evolves from Legacy technology to Next-Gen technology, high fidelity separation using chromatographic systems is moving further up the process. In the legacy processes, chromatography was primarily relegated to the back because chromatographic systems are limited to dealing with a very small range of molecules. As the processes evolve, chromatography has moved upstream, allowing for companies to perform chromatography during clarification, using technologies such as 3M™ Emphaze™ AEX Hybrid Purifier. Moving into 2021, biopharmaceutical companies will be able to perform high fidelity separation operations everywhere in the process now that chromatography is available from clarification to the final polish. This enables these processes to become smaller, controlled and scalable.

The organizational benefits of advanced materials to Next-Gen technology include:

- **Re-imagining "Chromatography of Everything"**—Expanding applications beyond proteins and small molecules to soluble and insoluble particles that are either very small or very large.
- **Increased Robustness**—Developing chemistry that expands applications to a wide range of conditions.
- **Move to Advanced Single-use Systems**—Modular approach that is easily scaled and deployed across global manufacturing footprints to effectively meet the needs of chronic conditions or global pandemics.

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PERSPECTIVES FROM PANEL:
Improvements in Media Material and Process Innovation and How Process Simplification Can Support Building Next-Generation Biopharmaceutical Manufacturing Platforms

Voloshin also noted that new modalities, such as gene and cell therapies, have different sizes and properties compared to proteins from the point of view of both physics and chemistry. "Biopharmaceutical companies need to relook at everything from separation media to bioprocess design in order to address these unique differences," he added.

Hani El-Sabbahy, Advanced Application Engineering Specialist, 3M, said that he too believes that biopharmaceutical companies now have superior understanding of manufacturing workflows that will facilitate design of better processes, media and unit operations to feed into those processes. He expressed that process simplification is a reality. "When we're looking at simplification, essentially, what we need is those unit operations to do more and in fewer steps," he said.

In response, Andrew Sinclair, President and Founder, Biopharm Services, shared that biopharmaceutical companies need to think about process simplification in the context of the entire manufacturing facility. He expects process simplification to bring a net positive impact by improving yield quality and reduction in life cycle costs through reduced use of consumables. "Biopharmaceutical companies should think [about] how simplification impacts facility volume and how it can provide greater flexibility," he noted.

> Biopharmaceutical companies need to relook at everything from separation media to bioprocess design in order to address these unique differences.

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PERSPECTIVES FROM PANEL:
Future of Next-Generation Biopharma Manufacturing Platforms and Types of Innovation Solutions (Example-Intensified Processes) Needed to Drive This Shift

Voloshin noted that as the biopharmaceutical industry evolves, both continuous and batch manufacturing will have their own place, whether companies are trying to manufacture a lot of product very quickly or they are trying to get away with a different form factor of unit operation. “Both of these modes will continue to exist and evolve in terms of their ability to advance bioprocessing strategies,” he added.

El-Sabbahy shared his perspective. He explained that the choice of technology, whether it's continuous or batch or hybrid approach, will depend on which one provides best economic and productivity benefit. “Implementing an intensified process backed by smarter technologies that combine steps and reduce the size of the steps will drive up yield and increase productivity,” he noted.

Sinclair agreed that there is a lot of innovation and intensification that meshes between upstream and downstream space. He cited examples that pressed the importance of bringing buffer systems to purification workflows in a simple and effective manner while combining unit operations. In his opinion, online analytical measurement approaches need to play a much bigger role in terms of how biopharmaceutical companies manage process information. “When we go to more intensive, connected, continuous processing, we need to be able to understand what's going on in the process and ideally use that information to keep the process in control because, unlike a batch process, we don't have that opportunity to hold the product and adjust as required,” he said.

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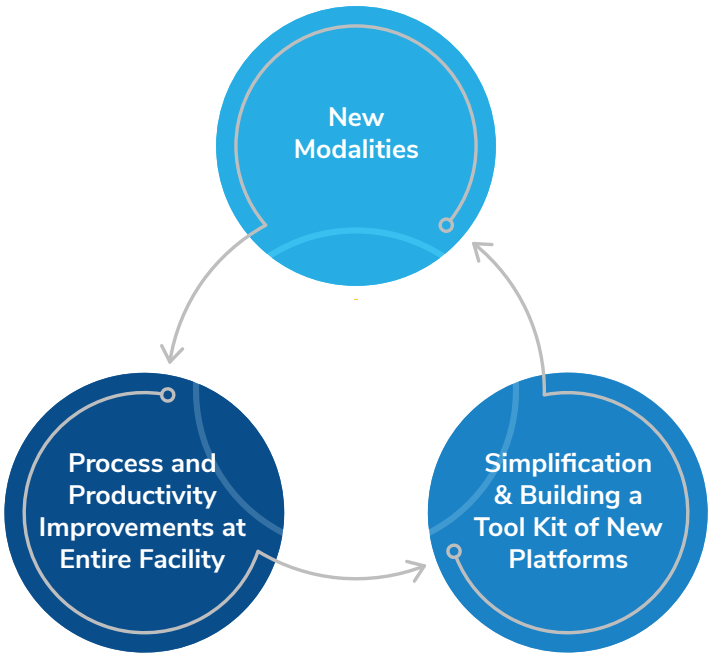
Setting High Bars for Next-Generation Biopharmaceutical Manufacturing Platforms: Next Steps

The CoVID-19 pandemic has forced companies to reassess their approach to manufacturing, whether expanding their established platforms or capabilities or just starting new centers of excellence out of necessity. Next-generation processing is quickly gaining traction in the industry because of the significant impact it will have on bringing innovative therapies to patients. This manufacturing evolution will intensify the manufacturing process from multiple unit operations to a continuous flow-through process.

Nitin Naik, Global Practice Area Leader, Healthcare & Life Sciences, Frost & Sullivan, noted, "The rapid growth of different modalities, simplification and building a toolkit of new generation platforms and then, finally, making sure the impact of these platforms are on the entire facility and not just a single process, will drive transformations in the biopharmaceutical manufacturing industry (Figure 3). Advanced materials can help Next-Gen technologies expand applications to a wide range of conditions and improve portability of the processes."

Figure 3: Transformations in Biopharmaceutical Manufacturing Industry



He concluded, "Customized technologies are being developed to meet next-generation therapy process requirements both today and in the future. Frost & Sullivan has identified "Flexible Manufacturing" as a digital pillar of growth for biopharma companies, eliminating significant risk from manual and open processes. Complete integrated process workflows enable biopharma to rapidly create the manufacturing capacity needed for both clinical and commercial production."

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