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Perspectives on Next-Generation Harvest and Clarification Technology

Leveraging a structured strategy for innovation yielding enhanced process efficiency and performance

By Daniel Ruppar, Consulting Director – Healthcare & Life Sciences, Frost & Sullivan

FROST & SULLIVAN CASE STUDY

KEY TAKEAWAYS:

- **Structured and Scalable Adoption:** Sanofi employs a systematic, stepwise approach—starting with scouting, evaluation, and governance—to integrate new harvest and clarification technologies without disrupting critical timelines.
- **Flexible Toolbox Strategy:** Recognizing the diversity of its product portfolio, Sanofi has built a flexible "toolbox" platform that accommodates a wide range of modalities, ensuring that processes remain robust across scales from clinical to commercial production.
- **Data-Driven Decision-Making:** Financial rigor through net present value (NPV) calculations and risk simulations, combined with hands-on experience and cross-functional input, reinforces confidence in technology adoption, even in the face of significant operational challenges.

In today's rapidly evolving biopharmaceutical landscape, innovation in process and manufacturing technologies is not just an operational necessity—it's a strategic imperative.

This case study explores an approach regarding challenges, requirements, strategies, and lessons learned in adopting next-generation technologies that are crucial to maintaining a competitive edge in process development and manufacturing. Sanofi's journey in enhancing its harvest and clarification technologies provides an example of how a major biopharmaceutical company can balance the need for innovation with the demands of scale, quality, and cost-effectiveness.

The State of the Biopharmaceutical Industry

The biopharmaceutical market is undergoing a significant transformation driven by advances in modalities, shifts in therapeutic area focus on chronic diseases, and innovations in manufacturing technologies. Biologics are a major growth driver for the industry in marketed products, and to address pipeline gaps, large pharma companies are acquiring promising biotech start-ups via smaller transactions to take advantage of growth opportunities.[1]

> Biopharmaceutical companies are investing in innovative technologies across the entire product value chain—from early discovery and clinical trials to tech transfer, manufacturing, supply chain, and post-market surveillance.

The goals of these investments include minimizing the product development timeline, lowering the cost of drug development, improving consistency in quality and throughput, enabling operational sustainability, addressing global regulatory complexity, and unlocking the value from available data, both enterprise-held and real-world.[2]

Today's biotechnology manufacturing systems and technologies must support a variety of modalities beyond monoclonal antibodies and embrace site flexibility to meet the evolving needs of biopharmaceutical process development and manufacturing.[3,4] Ensuring efficiency and alignment between upstream and downstream processes is challenging while making systemic changes, especially as companies explore innovations, platforms, technologies, and processes[5]. Historically, the adoption of innovation into scaled commercial processes has taken a decade or more.[6] Moving forward, process development and manufacturing should remain agile, with a streamlined timeline to embrace innovations in commercial processes.

1 Frost & Sullivan (2024). Growth Opportunities in Global Biotech Investment, 2024. Report PFGA. Frost & Sullivan, San Antonio, Texas. www.frost.com.
2 Frost & Sullivan Research tracking of top pharmaceutical industry value-chain trends.
3 Frost & Sullivan (2025). Top 6 Growth Opportunities in Pharma-Biotech, 2025. Report PFR2. Frost & Sullivan, San Antonio, Texas. www.frost.com.
4 Szkodny, A.C., Lee, K.H. (2022). Biopharmaceutical Manufacturing: Historical Perspectives and Future Directions. Annual Review of Chemical and Biomolecular Engineering, 13: 141-165. https://doi.org/10.1146/annurev-chembioeng-092220-125832
5 Shukla, A.A., Wolfe, L.S., Mostafa, S.S. and Norman, C. (2017). Evolving trends in mAb production processes. Bioengineering & Translational Medicine, 2: 58-69. https://doi.org/10.1002/btm2.10061
6 Szkodny, A.C. Ibid.

Background and Challenges

Sanofi is a global leader in healthcare and biopharmaceuticals, discovering, developing, and delivering medicines and vaccines for millions worldwide.[7] With the increasing complexity of biopharmaceutical manufacturing, Sanofi faced challenges in adopting new biomanufacturing technologies and processes. Historically, Sanofi's therapeutic biotechnology portfolio and pipeline, like much of the rest of the industry, was dominated by monoclonal antibodies and enzymes. Over the past 10 years, the portfolio has expanded to include a diverse range of biopharma modalities and technology platforms, including multi-specific antibodies and other novel formats.[8]

This product diversification and portfolio evolution required a shift from traditional manufacturing practices to a more flexible and scalable approach and philosophy for biopharmaceutical manufacturing. At the same time, hurdles needed to be crossed, such as cost constraints, supply chain risks, facility fit, equipment constraints, and change management resistance along the way.

7 For Sanofi corporate overview, visit https://www.sanofi.com/en/our-company. Last accessed March 2025.
8 For information on Sanofi's technology platforms, visit https://www.sanofi.com/en/our-science/technology-platforms. Last accessed March 2025.

A Structured Approach to Technology Adoption

An optimal approach to adopting new product and process technologies is underpinned by a rigorous, structured methodology. The process should begin with an extensive scouting phase where dedicated teams or experts continuously evaluate emerging technologies.

> We have team members and groups of the organization that are consistently taking new technologies from vendors, trying to evaluate those across a range of molecules, to benchmark them and to understand their performance in our hands.

This initial phase is critical for identifying technologies that are not only innovative but also capable of addressing Sanofi's evolving challenges. Once a promising technology is identified, it undergoes a detailed evaluation followed by a governance process that ensures that any new technology aligns with the company's strategic objectives and existing manufacturing protocols.

Furthermore, Sanofi's stepwise approach to adopting new process technologies decreases the risk of operational disruption. When a technology is proven effective on a small scale, it is then integrated into the broader platform—complementing the existing toolbox of process consumables and preferred tools that Sanofi relies on across its manufacturing sites.

Building a Flexible Platform: The Toolbox Strategy

> When we started setting our platform, maybe a decade ago, our portfolio was 80–90% monoclonal antibodies and enzymes. Today, less than half of our projects are monoclonal antibodies.

One of the most compelling aspects of Sanofi's strategy is its toolbox-based approach. As the company's portfolio has evolved from predominantly monoclonal antibodies to include a diverse range of biopharmaceutical products, the need for a flexible platform has grown significantly.

> It truly is a toolbox. Our platform is built around a library of processing consumables that teams can choose from based on specific challenges. We have default tools that are recommended, yet guidance exists for when alternative techniques are needed—increasing the likelihood that our MFG sites have the right hardware and inventory to support the chosen technology.

This flexible framework allows Sanofi to tailor its approach based on the specific challenges associated with different molecules while providing overall guidance and structure along with a set of defined tools. For instance, the same chemical functionality in filters is maintained across varying scales even though the physical challenges, such as particle size distributions, differ between small-scale clinical trials and large-scale commercial production. Sanofi achieves this part of their toolbox strategy via use of Solventum's next generation harvest and clarification solution, part of their purification and filtration portfolio, which use a Q-functional (quaternary amine) anion exchange ligand optimized for removing soluble and insoluble impurities. Such continuity is beneficial to ensure that the transition from one scale to the next does not introduce unexpected performance issues. Sanofi achieves this part of their toolbox strategy via use of Solventum's next generation harvest and clarification solution, part of their purification and filtration portfolio, which use a Q-functional (quaternary amine) anion exchange ligand optimized for removing soluble and insoluble impurities.

Overcoming Adoption Hurdles

Introducing new technologies in an environment where operational timelines are tight and the stakes are high is not without its challenges. The team at Sanofi is acutely aware of the potential hurdles—ranging from costs and supply risks to the practicalities of facility modifications and operator training. In addressing these issues, the company has adopted a tiered strategy that balances innovation with risk management.

> For items that require specific holders and occupy floor space, we have to carefully consider facility fit, costs, and procedural updates… if we can make the change without impacting timelines or quality, we do it; otherwise, we defer until it's less disruptive.

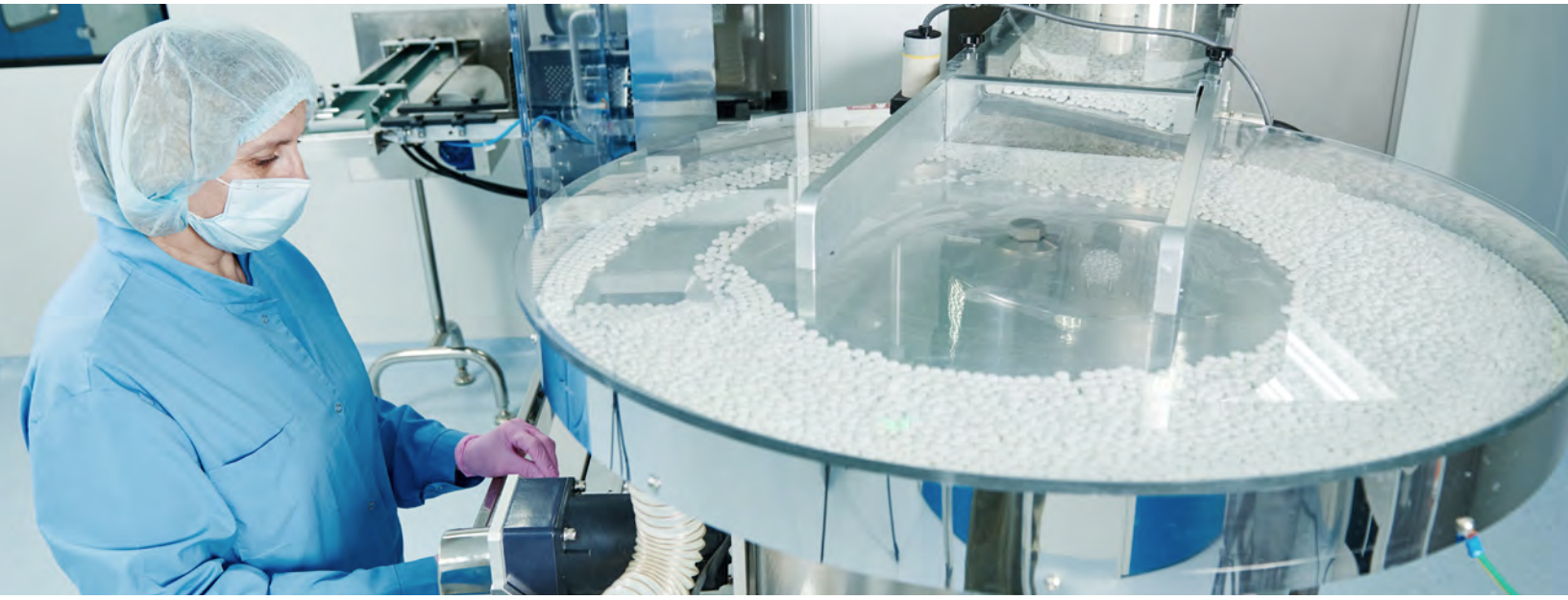
While some process components can be swapped out with relative ease, others demand a more cautious approach. By planning changes to occur off the critical path of product development, Sanofi effectively minimizes the risk of disrupting ongoing programs. When coupled with risk assessments and financial modeling—including NPV calculations—this strategic deferral ensures that any new technology introduced into the platform is economically viable and operationally sound.

Motivation Behind Next-Generation Harvest and Clarification

The decision to implement next-generation harvest and clarification technologies was driven by two primary factors: the need to enhance impurity removal and the challenge of scaling processes across different manufacturing phases. Traditionally, the clarification step was not the focus of significant process innovation. However, as Sanofi's portfolio expanded into more complex modalities, the limitations of older technologies became apparent.

> There were a few parts to this journey. One was about setting our platform—as we moved into new modalities and more challenging molecules, we recognized the need for purification across multiple steps… we saw an advantage in using technology that could improve [impurity removal].

Additionally, Sanofi recognized that early clinical production and large-scale commercial manufacturing present vastly different challenges. A technology that performs well in a small bioreactor may not be suitable for a 10,000-liter commercial reactor. Thus, adopting technologies that minimize changes across scales was essential to reducing the risk of unexpected performance issues during scale-up.



Integration Across Departments and Building Confidence

A significant part of Sanofi's success in adopting new technologies lies in its cross-functional approach. The decision-making process brings together experts from process development, manufacturing sciences, procurement, finance, engineering, and operations. This collaborative model ensures that all relevant aspects—from technical performance to financial impact—are thoroughly evaluated.

Moreover, building confidence in new technology is not solely about data from lab experiments. Real-world, repeated scale-up is critical.

> The only way that I found you build confidence is through experience… until it works at scale, over and over again, across operators, across lots of raw materials, across different programs, it's still something that people ask and are nervous about.

This focus on robustness and repeatability is essential. Sanofi's emphasis on scale-up repetition and the prior knowledge built from previous experiences with reputable suppliers demonstrates the company's ability to adopt new technologies confidently.

> It is not enough for a technology to work in theory or on a small scale; it must demonstrate consistent, reliable performance in a real manufacturing environment.

Financial and Strategic Considerations

Financial discipline is at the core of Sanofi's approach to technology adoption. Every new technology is subjected to rigorous financial scrutiny, including cost-of-goods analyses and risk simulations. This ensures that any investment in new technology not only meets performance criteria but also contributes positively to the company's overall economic model.

> We evaluate cost and cost of change in several ways… our approach includes calculating cost of goods and capital expenditure—using these [and other factors] to run NPV calculations.

This detailed financial modeling allows Sanofi to make informed decisions that balance the potential benefits of new technology against the risks and costs associated with change. The collaborative nature of the decision-making process—drawing insights from multiple departments—further ensures that all perspectives are considered.

CONCLUSION:
Lessons for the Biopharmaceutical Industry

Sanofi's approach to integrating next-generation harvest and clarification technology demonstrates that innovation in biopharmaceutical manufacturing is not a one-off event, but a continuous, evolving process. By employing a structured, stepwise adoption process, maintaining a flexible toolbox strategy, and grounding decisions in robust financial analysis and real-world testing, Sanofi has positioned itself to meet both current challenges and future demands.

What Can Other Biopharmaceutical Companies Learn from Sanofi's Experiences?

Other biopharmaceutical companies can take several key lessons from Sanofi's approach. First, adopting a structured, tiered process for technology integration minimizes operational risks while allowing for rapid innovation. Second, maintaining a flexible, modular platform (or toolbox) that can adapt to a diverse product portfolio is essential for scalability and long-term competitiveness. Finally, the importance of cross-functional collaboration cannot be overstated—integrating insights from R&D, manufacturing, finance, and operations ensures that both technical performance and financial viability of manufacturing technology and solution investments are thoroughly evaluated. In today's competitive environment, a data-driven, collaborative, and flexible approach is crucial for successfully implementing new technologies and sustaining innovation over the long term.

Frost & Sullivan interviewed Kevin Brower, Global Head of Purification Development at Sanofi, for this piece and thanks him for his time and participation.

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