Shaping the Future of Biomanufacturing

Insights from the Sartorius Process Intensification Forum

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The biopharmaceutical industry is undergoing a transformation, with process intensification (PI) emerging as a key enabler for high-throughput and efficient production. Interest in concepts such as continuous biomanufacturing and PI has surged dramatically over the past decade, reflecting a broad industry shift toward innovative solutions. Although traditional manufacturing methods still prevail, intensified processes offer significant opportunities to enhance scalability, efficiency, and sustainability (Figure 1).

To drive that shift forward, Sartorius hosted the Process Intensification Forum in Göttingen, Germany, on 17–19 September 2024. The event brought together more than 200 experts in process development, manufacturing operations, and technology innovation to collaborate on strategies for enhancing biopharmaceutical production through intensified approaches.

Current Challenges in PI

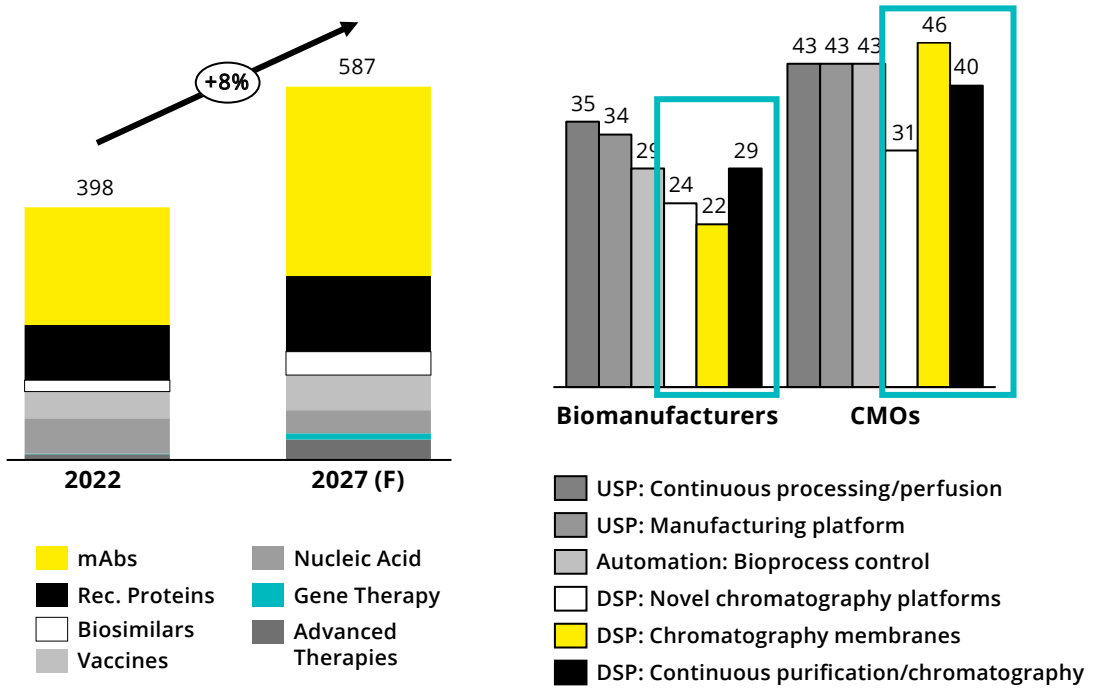
René Fáber (head of Sartorius BPS division) kicked off the forum by urging the biopharmaceutical industry to consider PI as a game-changing opportunity. He compared current hesitancy about PI approaches with the initial skepticism faced by single-use systems, which have become industry standards over the past couple of decades. Fáber highlighted that innovation ultimately paves the way for groundbreaking advancements. He emphasized the transformative potential of intensified processes in making life-saving drugs more accessible than they are today, urging the industry to move beyond traditional practices to address global healthcare challenges. As Fáber stated, "The industry needs more affordable drugs. Only a privileged group of people today have access to those drugs, and that needs to change."

Key Trends in Process Intensification

Published in April 2024, the annual *Report and Survey of Biopharmaceutical Manufacturing Capacity and Production* from BioPlan Associates highlighted a number of bioprocessing innovations related to PI:

- Strong and enduring interest in evaluating upstream continuous bioprocessing (CBP) technologies, with 36.5% of survey respondents reporting that they planned evaluations in 2024 (similar to 36.4% in 2018).
- Increased focus on upstream perfusion technologies and automation for bioprocess control, with interest in the latter rising from <1% in 2018 to 31.3% in 2024.
- Automation identified as a top budget expense for 2024, with 37.3% of responders prioritizing it to enhance efficiency, flexibility, and cost-effectiveness.
- Growing interest in continuous chromatography for downstream operations (increasing from 24.2% in 2023 to 30.8% in 2024), highlighting the need for scalable downstream innovations.

Figure 1: Market insights affirm the need for process intensification. The overall biologics market is expected to grow at an 8% compound annual growth rate (CAGR) from €398 billion to €587 billion by 2027 (**1**). Antibodies and other recombinant proteins will continue to be a dominant market. To accommodate such growth, international standardization must incorporate process intensification for more efficient biomanufacturing facilities (**2**). Cost reduction is needed to improve biopharmaceutical accessibility and affordability for new and expanded markets. Factors that will influence cost of goods (CoG) include raising yields, reducing turnaround times, implementing platform technologies, increasing facility capacities, and incorporating continuous bioprocessing technologies.



René Fáber, head of Sartorius BPS division

Eric Langer (president and managing partner at BioPlan Associates) reinforced that perspective, emphasizing that the industry increasingly is aware of the benefits of continuous processing (**2**). Although challenges related to integration and operational shifts remain, they also present opportunities for growth and ingenuity. Langer noted that adoption barriers are not rooted in the technology's complexity, but rather in recalcitrant mindsets and misconceptions. With appropriate strategies and collaboration, the industry can transition confidently from established batch processes to efficient methods for continuous manufacturing, unlocking new possibilities for biopharmaceutical production.

Langer called out the industry's reluctance to move away from traditional batch processing even as it recognizes continuous manufacturing's potential: "The industry is happy doing batch processing, partly because the process is well known to regulators and to operators. Even though the industry understands the potential benefits of continuous processing, inertia is creating roadblocks to adoption. So the job of industry innovators is to get companies off that comfortable spot and demonstrate to them the benefits of implementing something that is not yet comfortable." He expressed optimism that the biopharmaceutical industry eventually will embrace continuous manufacturing, as evidenced by sustained interest in the approach and in events such as the Process Intensification Forum, which are driving conversations about the intensification space.

Technological Innovations and Solutions

The forum showcased an array of technologies and strategies developed by **Sartorius research and**

Biostat STR system with Xcell alternating tangential-flow (ATF) filtration technology

High-throughput perfusion process development with Ambr HT perfusion

development (R&D) teams to drive PI across different domains of biomanufacturing. One team reported on an integration of process analytical technology (PAT) and process simulation technology into digital-twin infrastructure, which raised transformative possibilities for real-time process monitoring and optimization. Advanced tools such as the Ambr 250 bioreactor platform showed promise for breakthroughs in upstream process development, offering streamlined and scalable solutions. Case studies on the Biostat STR 50-L clinical-scale bioreactor platform (pictured above) with Sartorius media underscored both the challenges and benefits of PI implementation.

Discussions emphasized the importance of early stage evaluation of PI strategies during cell-line development (CLD), reinforcing the idea, as one participant observed, that it is "never too early, never too late" to adopt innovative approaches. A case study described implementation of membrane chromatography, exemplifying the transition from development activities to continuous manufacturing. Other participants provided practical lessons about the journey from bench scale to good manufacturing practice (GMP) operations.

Presenters highlighted new tools for flexible automation and digitalization, showcasing their effects on connected and intensified upstream unit operations. Exploration of responsible and transparent artificial-intelligence (AI) and machine-learning (ML) applications emphasized the pivotal roles that such technologies will play in advancing process understanding and fostering innovation.

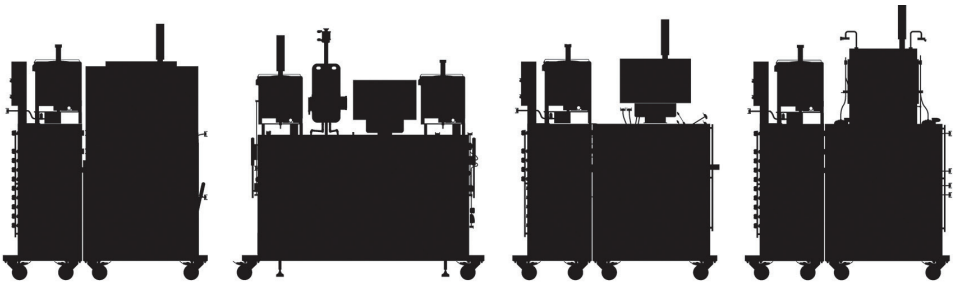
Industry Insights

Kevin Brower (global head of purification development at Sanofi) highlighted the transformative potential of PI in enabling at-scale

Demo in the Sartorius Application Center

development and streamlining development and technology-transfer strategies. "PI simplifies transfer, enhances control-strategy development, offers opportunities to streamline validation," he stated, emphasizing the role PI can play in modernizing legacy processes. For example, enzymes that are incompatible with traditional fed-batch processes have been identified as strong candidates for intensified continuous biomanufacturing to drive increased productivity, reduced cost of goods (CoG), and improved robustness.

Sanofi successfully transformed a legacy process into a high-density perfusion system. The team also automated antibody capture using a multicolumn-chromatography setup, ensuring consistent process performance and high quality for a commercially available product. Process performance qualification was conducted leveraging non-GMP and GMP facilities due to the intensification offered by the improved process. According to Brower, that strategy helped Sanofi to decouple critical timelines and enabled generation of data while the company built a new facility to house the intensified process. That streamlined



Pionic technology platform

Kevin Brower, global head of purification development at Sanofi

approach resulted in an efficient and cost-effective manufacturing process.

"PI is critical, but really it's a means to an end, and that end might be different for you," Brower continued. "So please approach your stakeholders and your decision-makers with that [goal] in the back of your head." He added that certain aspects of intensification are well-matured across the industry: "It is doable. It has been done, and you can leverage that experience." Brower went on to underscore the importance of understanding the similarities and differences between batch and intensified processes, particularly in areas such as chromatography, for which integration with other operations should be considered. Continuous processes may run at different flow rates than corresponding batch processes, requiring targeted adjustments in process-development methodology. Although developing integrated, continuous processes may require additional effort, established engineering principles from batch approaches remain applicable.

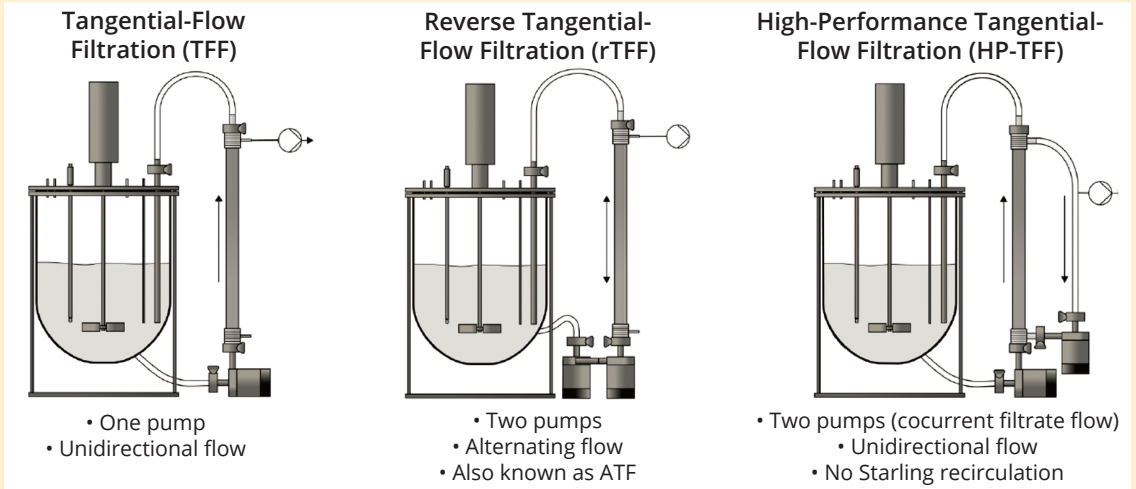
He likewise stressed the need for control in continuous bioprocesses, in which rapid responses to upstream variability are vital. Sanofi is developing approaches to address variability and disturbances. Tested on diafiltration (DF) technology from Sartorius, Sanofi's approach seeks to enable real-time decision-making to maximize productivity while incorporating mechanisms to divert to waste when necessary. That approach ensures resilience, efficiency, and adaptability in intensified processes.

Sanofi seeks to progress its PI journey, particularly with a focus on continuous manufacturing. As Brower explained, "Continuous manufacturing makes you intensified. It makes things small. And once you get to things that are small, then you can start thinking about modular, flexible manufacturing. That is near and dear to us at Sanofi."

Through a collaboration with Sartorius, Sanofi aims not only to enhance its manufacturing networks, but also to yield industry-wide benefits. The collaboration progresses at pace, and the companies intend to deliver on their intended goals through realization of the Pionic technology platform. In 2025, the joint team will begin testing modular systems to generate application data on functional prototypes, with presentations anticipated across a breadth of technical conferences and potential early adopters.

Lisa Connell-Crowley (senior vice president of process and product design at Just – Evotec Biologics) shared her company's journey and rationale for implementing continuous processes. The company's name stems from its founders' vision for creating cost-effective drugs. Connell-Crowley explained, "They wanted to start the company with the mission to design and apply innovative technologies to dramatically expand global access to biotherapeutics. Most people cannot afford biologics, so how do we change that?" Cost reduction, speed, and efficiency are key drivers for

Figure 2: Comparing different tangential-flow filtration (TFF) techniques



adopting intensified production technologies, she said, citing Just – Evotec's collaboration with the Bill and Melinda Gates Foundation: "Our first grant from [the organization] supported developing a platform for low-cost, fast manufacturing to improve global access to biotherapeutics."

Just – Evotec's focus on reducing costs and maximizing efficiency heavily influenced the design of its first manufacturing facility in Redmond, WA. "The whole concept of that facility was to make it as small as possible to reduce costs," explained Connell-Crowley. Spanning 130,000 ft^2 with a cleanroom footprint of just 600 ft^2, the facility was built in only 18 months. To achieve that, Just – Evotec Biologics leveraged single-use technology and modular, prefabricated J.POD cleanrooms, minimizing both operating footprints and costs while ensuring process flexibility.

From humble beginnings in a small garage, Just – Evotec Biologics has grown into a leader in innovative biomanufacturing, leveraging compact, mobile, and modular setups to lower production costs and scale operations as needed. That approach not only supports the company's mission to increase biotherapeutic accessibility, but also helps in reducing environmental effects. Those principles are guiding the design of Just – Evotec's new facility in Toulouse, France, which replicates the Redmond facility's layout, capacity, and equipment to maintain consistency and efficiency.

Thomas Villiger (lecturer and head of the bioprocess technology laboratory at the University of Applied Sciences Northwestern Switzerland) explored current technical bottlenecks and proposed cutting-edge techniques to resolve them. Some presenters upheld advanced tangential-flow filtration (TFF) technologies to resolve product sieving and filter blocking issues in cell-retention devices for intensified upstream processes. Together, such insights painted a detailed picture of how the biopharmaceutical industry seeks to meet evolving demands.

Thomas Villiger of the University of Applied Sciences Northwestern Switzerland

For many years, cell retention has posed challenges for perfusion-based drug-production processes, with methods such as TFF often hindered by filter fouling over time. Although perfusion is well suited for continuous manufacturing, with cells growing in a medium that is harvested and replenished continuously, filter fouling caused by cell debris can limit continuous-process efficiency. Villiger highlighted the root cause: "Starling recirculation can be one of the major causes of hollow-fiber filter fouling." When applied as cell-retention devices, TFF systems using hollow fibers are run at relatively low filtrate fluxes. That factor, combined with significant drops in axial pressure, generates reverse flow (known as Starling recirculation) of filtrate (**3**). "That process can be

UniVessel bioreactor

Ksep 400 system

Ying Wang, senior vice president and head of global MSAT at WuXi Biologics

critical for filter fouling," Villiger said. "As an industry, we use our filters in an inefficient way." Such insight opens the door to rethink filtration approaches for intensified processes. Recent research by Villiger and his colleagues points to a possible solution inspired by a technique published almost 30 years ago. However, the principle only came to fruition in cell-culture processes when it was combined with modern disposable pumps and controls.

Instead of modifying filters themselves, Villiger and his team adopted an approach called *high-performance tangential-flow filtration* (HPTFF), which equalizes pressure differentials across filters using pumps. Highlighting the value of interdisciplinary innovation, Villiger showcased his team's research on reverse tangential-flow filtration (rTFF) and HPTFF, offering a fresh perspective on overcoming longstanding obstacles in continuous bioproduction (Figure 2).

> "Starling recirculation — **REVERSE FLOW** — can be critical for filter fouling. As an industry, we use our filters in an inefficient way." —Thomas Villiger

Case Studies: Advances in Upstream and Downstream Intensified Processes

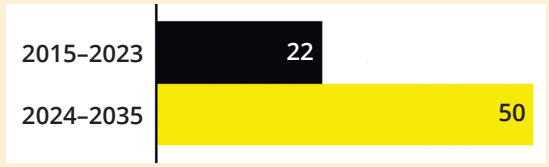
Several case studies presented at the forum highlighted successful implementations of intensified processes. One such success story came from **Ying Wang (senior vice president and head of global MSAT at WuXi Biologics).** Known for its innovative WuXiUP intensified platform, WuXi Biologics has embraced digital twins as powerful tools for process development and control. Digital twins enable in silico replication and optimization of customer processes, significantly reducing time and costs associated with traditional process-development methods. The company's approach also facilitates real-time monitoring and control of manufacturing processes, ensuring consistency and quality while streamlining technology transfer and optimization. Wang's presentation underscored the transformative potential of digital technologies in advancing PI efforts.

Other forum speakers explored how downstream processes are evolving to match the rapid advances in upstream productivity, driven by innovations in cell-line engineering, media formulation, and process optimization. Because bioreactor titers and yields have improved significantly over the past few decades, progress now has shifted to addressing the bottleneck of downstream processing. With purification steps accounting for up to 80% of total manufacturing costs in some processes, the question remains: Are downstream technologies advancing quickly enough to handle high bioreactor titers? Discussion at the forum underscored the critical need for downstream innovation to support the efficiencies achieved upstream, helping entire biomanufacturing processes to become streamlined, cost-effective, and scalable.

Célia Valentim (purification process development scientist at Sanofi) shared details on the company's accelerated, seamless antibody purification (ASAP) process, which has played a pivotal role in streamlining purification workflows and moving toward a fully connected

Vincent Dechavanne, senior scientist at SwissBiosim R&D Center of Fresenius Kabi

Figure 3: Number of biologics coming off patent



Pierre Springuel, UCL PhD candidate

biomanufacturing process. “At Sanofi, innovation and process improvement are part of our DNA. For almost 15 years, we have been assessing new technologies and looking for opportunities to make our processes more efficient,” Valentim stated. The ASAP process begins with protein A affinity chromatography to capture expressed mAbs, followed by further purification via two polishing chromatography resins . The key advantage of such a process over traditional purification approaches is increased utilization of protein A resin that brings significant cost savings. Additionally, the linked steps make the process faster, as Valentim explained: “You don’t have to wait for all the cycles of one step to be done. If you have the product, you can go directly to the second step.” That streamlined approach has made the technology efficient in both development and GMP contexts.

Importance of PI for Biosimilar Manufacturing

With numerous blockbuster biologics approaching patent expiration (Figure 3), the biosimilars market is poised for significant growth. To make such drugs more affordable than the originator alternatives, biosimilar manufacturers must focus on developing facilities and processes with substantially lower CoGs. That theme featured prominently in a presentation by Vincent Dechavanne (senior scientist at the SwissBiosim R&D Center of Fresenius Kabi), who showcased advancements in intensified downstream processing for biosimilars. His team evaluated continuous processing modes such as sequential multicolumn capture (S-MCC) and sequential multimembrane flowthrough (S-MMF) on a Sartorius Resolute BioSMB platform to improve efficiency and reduce costs. The team also enhanced protein A capacity through MCC, replaced AEX resin with AEX membranes, and used ceramic hydroxyapatite (CHT) chromatography and Rapid A membranes for antibody purification, increasing productivity and cost savings. A comparison of batch and continuous processing confirmed that continuous methods uphold biosimilarity standards while reducing buffer consumption and CoG, increasing resin lifespan, and boosting productivity. Dechavanne’s presentation concluded with strategies for further optimizing downstream processing through integrated steps and comprehensive membrane-based approaches, demonstrating a clear path toward efficient and cost-effective biomanufacturing.

Kevin Botelho Ferreira (downstream process lead scientist at Merck) similarly discussed advancements in membrane-chromatography technology, emphasizing its criticality to the development of fully continuous manufacturing. Such talks underscored the industry’s commitment to advancing downstream processes and thus complement gains achieved by upstream intensification.

PI Implementation for New Modalities

PI implementation no longer is confined to protein production. Now the biopharmaceutical industry is exploring the benefits of perfusion for emerging

Figure 4: Adenoassociated virus (AAV) bioprocess integration and intensification

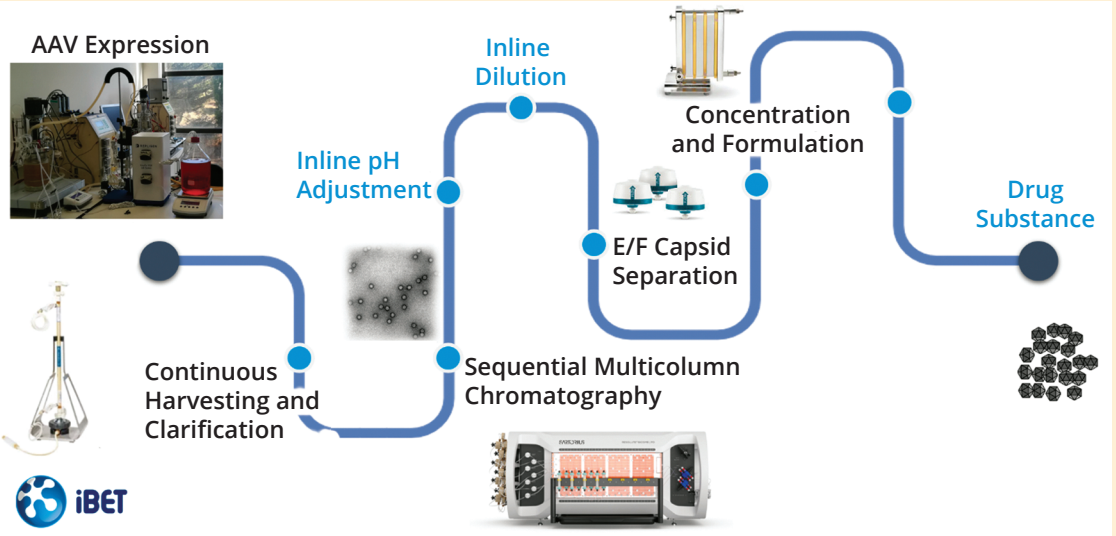
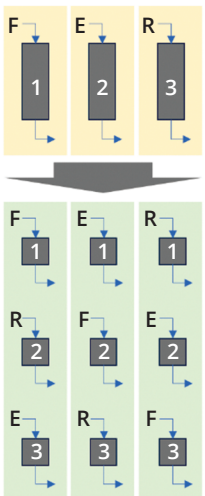
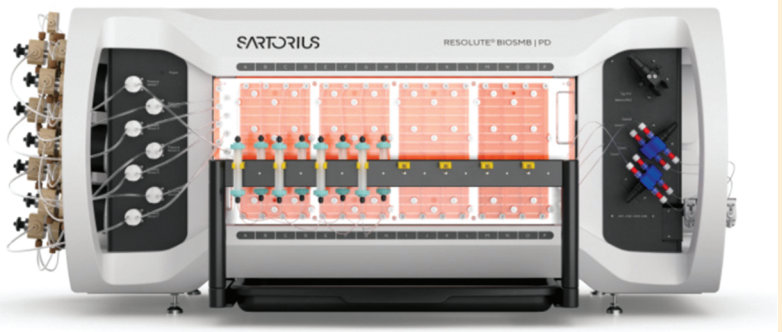


Figure 5: Batch multicolumn chromatography (MCC) goal 1 is to develop a capture step that is capable of handling a continuous feed stream.



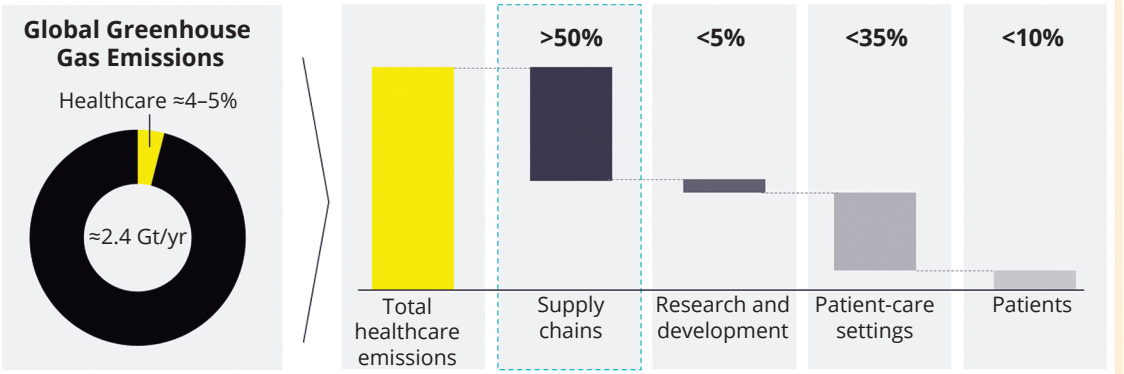


Resolute BioSMB PD
- Disposable valve cassette with valves
- Seven pumps
- Up to 16 columns
- UV, pH, and conductivity detection

products such as chimeric antigen receptor (CAR) T-cell therapies. **Pierre Springuel (biochemical engineering researcher at University College London, UK)** shared his work on maximizing CAR-T yield and quality while reducing expansion time to reach therapeutic doses. By leveraging Ambr 250 high-throughput perfusion systems, Springuel and his team developed and optimized perfusion parameters to address challenges such as variability in donor material. He demonstrated how scale-up from 250-mL to 2-L bioreactors was optimized further using the UniVessel SU system, enabling automated cell harvesting through a Ksep 400 system. Such optimization led to a remarkable 4.5-fold increase in CAR-T yields and >10% reduction in medium consumption, lowering costs for patients.

Since 2017, the US Food and Drug Administration has approved seven CAR-T therapies, each typically costing over US$500,000 per dose. More recent T-cell receptor (TCR) therapies, such as Tecelra (afamitresgene) — approved in August 2024 for synovial sarcoma — are priced even higher, around $750,000 per dose. “Therefore, from a manufacturing or CoG perspective, you can see why we need PI,” said Springuel. He added that his team’s processes are compatible with both autologous and allogeneic CAR-T manufacturing,

Figure 6: Greenhouse gas emissions of the healthcare industry (from *Decarbonising Healthcare Supply Chains.* Sustainable Markets Initiative: London, UK, 2022)



offering scalable and efficient solutions for advanced cell-therapy production.

A presentation by **Ricardo Silva (principal scientist at Portugal's Instituto de Biologia Experimental e Tecnológica, iBET)** investigated how intensified processes are transforming both upstream and downstream processes for new modalities (Figures 4 and 5). He highlighted some distinct challenges and opportunities posed by gene therapies, emphasizing that process integration will be essential for developing scalable, robust, and GMP-compliant processes for cell and gene therapy (CGT) products alike. Although end-to-end continuous processing is not universally applicable at present, Silva highlighted how intermediate solutions could optimize manufacturing workflows in the meantime. He then presented iBET's work on developing a continuous affinity-capture step for adenoassociated virus type 8 (AAV8) using a Resolute BioSMB system operated in MCC mode. That innovation enhanced media use and improved elution recovery, increasing yield and reducing costs for that step in the gene-therapy manufacturing.

Future Directions and Opportunities

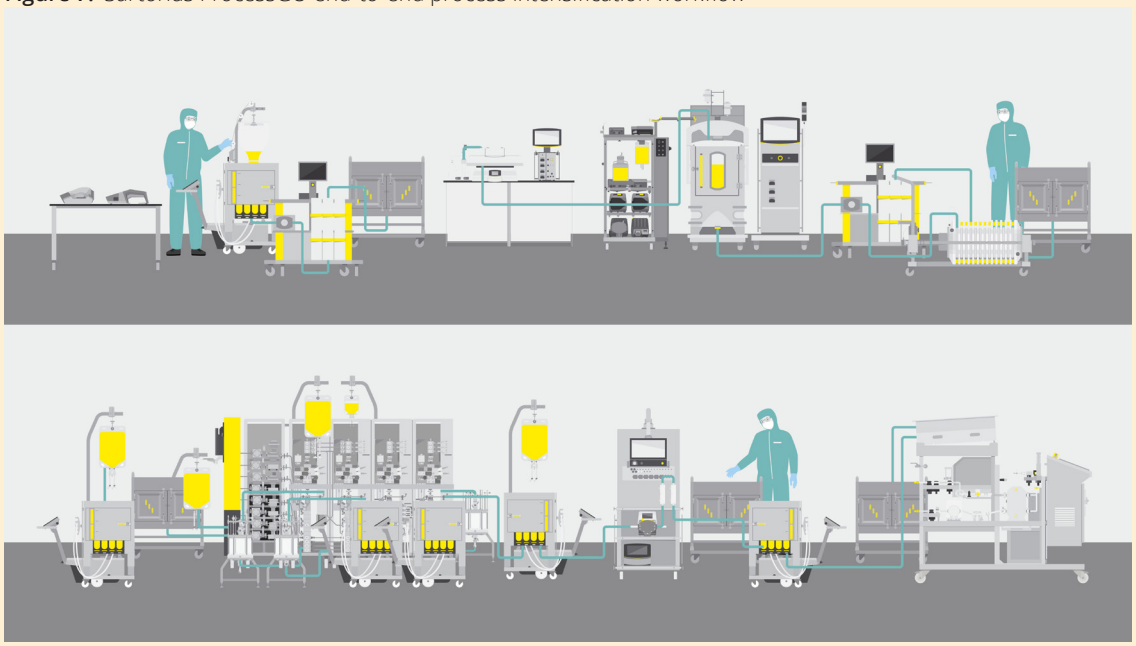
PI and Sustainable Biomanufacturing: The forum underscored the importance of ongoing innovation and collaboration among industry stakeholders in advancing biomanufacturing. PI presents a powerful pathway not only for reducing costs and making therapies accessible, but also for addressing industry sustainability goals. The environmental benefits of intensified processes, such as reduced resource consumption and waste generation, are increasingly significant as the industry strives to prioritize sustainable practices. With the healthcare sector being responsible for 4–5% of global emissions — 50% of such emissions stemming from healthcare supply chains (Figure 6) — the pharmaceutical industry must take immediate action to reduce its carbon footprint in the pursuit of global health (**4**).

> Through cutting-edge technological innovations, process intensification offers substantial **IMPROVEMENTS** in efficiency, sustainability, cost reduction, and time to market.

Andrew Falconbridge (senior consultant and owner at Try3i) outlined a strategy for implementing PI and reported that sustainability is becoming a top priority for an increasing number of biopharmaceutical companies. Beyond meeting environmental obligations, that goal could deliver significant business benefits, including improved financial performance, strong market positions, and enhanced brand images. Falconbridge stressed the importance of engaging stakeholders across the entire value chain effectively by fostering collaborative efforts that drive meaningful progress in sustainable practices.

Regulatory support will be vital to accelerating the industry's shift toward sustainable operations, as suggested by **Miriam Monge (head of customer and industry advocacy at Sartorius).** Agencies such as the FDA are backing continuous manufacturing to simplify supply chains, improve drug quality, and enhance sustainability. Monge said, "The FDA has been pushing to drive forward continuous

Figure 7: Sartorius ProcessGO end-to-end process intensification workflow



Miriam Monge, head of customer and industry advocacy strategy of Sartorius BPS division

manufacturing. There are several reasons for that. Obviously, the agency wants to make biologics affordable and of high quality, but also it wants to 'decomplexify' the global supply chain." She added that contract development and manufacturing organizations (CDMOs) will play a key role in urging further PI adoption. That is because CDMOs often are early adopters of new technologies, seeking to offer flexible and efficient manufacturing solutions that meet evolving customer needs.

To meet growing demand for intensified processing, Sartorius and G-CON have teamed up to provide sustainable, flexible facilities that are compliant with current good manufacturing practices (CGMPs) at an accelerated pace. By combining G-CON's rapidly deployed POD cleanroom structures with the Sartorius ProcessGO system (Figure 7), the partners seek to address key industry needs such as speeding up facility delivery with prefabrication in timelines of under six months followed by streamlined installation and simplified qualification. The collaboration also promotes cost efficiency by offering predictable bioprocess workflows and reduced facility footprints with limited heating, ventilation, and cooling (HVAC) requirements, which in turn will lower operating costs. The POD technology's flexible design allows for easy replication across multiple sites and offers potential for reconfiguration and relocation, supporting both operational efficiency and environmental goals.

Fostering Further Discussion: The Sartorius Process Intensification Forum highlighted the significant potential of intensified manufacturing processes in the biopharmaceutical industry. Through cutting-edge technological innovations, PI offers substantial improvements in efficiency, cost reduction, and time to market. Such advances are crucial not only in making life-saving therapies accessible, but also in reducing the environmental effects of supply chains and production-related activities. Moving forward, fostering collaboration and securing regulatory support will be essential to realizing the benefits of PI. By integrating emerging technologies, the industry can meet growing demand for affordable medicines while contributing to a more sustainable future in biomanufacturing.

PI holds the key to optimizing biopharmaceutical production across multiple dimensions, boosting productivity, reducing costs, and minimizing environmental impacts. The presentations, workshops, and technology demonstrations at this forum illustrated how integrating intensified processes into both upstream and downstream operations can unlock greater efficiency and scalability. With continued technological progress, industry collaboration, and regulatory support, PI can improve biomanufacturing significantly. As the industry evolves, embracing such innovations will be fundamental to building a resilient, cost-effective, and environmentally responsible healthcare system.

Sartorius will host its second Process Intensification Forum in Boston, MA, on 24–26 June 2025. For more information, please visit https://www.sartorius.com/en/company/exhibition-conferences/local-events/sartorius-pi-forum.

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