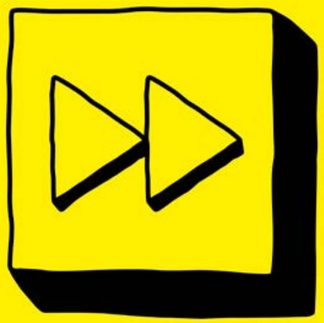
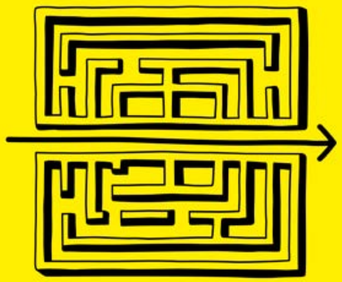




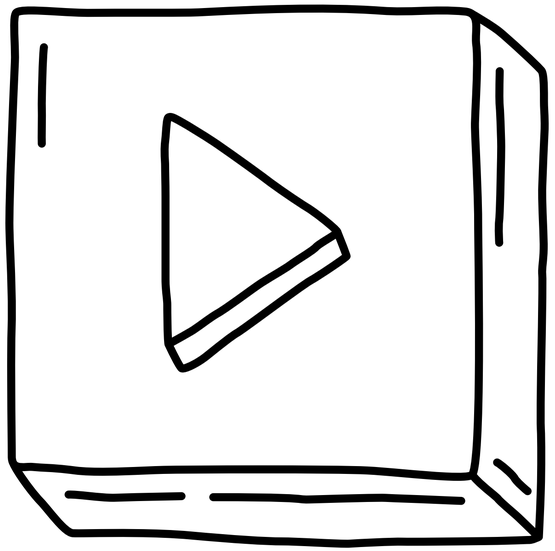
Simplifying Progress

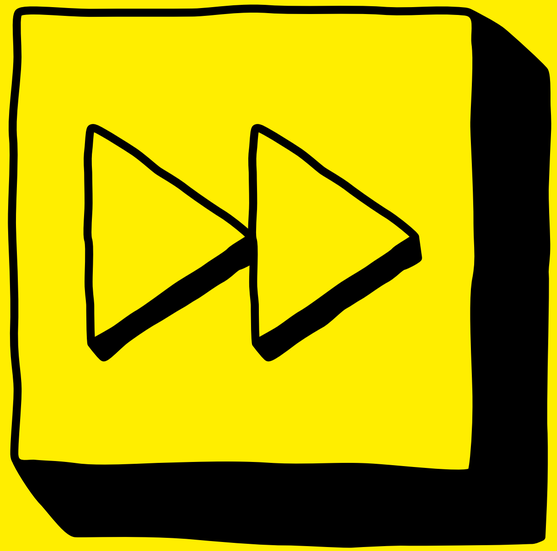
Insights from process intensification experts

How the industry is scaling smarter, faster, and more sustainably

Click here to start

SARTORIUS





Introduction

The biopharmaceutical market is evolving rapidly. Rising demand for diverse therapies—monoclonal antibodies, bispecifics, and advanced modalities—along with economic pressures and global competition are reshaping how medicines are manufactured. Smaller production scales, complex molecules, and the need for cost efficiency require approaches that go beyond traditional methods.

This e-book explores process intensification (PI) as a strategic response to these challenges. Through expert insights and real-world examples, we highlight how PI enables manufacturers to increase productivity, reduce costs, and accelerate time to market while supporting sustainability goals. From upstream and downstream innovations to digitalization and automation, these conversations reveal why PI is becoming essential for companies seeking agility and long-term success.

Meet the experts

Magali Barbaroux
Research Fellow,
Advanced Materials,
Corporate Research,
Sartorius

Himanshu Gadgil
CEO, Enzene Biosciences Ltd

Miriam Monge
Head of Customer and Industry Advocacy Bioprocess Solutions,
Sartorius

Eric Sorge
Associate Scientist,
Merck & Co

David Brown
Associate Director,
Downstream Process Development,
KBI

Priyanka Gupta
Senior Expert
Bioprocess Solutions,
Sartorius

Pierre Moulinie
Head of Global Technical Marketing (Healthcare),
Covestro

Gerben Zijlstra
Senior Expert
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Antonio Costa
Founder and CEO,
DIANT Pharma

Courtney Hazelton-Harrington,
Senior Scientist,
Research & Development,
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Behnam Partopour
Principal Scientist,
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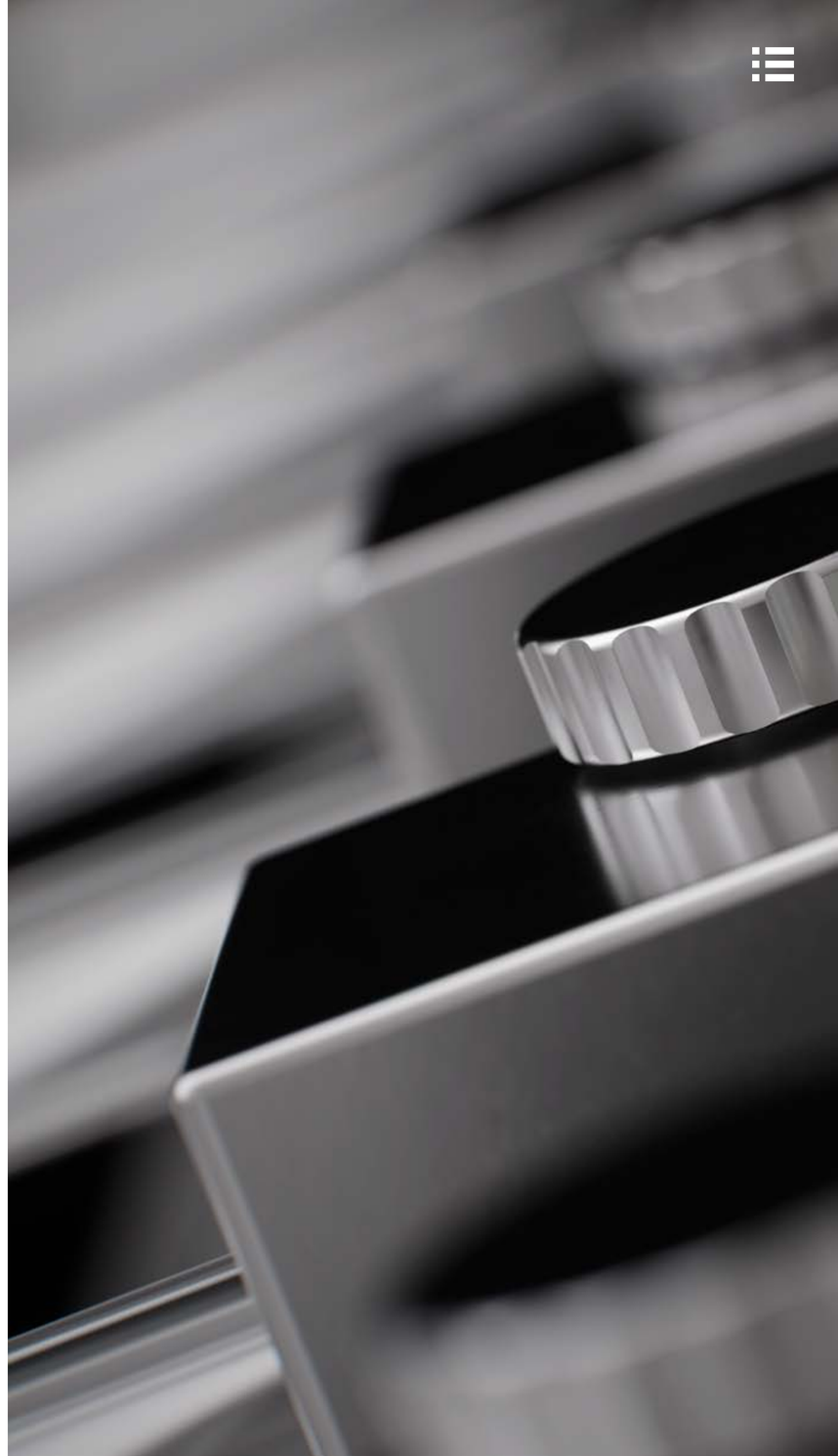
Bob Davis
Sales Development Specialist, Data Analytics,
Sartorius

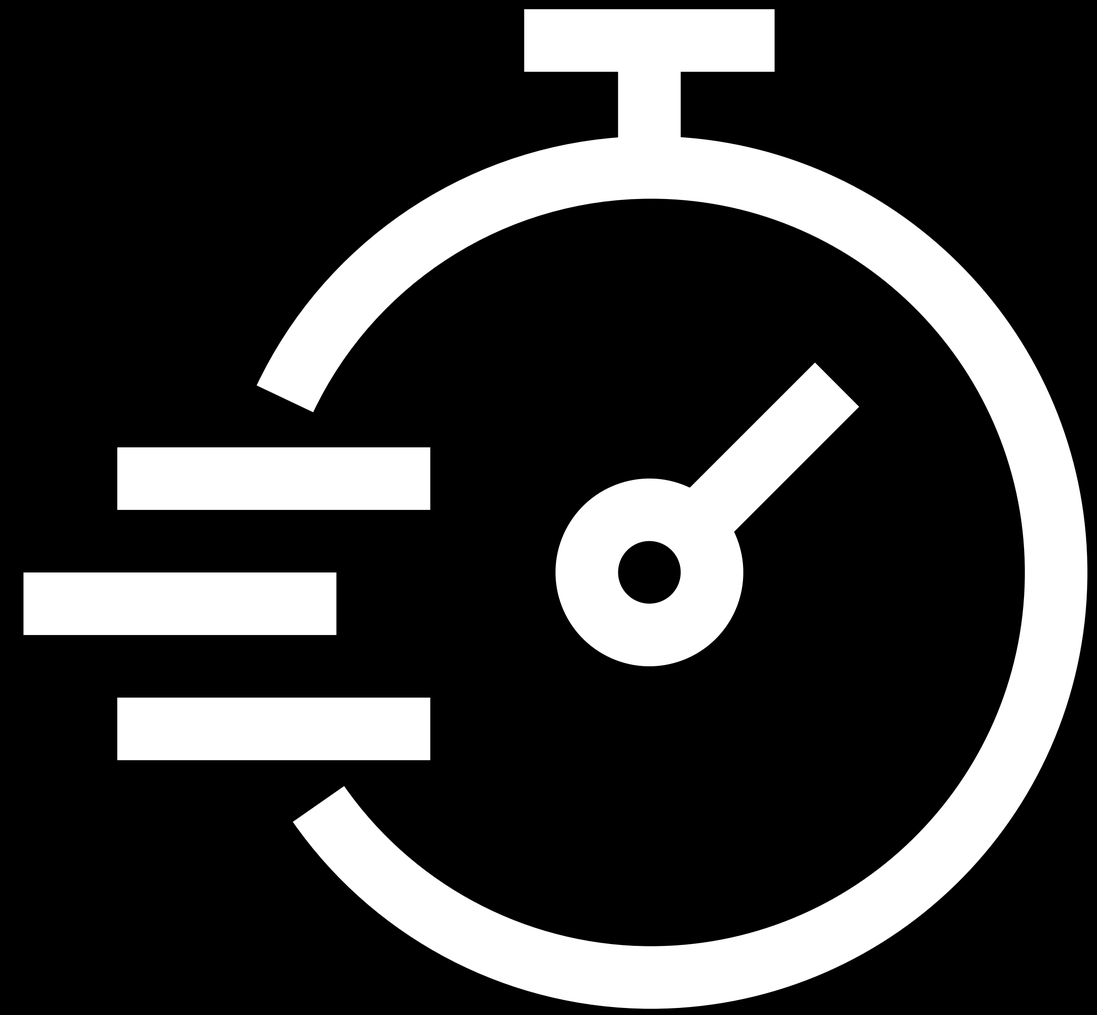
Steve Miller
Market Development Manager DSP Digitalization,
Sartorius

Dennis Powers
Senior Vice President of Product & Strategy,
G-CON

Content



The time is now: Market drivers behind PI



Why PI matters — Market dynamics and innovation

How does process intensification help companies meet both today's market demands and long-term sustainability goals?

The demand for biopharmaceuticals is rising rapidly not just in terms of volume, but also in the diversity of drugs available. There are more monoclonal antibodies on the market addressing a wider range of diseases than ever before. New cell and gene therapies are also emerging.

To meet this growing demand, improving process efficiency is essential. Process intensification is the most important tool we have today to address this need, enabling us to use existing facilities more efficiently or even reduce the footprint of future facilities.

As demand grows, so can the environmental impact — but process intensification helps reduce both the environmental footprint and energy needs, especially those related to plastics.

This approach will continue to reduce costs and environmental impact now and in the future, while ensuring patients get the treatments they need.

Behnam Partopour
Principal Scientist, Advanced Bioprocessing, Corporate Research, Sartorius

What market factors are driving the need for process intensification?

The market has changed significantly since COVID. We now see more complex molecules like bispecifics and trispecifics, which require new manufacturing methods because they do not perform well in typical fed-batch processes. Additionally, there is a biosimilar patent cliff, with the patents of many drugs scheduled to expire soon. Biosimilar manufacturers are highly focused on efficiency and low cost. We also see that more molecules require less than 500 kilograms per year, and nearly half need less than 100 kilograms annually. These smaller quantities are well-suited to small-scale, single-use, intensified facilities. The economic situation also plays a role — higher material costs and potential import tariffs in the US mean drug prices are rising, so efficiency is more important than ever.

Miriam Monge
Head of Customer and Industry Advocacy Bioprocess Solutions, Sartorius

What were the major reasons for you to establish a continuous platform?

When we started about ten years ago, our main goal was to make medicines more affordable, especially for emerging economies like India, where the cost of goods directly impacts accessibility. We realized that a significant portion of costs comes from indirect expenses — facility footprint and capital depreciation. To minimize these, we aimed for a compact footprint, which led us to develop a continuous and connected process.

Himanshu Gadgil
CEO, Enzene Biosciences Ltd

It´s time to intensify — Seizing the PI opportunity

Why is now the right time to intensify?

All these factors — complex molecules, biosimilar competition, smaller production scales, and economic pressures — make process intensification a timely and necessary strategy for the industry. Companies that act now will be better positioned to deliver cost-effective, high-quality therapies in an increasingly competitive market.

When should you start with PI in upstream?

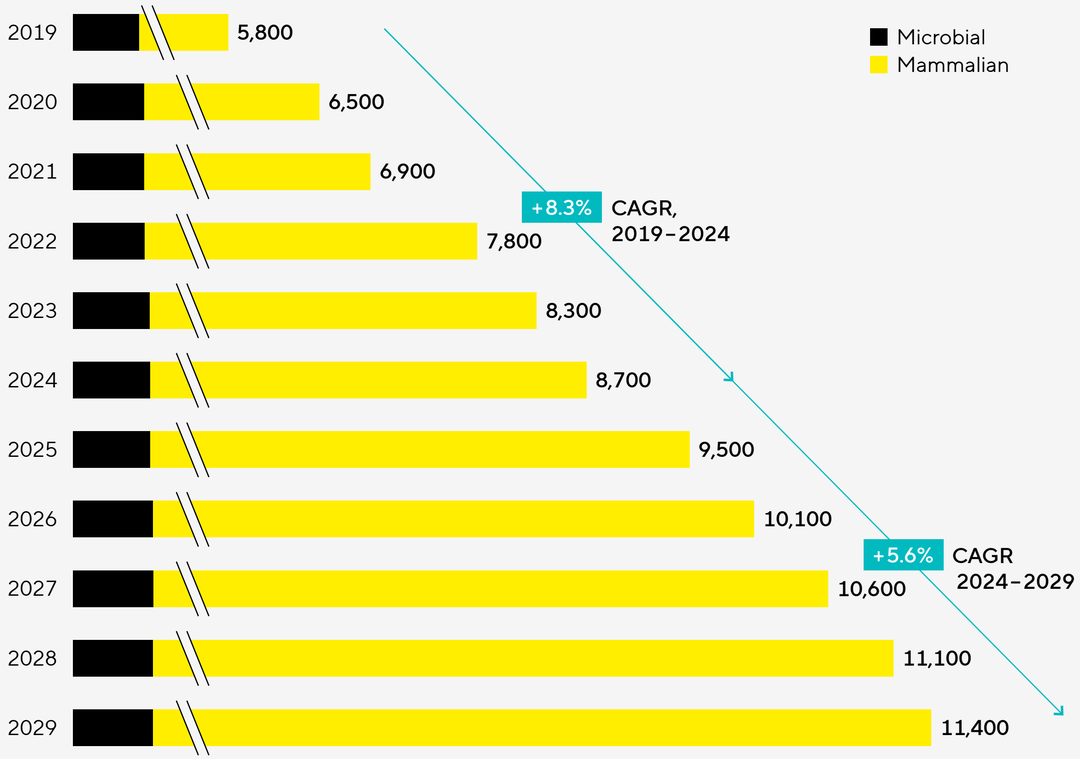
It's never too early to start with process intensification, but it's also never too late. Ideally, beginning early allows you to select the right clones, optimize media, and refine the process from the outset. However, if you're working with a low-producing clone in an early-phase project, you might need to intensify the process later to make the project feasible. Even then, you can optimize your process with PI techniques like N-1 perfusion to boost titers in your fed-batch.

Miriam Monge
Head of Customer and Industry Advocacy Bioprocess Solutions, Sartorius

Gerben Zijlstra
Senior Expert Bioprocess Solutions, Sartorius

Installed capacity: Mammalian and microbial capacity

Global Installed Capacity, 2019–2029 (kL per year)*



*Source: BioTrak database as of H1 2025; Sartorius analysisogies, Chemical Engineering Progress (CEP), 121 (7), 39-46. July 2025

What's next—The future of intensified bioprocessing

Which process intensification implementations are likely to have the biggest impact in the next few years?

Looking ahead, N-1 perfusion on the upstream side is expected to be widely adopted and beneficial for all processes, whether batch or continuous. On the downstream side, the use of protein A membranes for clinical manufacturing is gaining momentum due to their cost and efficiency advantages.

While traditional batch resin-based approaches remain available, membrane technologies offer compelling benefits that are likely to drive innovation in bioprocessing.

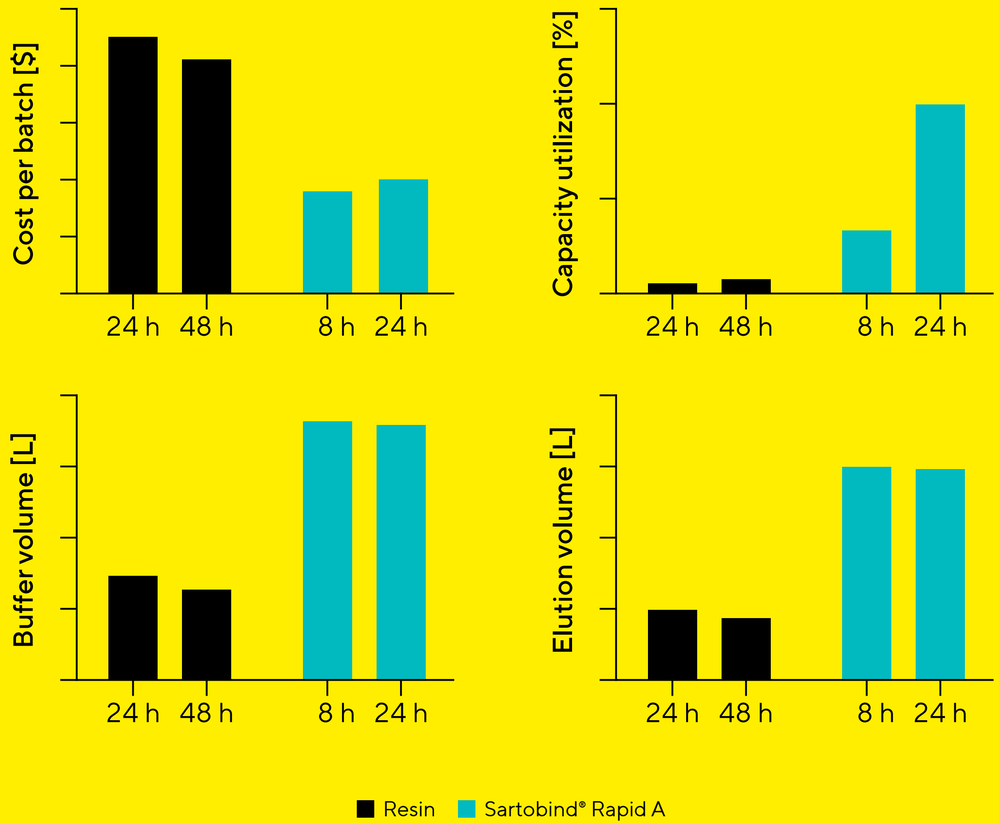
David Brown
Associate Director, Downstream Process Development, KBI

How receptive are your customers to implementing continuous processes?

The field is growing rapidly. Last year at CPHI, when attendees were asked about the top innovation for reducing cost of goods, most voted for continuous manufacturing. Thanks to the work we've done and others in the industry, awareness of continuous manufacturing and its benefits is increasing, and we're seeing more interest from clients wanting to access the platform.

Himanshu Gadgil
CEO, Enzene Biosciences Ltd

Protein A resin vs. Sartobind® Rapid A membrane across key performance metrics



Chapter 2

Breaking barriers and unlocking value in PI

PI Challenges — Biopharm industry evolving towards intensified processing

What's the biggest hurdle when it comes to implementing intensified processes?

One major hurdle is the prevalence of existing stainless-steel facilities. Companies can't simply switch everything to intensified processes immediately. Often, they try to integrate one or two intensified unit operations into existing setups, which is challenging due to legacy control systems. Ensuring different control systems and data analytics platforms can communicate effectively is a significant challenge in integrating intensified processing.

Beyond infrastructure, the biggest hurdle revolves around mindset. Large companies don't always feel urgency to move away from what they perceive as working, especially if they have invested heavily in such facilities and systems. Teams worry that switching to intensified processes requires extensive training, regulatory filings, and change notifications, plus proof that product quality remains consistent. Beyond this, a lack of technological advancement in the downstream has been a major hurdle, though this is finally changing and Sartorius is now investing heavily in developing solutions to address this gap.

Miriam Monge
Head of Customer and Industry Advocacy Bioprocess Solutions, Sartorius

Priyanka Gupta
Senior Expert Bioprocess Solutions, Sartorius

The time to intensify is now

1990–2010

Large stainless steel — batch, driven by low titers

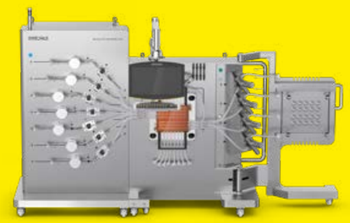
- High upfront investment costs and high Carbon footprint
- Long lead times
- Very limited flexibility

2010–2020

Smaller single use — batch, supported by higher titers

- Lower and later investment, reduced Carbon footprint
- Low risk of contaminations
- Higher flexibility

2020–2030



Intensified process — continuous, supported by technology innovation, digital solutions and automation

- Higher productivity
- Lower footprint, CoGs and CO_2

What are customers' main concerns about adopting process intensification?

Customers often express concerns rooted in their previous experiences, preferring not to change established processes. There is a common attitude of "if it isn't broken, don't fix it." However, process intensification techniques can outperform traditional methods, especially in upstream and downstream processes. Clients are particularly focused on ensuring the success of their first batch, which leads them to stick with familiar approaches. While innovation is necessary for future progress, comfort and reliability remain top priorities for many customers.

David Brown
Associate Director, Downstream Process Development, KBI

What technology gaps did you have when you started and how has the industry evolved since then?

Ten years ago, there were major technology gaps—no perfusion-specific media, and the media we used was still quite rich. Filtration mechanisms and integrating them into a continuous flow were also lacking. Over time, technology has evolved, and now these components are being customized for continuous manufacturing, closing many of the gaps we faced initially.

Himanshu Gadgil
CEO, Enzene Biosciences Ltd

PI benefits — Driving efficiency and value

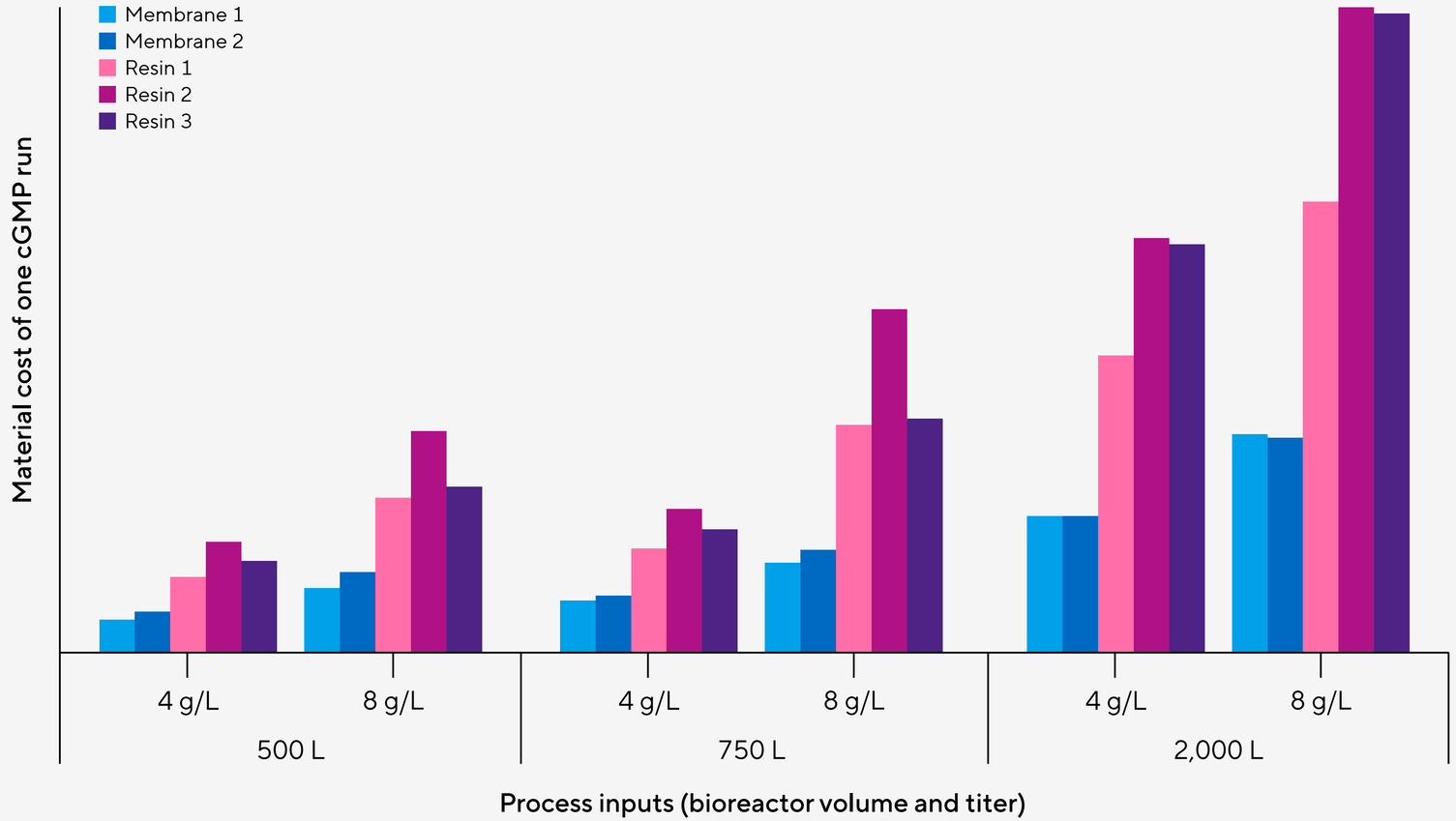
What is the single biggest business benefit of process intensification?

The greatest business benefit is the ability to generate more material with fewer resources. Upstream intensification improves yields and reduces bioreactor time, which lowers equipment usage and costs. This means more material can be produced with less input, benefiting both the company and patients through lower drug prices and shorter time to market for therapies.

David Brown
Associate Director, Downstream Process Development, KBI

Downstream process selection and cost implications

(cost estimates for membranes | resin + buffer only)



Can you shed some light on reduction in COGs and its importance?

We see at least a 50% reduction in cost of goods, primarily due to two factors: a very compact operational footprint and high volumetric productivity. In our fully-connected continuous manufacturing™ process, we achieve cell densities of 100 to 250 million cells per milliliter—compared to 15 to 20 million in batch processes. With similar specific productivity, this results in much higher volumetric output combined with the small footprint.

Himanshu Gadgil
CEO, Enzene Biosciences Ltd

Enabling PI — How Sartorius powers end-to-end solutions

How does Sartorius help customers simplify upstream PI implementation?

Sartorius addresses these challenges by providing efficient cell lines for customers who don't have their own cell line generation programs, specifically designed for intensified modes. We also offer cell culture media and, with our Ambr® systems, deliver high-throughput process development capabilities — making PI implementation and development much more efficient. Additionally, we provide large-scale systems and advanced digital solutions, including data analytics tools, to support advanced process control.

How is Sartorius helping companies move from standalone intensified steps to connected, end-to-end intensified processes?

Sartorius has always been a visionary in providing end-to-end solutions. We started with single-use solutions for all steps, then invested heavily in upstream continuous manufacturing with perfusion-based bioreactors and wave systems. We collaborated to connect clarification (Xcell® ATF) with Biostat STR® bioreactors, so the whole upstream is connected. For downstream, we acquired platforms like Resolute® BioSMB and Resolute® BioSC, which offer established continuous and connected systems. Now, we're launching a new solution called Pionic® platform, in collaboration with Sanofi, to connect all downstream steps from capture to final ultrafiltration | diafiltration. Step by step, Sartorius is helping customers move from upstream to downstream intensification, leading the industry toward a connected future.

The real challenge is making everything run together smoothly. That's where our connectivity tools and automation layers come in. ProcessGo® packages tie unit operations together and integrate with our Biobrain® Supervise and Biobrain® Operate automation systems. Sartorius also offers data analytics tools like Umetrics® Suite and SIMCA® Online that fold seamlessly into operations, so our customers get real time process insight.

Collaboration with partners like Sanofi help develop modular, fully connected downstream units, while our consulting teams help customers implement fully connected upstream and downstream continuous flows.

Gerben Zijlstra
Senior Expert Bioprocess Solutions, Sartorius

Priyanka Gupta
Senior Expert Bioprocess Solutions, Sartorius

Miriam Monge
Head of Customer and Industry Advocacy Bioprocess Solutions, Sartorius

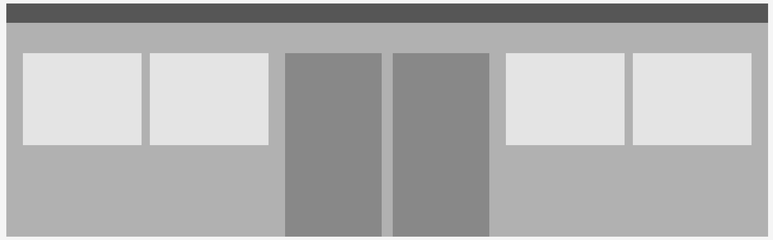
What strengths do Sartorius and G-CON bring to their collaboration?

Sartorius brings decades of process expertise and a broad portfolio of process technologies, including equipment, systems, consumables, automation, and technology platforms focused on continuous and connected manufacturing. Their solutions are pre-engineered and standardized, designed to intensify and connect client processes in a continuous format—this is embodied in Sartorius ProcessGo® platform. G-CON contributes extensive experience in designing and delivering prefabricated modular clean room infrastructure based on our pod technology platform. Our turnkey POD® cleanroom platform helps clients achieve cost-effective manufacturing capabilities. We both share a vision for helping clients achieve more efficient manufacturing.

Dennis Powers
Senior Vice President of Product & Strategy,
G-CON

Combining G-CON rapidly deployed cleanroom PODs® with Sartorius ProcessGo® addresses industry needs

+

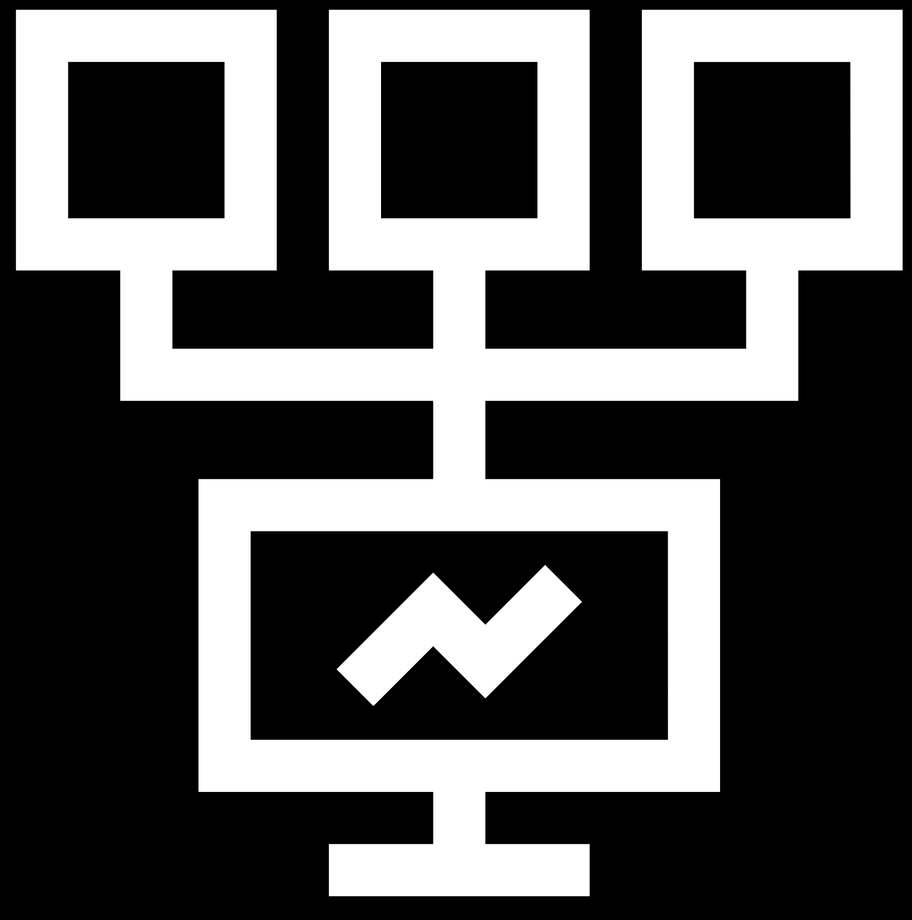


Delivers

- Speed
- Cost
- Qualification
- Flexibility
- Sustainability

G-CON

Digitalization and automation — Driving the future of PI



Overcoming automation hurdles and mindset shifts

What do you see as the biggest automation challenge when implementing connected single-use intensified systems?

One of the biggest challenges is the tech transfer from process development (PD) to commercial manufacturing. The control processes and automation strategies are built with supplier know-how, and these complex process units can't simply be rebuilt on new automation platforms. This makes tech transfer much more complicated on the automation side. Unless we change how we work, adopting these systems will remain a complex process.

Steve Miller
Market Development Manager
DSP Digitalization, Sartorius

What mindset shift is needed for teams transitioning to digital-first biomanufacturing?

Several mindset changes are needed. Process developers need to think about automation earlier, not just at the tech transfer stage. They'll need to collaborate with new teams, including automation and corporate IT. This is a big shift for everyone involved. Corporate IT and plant automation teams must also work with PD organizations to enable advanced control strategies and start gathering data earlier for advanced process models. A feedback loop is essential — without seamless collaboration among these groups, we won't achieve the cycle of insights from commercial manufacturing feeding back into process development.

Steve Miller
Market Development Manager
DSP Digitalization, Sartorius

How do digital tools like real-time monitoring and feedback control support continuous manufacturing platforms?

One of the main benefits of continuous manufacturing is the ability to monitor processes in real time. This allows us to receive feedback every second, or even every millisecond, providing a clear understanding of what is being produced at any moment. Real-time monitoring eliminates guesswork at the end of the process, ensuring complete knowledge of the material generated. This leads to greater assurance and higher quality products.

Antonio Costa
Founder and CEO, DIANT Pharma

Data-Driven PI — Digitalization and AI as enablers

Where do you see PI going with new developments in digital solutions, data analytics, and AI?

For process intensification, especially in connected processes, real-time data is critical. Process analytical technology (PAT) and the ability to measure and optimize control in real time are essential, which means you need access to all relevant data. The automation and digital solution layers are vital, and advanced process control tools — like data analytics and AI — are key to processing this data and dynamically improving set points. The progress enabled by these digital tools will be significant, and Sartorius is paving the way to help customers leverage these advancements.

Gerben Zijlstra
Senior Expert Bioprocess Solutions, Sartorius

What innovations do you see in process automation that will help with the adoption of continuous processing?

The biggest innovations aren't just in automation itself, but in how we integrate automation. For true process intensification, customers need modular automation solutions. This means suppliers who don't usually collaborate will need to work together. We need seamless integration — like a Bluetooth headset connecting to a mobile phone — across vendors in biopharma. Standards like OPC UA and Modular Type Package will be critical for enabling process units to communicate with different orchestration platforms in the future.

Steve Miller
Market Development Manager DSP Digitalization, Sartorius

PAT and advanced analytics — Transforming process control

How does Raman spectroscopy compare to other PAT techniques, and what impact has it had on quality and efficiency in biologics production?

Raman is an incredibly sensitive technology, which is fantastic for getting very accurate readouts. It also allows us to monitor several attributes simultaneously, enabling us to develop models for various metabolites in upstream and other parameters in downstream processes. Raman and other PAT tools are critical for process intensification, providing real-time monitoring and control for decision-making on the manufacturing floor. Traditionally, like many in the industry, we collected samples throughout the process for offline analysis in quality-control labs, which created bottlenecks.

Using Raman allows us to bypass this step and access real-time information, significantly improving process efficiency and ensuring higher quality outcomes.

When setting up this model, we leveraged expertise and tools from Sartorius, including SIMCA® software and SIMCA® Online, which were invaluable for model development and implementation.

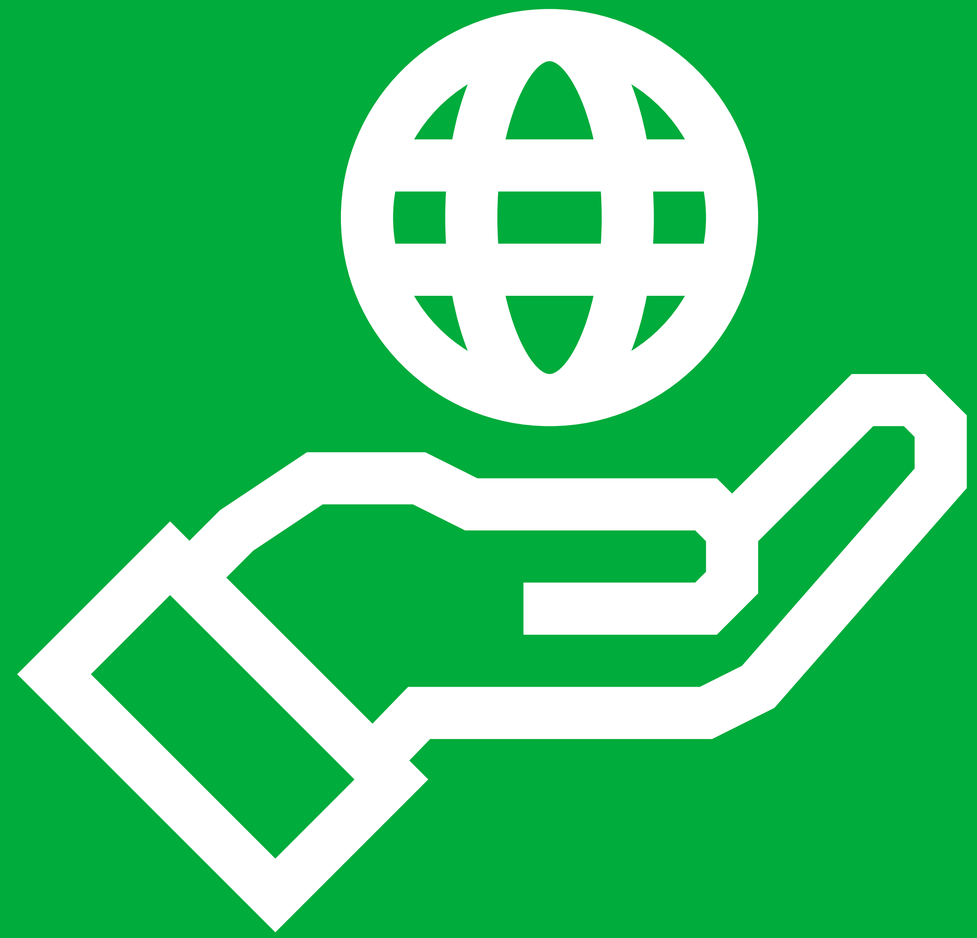
Courtney Hazelton-Harrington,
Senior Scientist, Research & Development,
Lonza Biologics

Do you see any innovations in automation that can speed technical transfer between the phase of a molecule's journey to the market?

Speeding up tech transfer will depend on automation solutions that suppliers provide, which can be used with user interfaces and self-contained process units, especially in PD. When moving to commercial manufacturing, companies want to use their traditional distributed control systems. Having a common automation platform that works in both PD and commercial manufacturing will be key. The deployment, use, and integration might differ, but the underlying automation should be the same. This is a key innovation needed in the industry.

Steve Miller
Market Development Manager
DSP Digitalization, Sartorius

From efficiency to sustainability — The role of PI and collective action



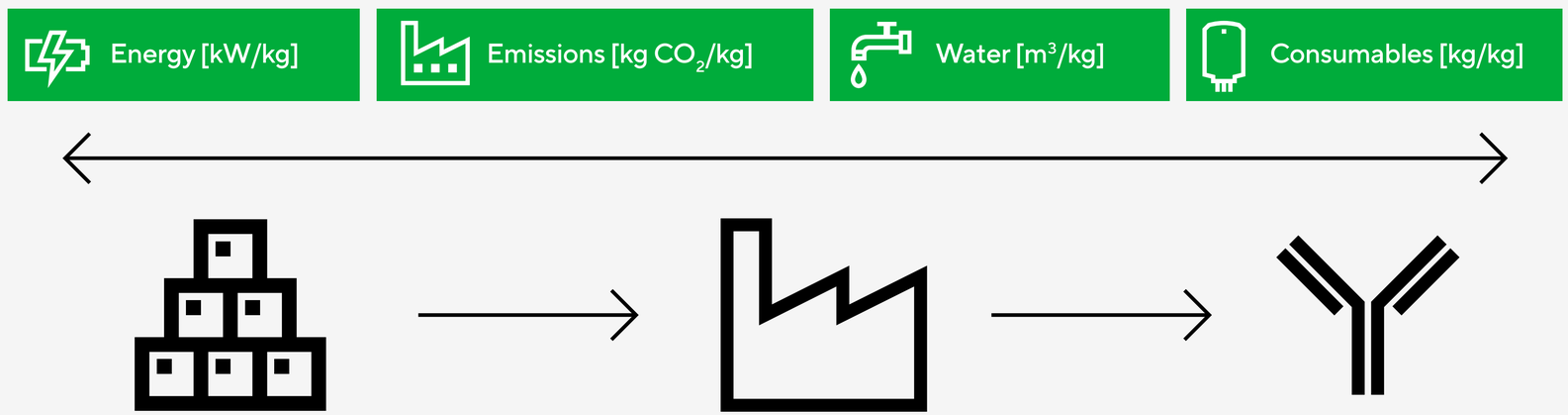
PI and sustainability—Doing more with less

How does PI contribute to sustainability goals?

Plastics are a major concern in biotech, but they're not the only environmental impact—energy, water, and other consumables also matter. PI means achieving higher output with fewer resources, leading to fewer runs, batches, and less material use. If we can increase yield per experiment or batch, we use fewer reactors, less energy, and fewer materials. Combined with recycling, PI can make the industry more sustainable overall.

Eric Sorge
Associate Scientist, Merck & Co

Environmental impacts of biomanufacturing



Manufacturing 1 kg of mAb requires 1,000s kW of energy and m^3 water, producing 1,000s kg of consumables waste and CO_2 emissions in scopes 1 and 2*

*Reference: Behnam Partopour, David Pollard, Magali Barbaroux, Toward Sustainable Biomanufacturing via Single-Use Technologies, Chemical Engineering Progress (CEP), 121 (7), 39-46. July 2025

How does intensified continuous manufacturing contribute to sustainability?

Higher productivity means we can produce more with less—using fewer input materials and smaller bioreactors and downstream processes. This not only reduces costs but also significantly lowers the amount of raw materials needed per kilogram of monoclonal antibody produced. In this way, we address both sustainability and cost requirements at the same time.

Carbon footprint comes from energy, HVAC, water consumption, and the grades of your facility rooms. Continuous manufacturing aims to reduce these areas—smaller facility footprints mean more closed systems, which require higher-grade clean rooms but less energy. With a smaller process footprint, water requirements decrease, especially since single-use systems can replace stainless steel, eliminating the need for CIP and SIP.

All these factors contribute to sustainability goals, such as achieving a low or even zero carbon footprint, which many customers are striving for.

Sustainability is closely tied to your operational footprint, and with our continuous platform, that footprint is much smaller. We're seeing clear sustainability gains—about 40 to 50% improvement compared to standard fed-batch processes. We're also taking a more holistic look to identify even more ways to enhance sustainability. But even now, it's clear that continuous processes offer a significant sustainability advantage over traditional methods.

Example of efficiency gain with fully continuous process vs intensified optimized fed-batch (IO-FB)

-24% annual **costs**

-51% facility **area**

-57% plastic **waste**

-54% CO_2 process **emissions**

*Multi-product facility with 2,000 kg/yr annual throughput Reference: Behnam Partopour and David Pollard, "Advancing Biopharmaceutical Manufacturing: Economic and Sustainability Assessment of End-to-end Continuous Production of Monoclonal Antibodies", Trends in Biotechnology, 43(2) 2025: 462–475; https://doi.org/10.1016/j.tibtech.2024.10.007.

Behnam Partopour
Principal Scientist, Advanced Bioprocessing, Corporate Research, Sartorius

Priyanka Gupta
Senior Expert Bioprocess Solutions, Sartorius

Himanshu Gadgil
CEO, Enzene Biosciences Ltd

Enabling sustainable operations—Technology and regulatory momentum

Are regulators and customers pushing harder for more sustainable processes?

Yes, regulators like the FDA have been advocating for continuous manufacturing for over 15 years, aiming to improve drug accessibility and lower costs for patients. Automation and advanced process control also enhance drug quality and reproducibility. Additionally, process intensification reduces the process footprint, which allows for the design of smaller clean rooms.

Smaller cleanrooms require less extensive HVAC systems, and since HVAC is typically the largest energy consumer in pharmaceutical facilities, this leads to significant energy savings. Both regulators and clients are clearly pushing for more sustainable facilities, and process intensification is a key part of the solution.

Miriam Monge
Head of Customer and Industry Advocacy Bioprocesss Solutions, Sartorius

How does the combination of Sartorius ProcessGo® platform and G-CON POD® cleanroom platform enhance sustainable manufacturing?

Sartorius designs continuous process platforms that reduce the overall footprint and automate processes, which fits well with G-CON's prefabricated modular clean room solutions. A smaller process footprint means a smaller clean room, less HVAC, and lower energy consumption for operating clean room environments.

Dennis Powers
Senior Vice President of Product & Strategy, G-CON

How can advanced analytics support efforts to intensify bioprocesses—reducing footprint, energy use, and waste?

For years, SIMCA® software has helped companies reduce waste and prevent lost batches of pharmaceuticals. Now, we're applying the same analytics to help them operate more efficiently, both in terms of operations and environmental sustainability goals.

Bob Davis
Sales Development Specialist, Data Analytics, Sartorius

Collaboration—Collective action for industry-wide change

How important is collaboration to reach sustainability goals?

Achieving sustainability won't happen without collaboration. A typical customer-supplier relationship is just a small part of the solution. To close the loop and lower carbon footprints, more parties need to be involved. We've collaborated with our own suppliers to reduce our carbon footprint, and solving plastic waste requires even broader collaboration. Successful examples already exist, and we aim to build on them, creating partnerships across the value chain to drive progress.

Pierre Moulinie
Head of Global Technical Marketing (Healthcare), Covestro

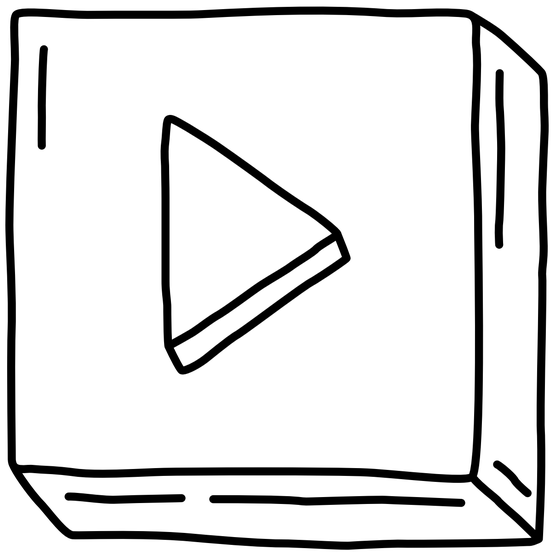
Can you share your experience leading sustainability-focused working groups and how these collaborations are driving industry-wide change?

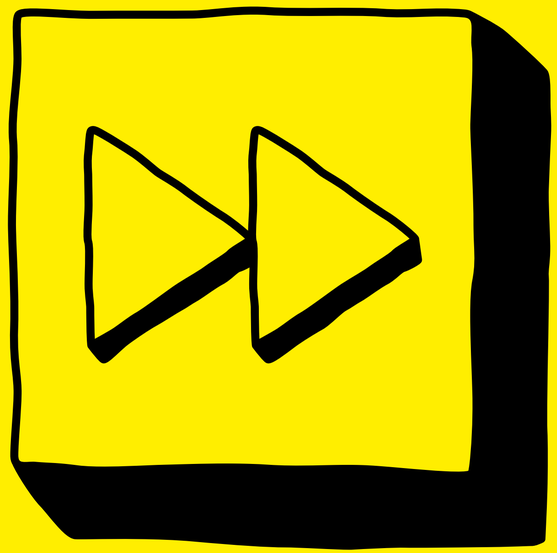
Sustainability is gaining momentum, and nearly every industry group now has a sustainability stream—whether it's NIIMBL, BioPhorum, BPSA, or ISPE. It's crucial to have these discussions in a non-competitive space, as sustainability benefits everyone. Each group brings different attendees and perspectives, so collaboration helps ensure we don't duplicate efforts or leave gaps. Working together allows us to identify common goals and advance the industry.

Magali Barbaroux
Research Fellow, Advanced Materials, Corporate Research, Sartorius

Sustainability and environmental impact require collaboration—no single person or company can make a difference alone. As a vendor, we work with suppliers and end customers, and when all parties including government agencies work together, we can make real changes. These groups bring everyone together with a common goal, regardless of competition or confidentiality. The discussions allow us to share data and create a global resource to understand what's happening across the industry. This collective approach helps drive more environmentally safe facilities and a sustainable future.

Priyanka Gupta
Senior Expert Bioprocess Solutions, Sartorius





Conclusion

Process intensification is no longer a future concept, it’s a present-day opportunity. As the industry navigates complex molecules, smaller production scales, and rising cost pressures, PI offers a pathway to do more with less: higher yields, smaller footprints, and reduced environmental impact.

To fully realize these benefits, the journey toward intensified, continuous, and digitally enabled bioprocessing requires collaboration across the value chain. Manufacturers, suppliers, regulators, and technology collaborators must work together to break barriers and unlock value. By embracing innovation and collective action, we can build a biopharmaceutical ecosystem that is not only more efficient but also more sustainable and resilient for the future.

It’s time to intensify. Learn more at:
sartorius.com/process-intensification

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