White Paper

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Driving Environmental Sustainability in the Biopharmaceutical Industry

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SARTORIUS

Abstract

Sustainability has been part of Sartorius' DNA since its foundation 150 years ago and continues to be one of our key values. We are a major player in the global single-use bioprocess systems market — our product portfolio contains a range of innovative solutions to support more efficient, robust, and sustainable bioprocessing.

As a leading partner in the biopharmaceutical industry, Sartorius is committed to contributing to a future where more people have access to effective and affordable healthcare. With its business model, Sartorius directly contributes to the United Nations' Sustainable Development Goal 3: Good Health and Well-Being. The COVID-19 pandemic highlighted the importance of such endeavors, and the rapid deployment of single-use biomanufacturing technologies made accelerated vaccine rollouts possible. At the same time, we are mindful of the environmental impact of our activities.

In this white paper, we consider our environmental footprint over four core themes: climate action, water use efficiency, materials and circularity, and partnerships. We discuss how our bioprocess solutions and expertise empower biopharmaceutical manufacturers to make their own processes more sustainable by adopting single-use technologies, improving process efficiency, and forging productive collaborations.

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”...it is a fact that without single-use technology and its characteristic agility, the COVID-19 vaccines available today could not have been developed and manufactured at the speed with which they were.”

(Eibl and Eibl, 2022, p1871)[1]

Prof. Dr. Regine Eibl

Prof. Dr. Dieter Eibl

Zurich University of Applied Sciences, Department of Life Sciences and Facility Management, Institute of Chemistry and Biotechnology

Introduction

In 2015, the countries of the United Nations General Assembly adopted the 2030 Agenda for Sustainable Development, which included 17 Sustainable Development Goals (SDGs) across economic, social, and environmental factors.[2] Biopharmaceutical companies are essential in supporting these goals, with SDG 3 Good Health and Well-being often being a top priority. The spotlight on environmental impact has historically focused on industrial sectors, such as mining, energy, and automotive industries. The ecological impacts of the healthcare industry, particularly the pharmaceutical sector, is now subject to increased scrutiny.

Sartorius' mission is to accelerate the development of new biotherapeutics, support efficient biomanufacturing, and improve patient access to essential medicines, meaning with our core business, we directly contribute to SDG 3. As a preferred partner of the biopharmaceutical industry, we aim to find efficient and innovative technology solutions to help our clients move scientific discoveries faster into effective patient care while progressing towards common sustainability goals. Single-use (SU) solutions are today used to manufacture biologics across all modalities, for example, monoclonal antibodies (mAbs) for the treatment of cancer or rheumatoid arthritis; the manufacture of life-saving cell and gene therapies for heart disease, diabetes, and immunodeficiencies; and recombinant, mRNA, and viral vaccines.

SU technologies for biopharmaceutical manufacturing were introduced in the early 1990s. There were multiple reasons for their introduction (see page 7). Firstly, they offer an opportunity to reduce the risk of contamination observed in stainless steel systems as a result of poor cleaning efficiency, remaining detergents, and sterility breaches. SU technologies are safer and can be deployed more rapidly in manufacturing facilities, shortening time-to-market for new life-saving therapeutics.

As the biopharmaceutical landscape became increasingly dynamic and fast-paced, drug developers and manufacturers faced mounting challenges, including pressure to reduce costs, reduce time-to-market, and meet rigorous quality requirements. SU technologies were a key way to overcome these hurdles.

An additional driver was that existing stainless steel manufacturing facility designs had not evolved significantly for many years. They are large, energy- and water-intensive, and require cleaning and steaming processes. Despite the reliance of SU bioprocessing solutions on plastic, these technologies enable significant sustainability advantages, with an overall reduction in environmental impact in the biomanufacturing process (see page 7).

Finally, SU solutions offer enhanced flexibility; stainless steel processes are inherently inflexible, which makes it difficult to redesign a facility to respond to changing needs. For protein-based biologics, which today make up the bulk of biomanufacturing capacity, fewer than one in ten drugs in the pipeline actually make it to market. The attrition rate might be even greater for newer modalities such as cell and gene therapies. This high failure rate means facilities were often built for molecules that did not reach commercial production. Bearing in mind the lengthy construction time of traditional stainless steel facilities, drug developers were often forced to repurpose them to manufacture products for which they were not inherently designed, resulting in inefficient production processes with oversized utilities. Selecting flexible SU solutions can delay capital investment until there is more certainty about drug approval and ensure more efficient biomanufacturing facility use.

These reasons—along with process improvements leading to increased titers—have driven downsizing in the scale of equipment required for biomanufacturing. This has enabled a broader industry deployment of SU technologies from process development to clinical scale and commercial manufacturing.

We are now in a phase where companies are exploring how they can increase efficiency in their biomanufacturing through process intensification, particularly for mature modalities such as mAbs (see page 11). This approach aims to improve the overall efficiency in manufacturing in other industries in terms of cost, quality, and related energy and water savings, discussed in detail later.

As we move towards more efficient ways of producing therapeutics, one crucial element is process sustainability and how our manufacturing choices impact the environment. The biopharmaceutical industry contributes to a relatively low amount of global plastic waste, estimated at around 0.01%.[3] However, the rapid growth of the market calls for responsible plastic use, such as using renewable resources during manufacturing and improving post-use handling through increasing material circularity.

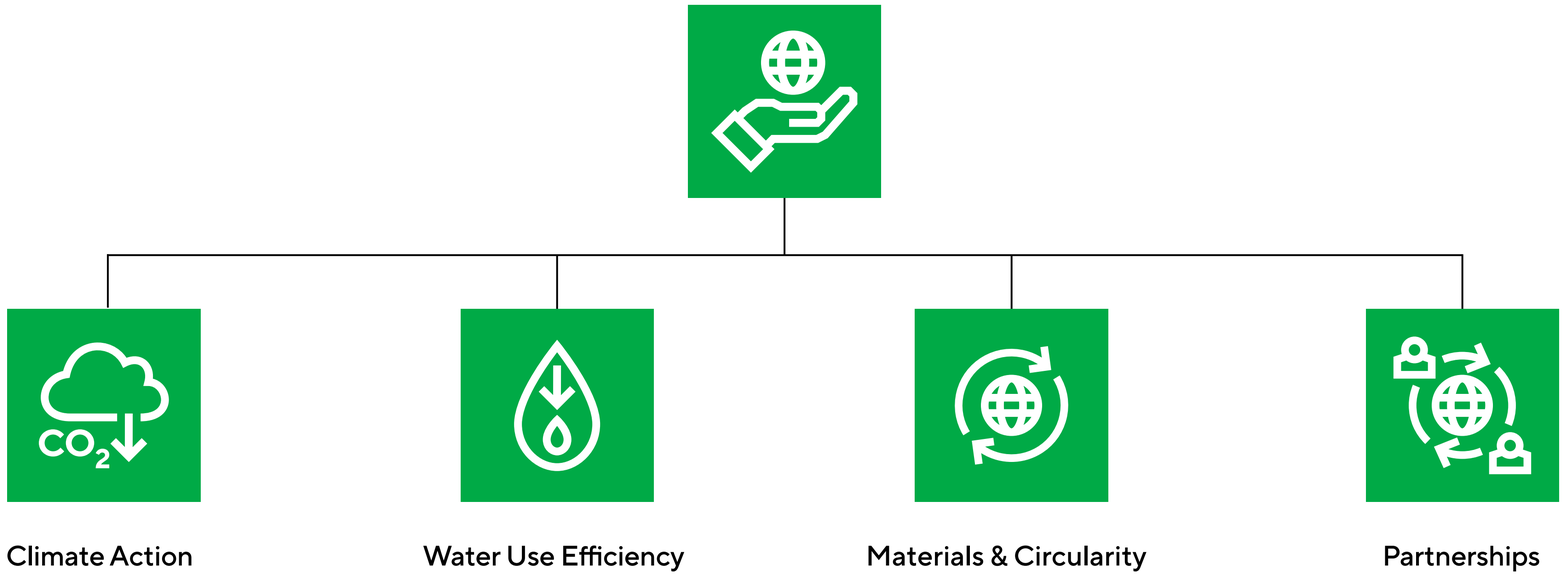
Clever implementation of SU technologies and process intensification offers an extraordinary opportunity to significantly reduce the consumption of energy and water. With mounting evidence compounded by the recent pandemic and rapid climate change, it is indisputable that the planet's natural resources are not infinite and should be used carefully.

As such, customers, end-users, regulatory bodies, and other stakeholders are increasingly looking for partners who prioritize sustainability.

Sustainability opportunities for the biopharmaceutical industry are to reduce environmental footprint, strive against resource depletion, and manage waste repurposing and recycling. As part of our role as an important partner in the industry, Sartorius is aiming to champion sustainability through setting a good example — we are implementing sustainable practices in our own processes, carefully choosing partners who share our sustainability values, and providing products and services to help our customers and partners prioritize sustainability. Our corporate sustainability program is currently exploring the opportunities outlined in Figure 1.

In this white paper, we detail how Sartorius strives to support our clients in biopharmaceutical development and manufacturing in reaching their sustainability goals without compromising their delivery of patient care solutions. We also discuss the significance of choosing technologies and manufacturing processes to boost environmental sustainability.

Figure 1: *Key Environmental Sustainability Themes Identified by Sartorius*



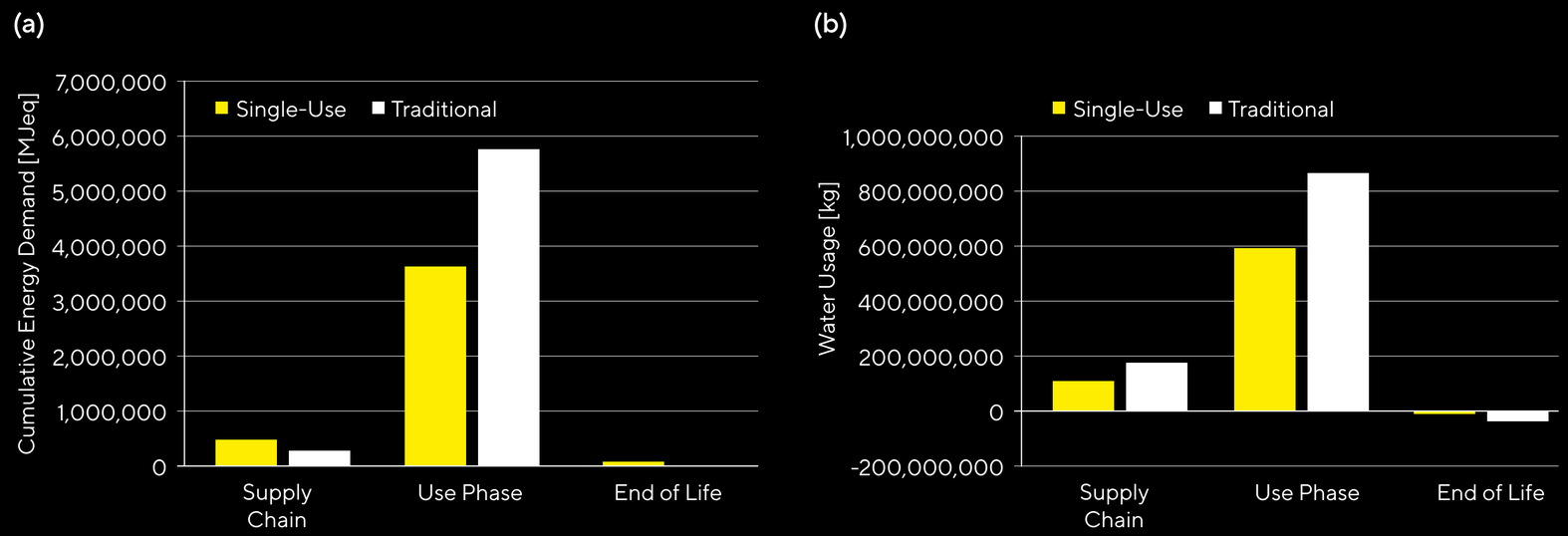
Highlight

Single-Use Solutions in the Biomanufacturing Industry

SU technologies are increasingly employed in modern biopharmaceutical manufacturing as an alternative to traditional stainless steel solutions, owing to their contributions towards reproducibility, flexibility, time efficiency, and safety. These technologies are implemented across the bioprocess workflow from cell line development to final filling, including storage bags, mixers, bioreactors, tubing, filters, chromatography systems, and sensors.

The adoption of SU technologies helps the industry reach environmental goals and strive against resource depletion, particularly water, energy, emissions, and footprint reduction[4] (Figure 2).

Figure 2: *The Impact of SU Solutions on (a) Energy Consumption and (b) Water Use.*



Note. Data From Flanagan et al (2011).[4] LCA of a mAb process at 2,000 L scale

Reasons for Industry Adoption of SU Technologies

- Improved consistency in manufacturing processes
- Flexibility to design a purpose-built facility and the ability to amend SU technologies as needed
- Fast process deployment and changeover
- Less initial investment in fixed equipment enabling significant cost-savings
- Reduced water use due to the elimination of steaming and cleaning procedures (Figure 2)
- Smaller facility footprint reduces the requirement for HVAC, the most significant factor for energy usage in the facility[5,6]

Key Single-Use Offerings at Sartorius

Linkit® AX with Flexsafe® Single-Use Bags

Celsius® FFT Freeze & Thaw Solutions

Maxicaps® MR

Sartopore® Platinum – Twin Pleated Technology

Biostat STR® Bioreactors

Resolute® BioSMB

Ambr® 250HT Perfusion

Opportunities to Improve Environmental Sustainability

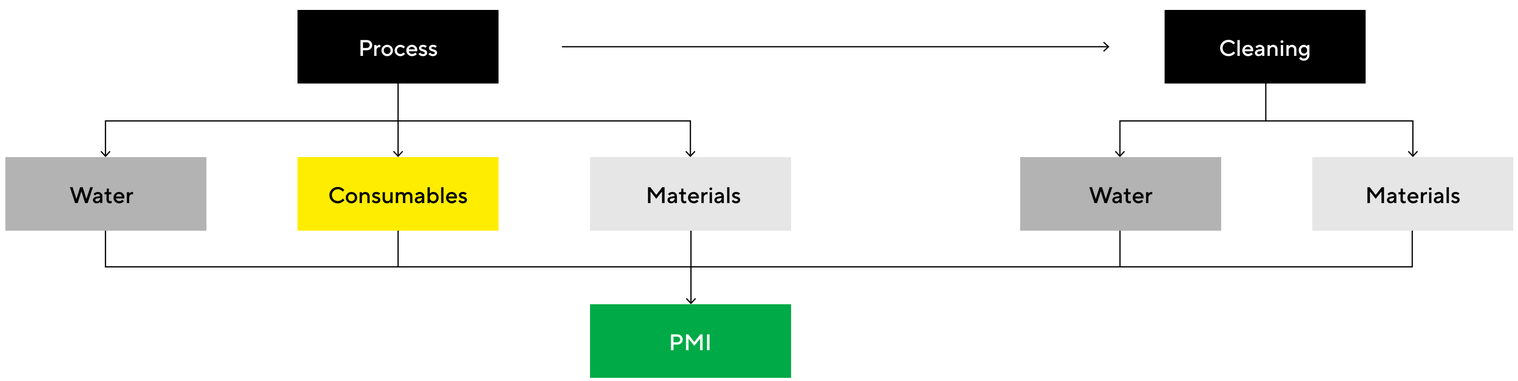
Measuring Sustainability

Before taking action to limit the environmental impact of a facility or process, it is crucial to understand how sustainability is measured. Metrics in this space are constantly evolving — for example, the topic of circularity requires further development. No unique key performance indicator accurately represents all aspects of sustainability.

Various indexes are used to characterize how a biomanufacturing facility and related bioprocesses impact the environment, including plastic disposal, supply chain footprint, greenhouse gas (GHG) emissions, energy sources, and water consumption.

Process mass intensity (PMI) is a metric employed within the biopharmaceutical industry to measure the environmental impact of the drug substance relative to its mass. It can therefore serve as a proxy for sustainability.[7] PMI is calculated by determining the total mass of raw materials, consumables, and water, divided by the total mass of the drug substance produced annually by given biomanufacturing methodologies in a facility (Figure 3). Biopharm Services developed a PMI tool within their BioSolve modeling software,[8] which is a calculator used by industry groups such as the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) and large pharmaceutical companies.

Figure 3: *Process Mass Intensity (PMI) is a Valuable Measure of Sustainability in Bioprocesses*



Calculation of Total PMI

$$\text{Total PMI} = \frac{\text{Total water, raw materials, consumables used (kg)}}{\text{Product (kg)}}$$

”Through intensification, you can reach some of your corporate sustainability goals, including reduced water use, footprints, and electrical capacity.”

David Pollard
Head of Advanced Bioprocessing, Corporate Research at Sartorius

PMI calculations reveal valuable information about how changes to facility operations—for example, adopting SU tools (see page 7) or process intensification activities (see page 11)—impact sustainability performance.

Once the PMI is determined, inputs derived from BioSolve modeling software contribute to the development of full life cycle assessment (LCA) calculations. This approach takes into account not only the process factors used to calculate PMI, but also the supply chain, HVAC, and disposal processes to calculate the impact of the process and facility. This is translated into impact results such as CO_2 equivalents (carbon footprint), energy footprint, and water consumption over the entire lifecycle. LCA results also reveal how the process influences human health, ecosystems, and resources. LCA can be considered a tool to transform complex models into more actionable results to identify hotspots for improvement. The scope and assumptions (functional units, included and excluded flows, the database used, and more) are critical in interpreting the results and require specific knowledge and care.

Process Intensification

A Case Study

Process intensification describes a holistic framework for improving the overall efficiency of production. It offers greater volumetric productivity while reducing waste and energy consumption, contributing to improved sustainability.[9]

In the biopharmaceutical industry, intensified processing can be applied both upstream and downstream. Upstream strategies have been the primary focus of intensification efforts so far and mainly involve perfusion cell culture, either in the seed train or in the production bioreactor. Downstream intensification strategies typically involve integration of several unit operations into one single flow-through step, creating continuous processes which are faster with higher yields.

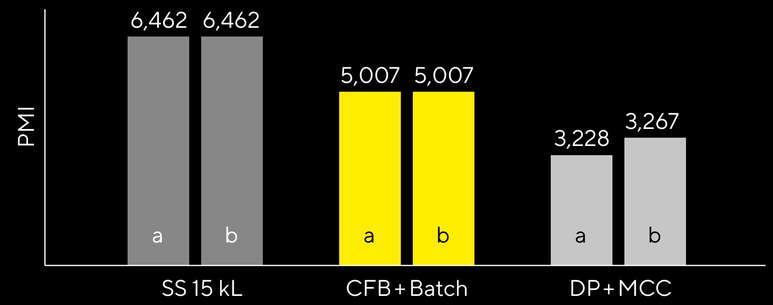
To assess the impact of process intensification on sustainability measures, Sartorius performed an in-house study using the sustainability matrix feature within the industry-recognized BioSolve modeling software. In our studies, the most significant impact was a 50% reduction in PMI with both upstream and downstream intensification (and SU technologies) compared to traditional stainless steel operations (Figure 4).

Additionally, although cell culture media usage increased in intensified operations, water consumption was still lower than in traditional processes.

Downstream process steps (specifically chromatography steps) are the most water-intensive operations of the entire biologics manufacturing process train. Multi-column chromatography (MCC) enables column overloading and thus increases resin utilization and reduces column size.[10] MCC also results in up to a 50% reduction in buffer consumption, an often-overlooked area. Combining these strategies with inline buffer dilution reduces footprint because it allows the storage of higher concentration buffers.

In summary, higher-yielding processes that are completed in less time, with an optimized number of process steps, enable a smaller process footprint within the cleanroom. This creates more compact manufacturing facilities with lower HVAC requirement, driving significant reductions in environmental impact. Next-generation facilities will combine process intensification scenarios with single-use solutions to maximize efficiency and limit environmental impact.

Figure 4: *Process Intensification Strategies Help Limit PMI*



Note. (a) 300 kg/year and (b) 1,500 kg/year throughputs.
PMI was measured for a traditional stainless steel fed batch process (SS 15kL), and two process intensification scenarios: an upstream SU concentrated fed-batch process followed by standard batch downstream process (CFB + Batch), and an SU dynamic perfusion (DP) process (continuous feed and harvest of the product through microfiltration), with downstream multi-column chromatography (DP + MCC). Data was generated using BioSolve modeling software.

Core Themes Across Sartorius' Environmental Sustainability Approach

- Climate Action
- Water Use Efficiency
- Materials & Circularity
- Partnerships

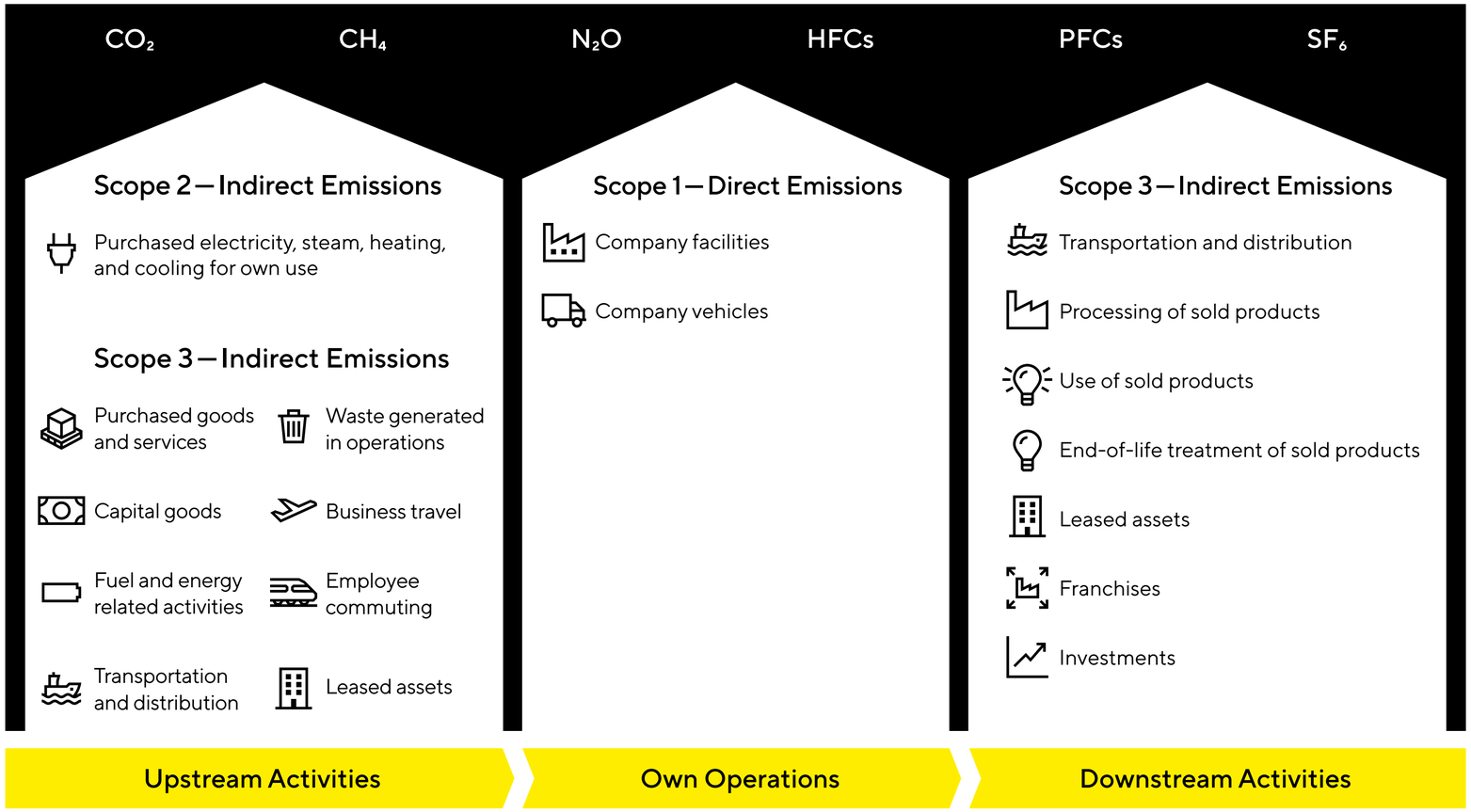
Climate Action

Climate Action

The health sector accounts for approximately 4 - 5% of global GHG emissions.[11] Given the current carbon intensity and the biopharmaceutical sector's accelerated growth, it is critical and timely to examine opportunities to cut carbon emissions across the industry. GHG emissions according to GHG protocol consist of three scopes (Figure 5).[12]

As the industry responds to increased demand and competition with more efficient manufacturing strategies, we must consider how these processes and manufacturing choices impact, above all, the climate (see page 11).

Figure 5: *Greenhouse Gas Emissions*[12]



Note. Scope 1 accounts for the company's direct emissions from energy combustion as well as fugitive emissions. Scope 2 accounts for the company's indirect emissions from energy purchased for electricity, heating, cooling, and steam. Scope 3 accounts for the company's further indirect emissions in the upstream and downstream value chain, e.g., for purchasing, products sold, logistics, and travel. Their categorization is complex; they are not the result of activities owned or controlled by an organization but by those up and down its value chain.

Sartorius´ Approach

Sartorius has over thirty production sites where our processes consume energy, release greenhouse gases, and produce waste. Approximately 0.025% of emissions from the health sector can be attributed to Sartorius.[13] Although our activities have a relatively minor influence on the industry, we see it as our duty to reduce our environmental impact as well as help our clients achieve their climate targets. We strive to make substantial efforts to limit our impact at our sites worldwide and in our value chain.

In the future, we aim to continue growing strongly while reducing our carbon footprint. Therefore, we are focusing on CO_2 emission intensity, defined as emissions volume in relation to revenue. We're aiming to achieve an ambitious average reduction of approximately 10% per annum over all emission categories. Our target is to reduce both scope 1 and 2 GHG emissions to zero by 2030. The target is subject to the reduction of unavoidable process emissions generated during membrane production as well as the availability of renewable energy at global locations. The analysis of scope 3 emissions is more complex and necessitates consideration of numerous interdependencies within the supply chain. Some 40% of the total emissions attributable to Sartorius occur in the upstream value chain, i.e., in connection with purchased goods, services, and business travel.

The largest share of emissions — roughly 50% — occurs in the downstream value chain, including the transportation of our products to customers as part of the products' further use and their disposal at the end of their life cycles. However, a large proportion of scope 3 emissions can only be reduced in partnership with our suppliers, transport contractors, and customers. We strive to support and expand these kinds of partnerships.

As a leading partner in the biopharmaceutical industry, we've made it a priority to provide product and process solutions that help our customers reduce their carbon footprint and achieve their sustainability goals.
Our product portfolio supports intensified processing, from minor adjustments within unit operations to building entire intensified manufacturing facilities. Implementing these solutions shrinks facility footprint and, as a result, contributes to reduce the carbon footprint.[9] Key products include perfusion-enabled Biostat STR® and Biostat® RM bioreactors, Resolute® BioSC or Resolute® BioSMB MCC platforms, and flow-through technologies like SU membrane chromatography which are suitable for different intensified processes and enable small, modular single-use facilities.

Our analytics software also empowers drug manufacturers to make data-driven decisions toward improving environmental sustainability in their processes. The Umetrics® Suite consists of tools that offer process insights and control to maximize efficiency and sustainability. For instance, staff at Michigan State University used multivariate data analysis (MVDA) to reveal operational changes that could potentially save more than $1 million USD per year in fuel and capital expenses, reduce carbon emissions, and extend equipment lifetime (see page 16).[14]

Our environmental policy is binding for all companies and sites in the Sartorius group. This approach helps us uphold a strong environmental position and maintain transparency with our internal and external stakeholders.[15]
As part of this policy, we work with our partners to ensure they offer a range of services that helps reduce greenhouse gases. In addition, our Code of Conduct for Business Partners states, "Energy-related services, including energy efficiency, energy use, and energy consumption, must be continuously improved through appropriate energy management and conscious action as well as by raising awareness among employees."[16]

Umetrics® Suite of Data Analytics Tools Help Drive CO_2 Reduction

"SIMCA® – the MVDA software from Sartorius – has processed data and isolated results for utility production and consumption using over 20,000 variables for a major research university campus of over 60,000 people. From that data and using a phased approach, **MVDA revealed plant repair and operational improvement opportunities that have been able to save or avoid substantial expense.**

Phase I, which was a pilot, achieved a reoccurring savings of approximately $120,000 USD in a single year and prevented 780 metric tons CO_2e. Phase I work also avoided further costly equipment damage by identifying the root cause of lubrication problems on high-speed electrical equipment. Encouraged by the success of the pilot, **Phase II** is presently in action with a more ambitious sustainability goal.

The goal in Phase II is to save $1 million USD per year and avoid approximately 10,000 metric tons CO_2e at prevailing fuel costs.

The diverse project team includes MSU plant engineering staff and faculty, students studying engineering, the local utility provider, and Sartorius engineers and data scientists."

Nate Verhanovitz
Performance Engineer Michigan State University

Highlight

Sartorius´ Key Environmental Sustainability Achievements

A Signatory of the United Nations Global Compact

The United Nations Global Compact is an initiative to encourage businesses worldwide to adopt sustainable and responsible practices.

The First Company in Our Sector to Sign the European Plastics Pact

The European Plastics Pact is a public-private coalition aiming to accelerate the transition towards a European circular plastics economy.

Solvent Circularity at Our Göttingen Facility

Organic solvents used during the manufacturing of membranes for filter cartridges are sent to a reprocessing plant on-site so that solvents can be reused in production operations. This way, we maintain closed-loop material cycles, minimize transportation requirements, and reduce the quantities of water used and wastewater produced.

Flexsafe® — The First Film Designed for Recycling

We have a strong partnership with our supplier Südpack for manufacturing S80 (Flexsafe®) and S71 (Flexboy® and Celsius®) ultrapure barrier films, which can be mechanically recycled in standard waste streams for polyethylene. Film trims are collected during extrusion, and our film manufacturer grinds all unused material for reuse in other applications such as food packaging.

A First Step to Optimize Waste Management of Our Filtration Consumables

Maxicaps® Sterile Filters are now packaged with 58% less cushioning material, reducing the overall weight by 28%. Now 30% more products can fit on a pallet, resulting in approximately 140 fewer delivery trucks.

We redesigned and repackaged Maxicaps® MR to be more eco-friendly with a lower storage space requirement. The new multi-use holder and filter capsule-to-capsule connection save approximately 15 kg (33 lbs) of plastic material (based on Maxicaps® MR6), representing an 80% reduction for these two assemblies compared to the previous generation.

Finally, Sartopore® Platinum was designed for excellent wettability to save water or high-value product solution during the flushing step. Sartopore® Platinum also offers a 40 – 60% higher filtration area compared to our other sterile filters. This results in lower shipping efforts and less waste for the same filtration area.

Water Use Efficiency

Water Use Efficiency

In this chapter, we focus on the potential water use efficiency improvements linked to the adoption of SU technologies and process intensification strategies.

Biologics manufacturing is a water-intensive operation. A benchmarking study used PMI analysis to determine that 90% of mass consumed during the production of a biologic comes from water.[7]

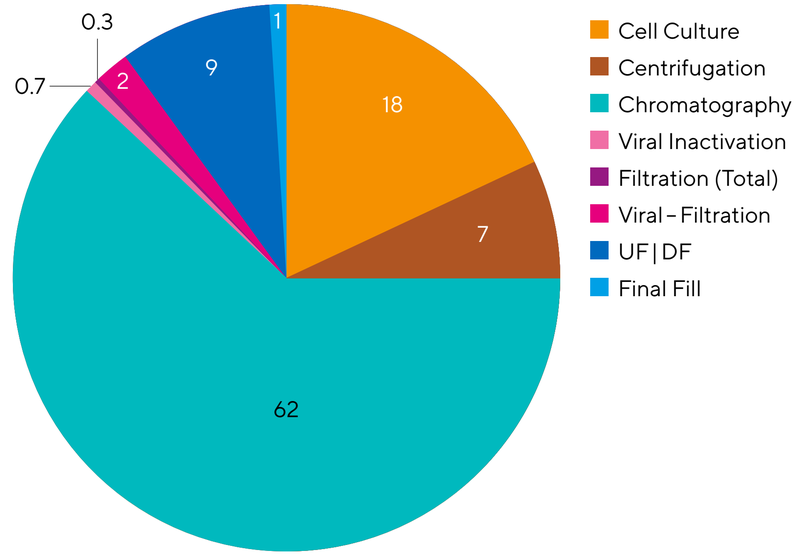
In a traditional stainless steel process, up to 80% of the water consumed comes from clean-in-place (CIP) and steam-in-place (SIP) procedures, meaning stainless steel facilities use significantly more water than their single-use counterparts (see page 7).[6]

Even after excluding water used for cleaning, downstream processes account for 75% of water consumption in a typical fed-batch mAb process.[7] Specifically, chromatography is the most water-intensive step, using more than three times the amount of water consumed during seed train expansion and in the production bioreactor (Figure 6). Therefore, a targeted approach to drive water savings in specific unit operations can result in disproportionate gains toward achieving sustainability goals.

Increasing productivity using MCC, replacing flow-through resins with polishing chromatography membranes, or implementing filtration products with superior wettability significantly reduces overall water and buffer consumption.[10,17,18] In our study, water use was reduced by up to 30% by employing single-use solutions and process intensification (see page 11, Figure 4, and Figure 7).

In summary, biomanufacturing facilities can significantly reduce their water consumption and improve their overall sustainability by embracing single-use technologies and increasing the productivity of the most water-intensive unit operations.

Figure 6: *Total Water Use for Each Unit Operation in a Generic mAb Bioprocess [%].*



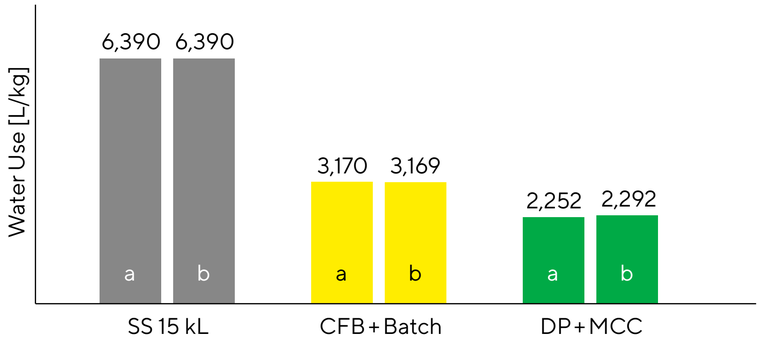
Note. From Budzinski et al (2019).[7] Data includes only process-related activities, not auxiliary steps such as CIP or SIP.

Sartorius´ Approach

Sartorius is a leading provider of solutions to support the implementation of process intensification. For example, the Resolute® BioSMB MCC platform can be used as part of both batch and continuous processes to offer our customers an opportunity to intensify their chromatography process, optimizing an exceptionally water-intensive operation.[10] Additionally, our Sartopore® Platinum filter platform, best known for its excellent wettability due to its modified PES double-layer membrane, significantly reduces required flushing volumes — requiring up to 95% less water than other filters.

In addition to supporting customers with solutions for their bioprocess, efforts have already been undertaken within Sartorius to reduce water consumption at our manufacturing plants. Particular attention has been paid to sites located in baseline water risk areas according to the Aqueduct Water Risk Atlas, such as Beijing (China), Mohamdia (Tunisia), and Göttingen (Germany).[19,20] Finally, the solvent circulation at our Göttingen plant also helps minimize the quantity of water used and wastewater produced (see page 17).[19]

Figure 7: *Process Intensification Combined with SU Technologies Supports Reduced Water Use*



Note. (a) 300 kg/year and (b) 1,500 kg/year throughputs. Water use (L/kg) was measured for a traditional stainless steel fed batch process (SS 15 kL), and two process intensification scenarios: an upstream SU concentrated fed-batch process followed by standard batch downstream process (CFB + Batch), and an SU dynamic perfusion (DP) process (continuous feed and harvest of the product through microfiltration), with downstream multi-column chromatography (DP + MCC). Data generated using BioSolve modeling software.

Materials & Circularity

Materials & Circularity

Our approach is inspired by the circular economy principles summarized by the Ellen MacArthur Foundation:[21]

1. **Designing out waste and pollution**

2. **Circulation of products and materials to maximize the value of resources**

3. **Regeneration of natural systems by preserving finite materials and exploring renewable resources**

The New Plastics Economy promotes the transition from a linear to a circular economy approach that will recover value from plastic materials and protect the environment from the effects of waste.[22,23] This is particularly important to the biopharmaceutical industry, where SU products offer significant operational and sustainability benefits (see page 7 and Figure 2).

Sartorius´ Approach

Sterile SU plastic products are a core component of our portfolio. However, with SU products come questions about how raw materials are sourced and what happens during a product's lifecycle. We're addressing these aspects by considering our products' environmental footprint and how we can foster circularity.[19]

Sartorius works toward the aspirational objectives of the New Plastics Economy[22] which include design, responsible use, recycling capacity, and the use of recycled content. Our approach is outlined in Figure 8 and listed below:

1. Develop products and solutions that will help the bioprocess industry achieve its goals for emission and circularity. These include single-use and process intensification-compatible products that maximize efficiency while limiting waste, including water, chemicals, and plastic.

2. Select the raw materials best suited for each application. Materials used in the biopharmaceutical industry are carefully selected to be compliant with standards and regulations such as pharmacopeia or REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals, a European Union regulation).[24] This approach prevents plastic from containing potentially harmful impurities.

3. Increase circularity at the beginning and end of life without compromising quality or safety, and pursuing emissions reduction. Sartorius has implemented a database of pre-qualified plastics to streamline its material portfolio. Our approach is to use material grades proven to be consistent, to ease and speed-up validation, reduce material variability, and limit the number of composite materials to enable further recycling. A holistic understanding of the product lifecycle is required with many stakeholders along the pipeline.

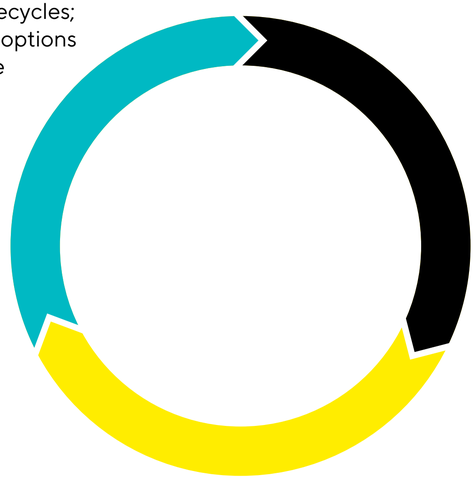
”Sartorius, Sanofi, and Veolia collaboratively explored whether carefully designed plastic parts used in bioprocessing for non-hazardous applications can technically be recycled into raw materials with quality equivalent to pristine grades of polymers.”

Magali Barbaroux
PhD, Research Fellow,
Corporate Research,
Sartorius

Figure 8: *Sartorius´ Approach to Materials & Circularity*

Promote Circularity Without Any Compromise on Quality
Understanding recycling barriers at the beginning and end of product lifecycles; investigating options for renewable feedstocks

Enabling our customers to produce more active ingredients with fewer raw materials



Select the Raw Materials That Best Fit the Application
Carefully select raw materials with no harmful chemical residues

The concept of circularity is not new to Sartorius. We have solutions in place to minimize the use of solvents in our Göttingen facility, which accounts for most of our solvent usage (see page 17). We also explore opportunities for plastics circularity in our facilities with initiatives aimed at directing operational waste to recycling streams, such as in Aubagne and Göttingen. Flexsafe® film — introduced to the market in 2014 — was the first film designed for recycling. In collaboration with Sanofi and Veolia, we recently demonstrated the technical feasibility of recycling Flexsafe® films and their quality in the circular economy.[25] Work is ongoing to overcome large-scale recycling challenges.

Today, we are identifying and analyzing all potential opportunities a circular economy offers to help design high-performing solutions to solve industry problems. We are actively working on providing support and building guidance for the industry on the circularity of SU bioprocess solutions. For example, we are exploring the recycling of packaging and products with our key customers. We are also pursuing sources of recycled and bio-circular materials, which could combine circularity and carbon footprint reduction for our solutions.

Finally, we continue to provide support and guide the industry on the circularity of SU products, especially with our material science expertise demonstrated with the development of the Flexsafe® film (see page 25).

Highlight

Sartorius´ Sustainability Goals

Our Group Target Is to **Reduce GHG Emission** Intensity by About 10% On Average per Annum in the Period Until 2030

Compared to 2019 as a base year.

Our Target Is to **Reduce Both Scope 1 and 2 GHG Emissions to Zero** by 2030

The target is subject to the reduction of unavoidable process emissions generated during membrane production as well as the availability of renewable energy at global locations.

Sartorius Is Working Towards Solutions Enabling **Products and Packaging Circularity** in the Industry Oriented Toward Four Aspirational Objectives:

1. Reusability and recyclability
2. Responsible use of resources
3. Collection, sorting, and recycling
4. Use of recycled materials

In the Next Few Years, We Aim to **Expand Our On-Site Capacity** for Renewable Energy

Partnerships

Partnerships

The United Nations Sustainable Development Goal 17 is to enhance global partnerships for sustainable development by sharing knowledge, expertise, and technology.[1] Collaborations within the biopharmaceutical industry are needed to achieve bioprocess sustainability goals that are transparently shared, harmonized, and standardized using comparable and equitable tools.

Fostering collaborations with suppliers, working groups, and regulatory bodies is essential to build a robust sustainability framework. An ideal solution to achieving sustainability goals would combine reducing carbon emissions and water use while implementing the concepts of material circularity. Such a solution relies on modern biomanufacturing principles, such as process intensification and single-use facilities. These are closely and complexly interconnected, and a holistic sustainability solution requires a complete overview of each product's lifecycle from feedstock to end of life — which are all in different hands.

Sartorius´ Approach

One of our demonstrated approaches is to cultivate fruitful partnerships. We commonly strengthen innovation activities through partnerships and cooperation agreements (see page 17). We engage in close and ongoing dialogue with our stakeholders, and we use this exchange to regularly discuss aspects of sustainability.

We also participate in sustainability analyses and ratings to gauge our performance with respect to our environmental practices. We are particularly welcoming of harmonization in the reporting practices in our value chain through shared platforms or frameworks. We communicate our efforts in our GRI (Global Reporting Initiative) report[19] and non-financial group statement[26] and use other reporting platforms such as CDP climate,[27] EcoVadis,[28] Ecodesk,[29] PSCI,[30] and Manufacture 2030.[31]

To set a benchmark for standards in the industry, we set high standards for our partners. Since January 2020, we have been verifying suppliers' compliance with our sustainability requirements via an external evidence-based ESG assessment. Finally, our Code of Conduct for Business Partners provides the basis for collaboration with our partners throughout the Sartorius Group.[16] Since December 2019, acknowledgment of the Code of Conduct has been part of the acceptance process for new suppliers. In 2020, we began systematically reviewing whether our existing suppliers have acknowledged the Code and, if not, asking them to do so.

”Our partnership with Sartorius started more than 10 years ago and is highly motivated by sustainability. The Flexsafe® film we are producing for Sartorius can be recycled and taken back into the material loop and is, therefore, an important milestone on the journey to circularity.”

Valeska Haux
VP Strategic Marketing,
SÜDPACK

Key Sartorius Partnerships

Sartorius collaborates with various industry advocacy, standards, and regulatory groups.

Sanofi | Veolia Working Group
Many end-users have the perception that their single-use systems must be incinerated after use because they are considered "bio-contaminated." To quell some of these assumptions, we worked with Sanofi and Veolia to technically assess the feasibility of recycling Flexsafe® bags following the recycling hierarchy provided in the New Plastics Economy.[25] We evaluated different mechanical recycling steps and characterized the materials generated to determine their suitability for further use.

Results showed that used bioprocessing bags were within the acceptable standard specifications range of the "before-use" original materials of construction.

Collaboration With va-Q-tec
va-Q-tec is a certified carbon-neutral company of temperature-controlled supply chain solutions and a manufacturer of high-tech insulation materials that solve thermal challenges during the transport of pharmaceutical products. As part of their portfolio, va-Q-tec offers multi-use solutions based on advanced passive technology using vacuum insulation panels and phase change material requiring no external power supply, which allows their customers to save energy and reduce waste. In our partnership, we launched the Celsius® FFT | FFT bulk shipper with dimensions fitting the inside of the va-Q-tainer®, a multi-use advanced passive shipper from va-Q-tec.

Industry Consortia

Bio-Process Systems Alliance (BPSA)
The BPSA is an industry-led international association dedicated to encouraging and accelerating the adoption of single-use manufacturing technologies used in the production of biopharmaceuticals and vaccines. Sartorius co-authored three articles published by the BPSA sustainability committee called *The Green Imperative*.[3,23,32] The first paper introduces major themes in the study and implementation of single-use technology for a more sustainable manufacturing environment[2]. The second article in this series outlines current thinking on designing materials, platforms, and processes supporting the "reduce, reuse, and recycle" paradigm of the circular economy for plastic and packaging principles and challenges.[23] The final paper illustrates current and future post-use handling methods and reprocessing technologies.[32]

BioPhorum Operations Group (BPOG)
BPOG is a B2B membership organization with the mission to create an environment where the global biopharmaceutical and device industry can collaborate and accelerate its rate of progress. Sartorius is involved in developing a sustainability roadmap and working groups to reduce plastics and water consumption.

National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)
NIIMBL is a public-private partnership with a mission to accelerate biopharmaceutical innovation, support the development of standards that enable more efficient and rapid manufacturing capabilities, and educate and train a world-leading biopharmaceutical manufacturing workforce, fundamentally advancing U.S. competitiveness in this industry.

NIIMBL has launched a program that includes a 10-year vision until 2029 to design and build bioprocesses to be carbon neutral. Sustainability is considered an essential process design criterion alongside cost, yield, robustness, and quality assurance. Sartorius is involved in different process intensification sustainability working groups such as BioSolve modeling and LCA.

”Our partnership with va-Q-tec helps customers in the biopharmaceutical industry to become more sustainable. The combination of va-Q-tainer® and its pay-per-use rental service with Sartorius´ Celsius® FFT(p) bulk shipper supports the customer in implementing more cost-effective and simplified logistics.”

Marion Monstier
Global Product Manager
Freeze and Thaw Technologies,
Sartorius

Take-Home Message

Front runners in the biopharmaceutical industry are expected to act responsibly and offer improved bioprocessing technologies. This means scoping resource-efficient and innovative technology solutions to transform scientific discoveries faster into patient care while progressing towards common sustainability goals.

We also approach this by implementing better practices throughout the product and packaging lifecycle and strive to ensure that our initiatives on sustainability (climate action, materials and circularity, water efficiency, and more) are in synergy. We know this can only be achieved through collaboration between end users, suppliers, and academia.

Despite their negative reputations today, plastic-based technologies can support sustainability goals in biomanufacturing if used responsibly. To achieve this, we must address concerns arising from plastic waste by ensuring that our practices optimize their use.

Alongside other efforts, responsible consumption and production support the transition to a circular economy. Sartorius is a responsible supplier engaged in sustainability initiatives across the biotech ecosystem. We view our industry collaborations as critical — all stakeholders along the value chain must work together to enact meaningful changes in the industry and beyond.

Climate Impact

Water Use Efficiency

Materials & Circularity

Partnerships

We are keen to establish strong partnerships with all our suppliers and customers in this domain. If you are interested, please reach out to:

sustainabilityforum@sartorius.com

Take part in our survey and help us drive environmental sustainability in the biopharmaceutical industry.

Sustainability survey

Author Bios

Matteo Alaria
Head of Product Sustainability,
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Matteo leads the team dedicated to developing and implementing the Product Sustainability roadmap for Bioprocess Solutions at Sartorius.

Matteo started his journey in sustainability as a consultant. He then joined the sustainability team at Ferrero before moving to Sartorius in July 2022. Across his 13-year career, he has guided companies in their strategic decisions to start, expand or speed up their sustainability journey. He has been setting challenging targets and developing programs to create value for their brands and stakeholders across different industries, including FMCG, chemical, automotive, and food and beverage.

Magali Barbaroux
PhD, Research Fellow,
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Magali works within Sartorius Corporate Research and manages Advanced Polymers research programs, with a strong focus on environmental sustainability and opportunities brought by the New Plastic Economy in biotech processes.

Magali joined Sartorius in 2000 and contributed to the development of bag products, primarily films and tubes, optimizing them for bioprocessing applications. Magali started her career with research into silicone for drug delivery and migration of active substances through polymeric membranes. She now has 30 years of experience in polymer science for healthcare applications.

Katy McLaughlin
PhD, Scientific Content Writer,
Sartorius

Katy is part of the Marketing Communications team at Sartorius, where she supports the creation of a variety of written pieces, from published articles to web content.

Before joining Sartorius in 2021, Katy was employed as a Post-Doctoral Research Associate at the University of Edinburgh, where she also completed her doctoral studies. Here, she carried out research in genetics and cellular biology and began taking on writing projects, eventually entering into a career as a freelance writer for various biotech companies and agencies.

Miriam Monge
Head of Marketing,
Fluid Management Technologies,
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Miriam is Head of Marketing for Sartorius Fluid Management Technologies, where she is responsible for defining and implementing our single-use technology marketing strategy. Her prior roles focussed on building SU process solutions across modalities as Head of Segment Marketing for Proteins and Virus based therapeutics and Director of Marketing for Integrated solutions.

Miriam started her career during the pioneering phase of the SU biopharmaceutical industry as Head of Marketing for Stedim Biosystems. During this period, Miriam founded and chaired the ISPE Disposable Community of Practice, focused on industry advocacy and education around implementing SU systems. She used process modeling tools to demonstrate the value of SU technologies compared to stainless steel solutions. Miriam has authored over 30 publications on single-use technologies and is also a columnist on SU technologies in Biopharm International and a long-term editorial advisor for Bioprocess International.

Katharina Tillmanns
Head of Corporate Sustainability,
Sartorius

Katharina is the Head of Corporate Sustainability at Sartorius. With her team, she develops the sustainability strategy for Sartorius and is responsible for steering and controlling all Sartorius sustainability activities. The team drives the ESG performance and supports the transformation towards more sustainable solutions and accelerated decarbonization.

Katharina is a member of the board of econsense – Forum for Sustainable Development of German Business e.V. and represents Sartorius at the United Nations Global Compact. Before joining Sartorius in 2017, she held various roles in investor relations, public relations, and sustainability communications.

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Abbreviations

BPOG	BioPhorum Operations Group
BPSA	Bio-Process Systems Alliance
CFB	Concentrated fed-batch
CIP	Clean-in-place
DP	Dynamic perfusion
EP	European Pharmacopoeia
ESG	Environmental, Social, and Governance
GHG	Greenhouse gas
GRI	Global Reporting Initiative
HVAC	Heating, ventilation, and air conditioning
LCA	Life cycle assessment
KPI	Key performance indicators
mAb	Monoclonal antibody
MCC	Multi-column Chromatography
MVDA	Multivariate data analysis
NIIMBL	National Institute for Innovation in Manufacturing Biopharmaceuticals
PMI	Process mass intensity
REACH	Registration, Evaluation, Authorization, and Restriction of Chemicals
SIP	Steam-in-place
SS	Stainless steel
SU	Single-use
TFF	Tangential Flow Filtration

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