Toward Sustainable Biomanufacturing via Single-Use Technologies

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Process intensification, recycling innovations, and increased industry collaboration will significantly improve biomanufacturing sustainability and reduce its environmental impact.

The healthcare industry, including therapeutic drug manufacturing, accounts for approximately 4–5% of global greenhouse gas (GHG) emissions *(1)*. Consequently, drug manufacturers, investors, and regulatory bodies are under mounting pressure to reduce the industry's GHG emissions and plastic waste streams.

Reducing emissions necessitates the optimization of manufacturing processes and the responsible sourcing of energy, water, and raw materials. Thus far, transitioning from stainless steel systems to single-use technologies (SUTs) has increased the environmental sustainability of bioprocesses. This is mainly due to a reduction in facility footprints, energy consumption, and water usage *(2)*. Furthermore, process intensification has increased the efficiency and selectivity of biomanufacturing, resulting in lower resource usage and higher throughput. Applying circularity principles to materials such as plastics can also play a key part in waste reduction, but it remains in its infancy. In addition, the ecological footprint of technology providers is interconnected to the final therapeutic product.

This article focuses on current efforts to reduce bioprocess environmental impacts via process intensification and the reduction of material footprints, with the production of monoclonal antibodies (mAbs) serving as the primary example.

Environmental sustainability for bioprocessing

The utilization of plastic in bioprocessing has sparked debate and research around three key sustainability challenges:

- transitioning from stainless steel to SUTs
- determining how to minimize the plastic waste from consumables
- minimizing the fossil feedstocks associated with plastic production, usage, and disposal.

The first issue has been addressed extensively in previously published literature; for example, a case study by Cochet *et al.* demonstrated that energy and water consumption per square meter in a SUT facility decreased by 62% and 80% when compared with an equivalent stainless-steel facility *(3)*, primarily due to the elimination of clean-in-place (CIP) procedures. Therefore, this article focuses on the second and third challenges.

Figure 1 summarizes the plastic waste problems associated with the lifecycle of SUTs and the corresponding solutions to increase environmental sustainability. The research on this topic encompasses all stages of the product lifecycle and collaboration with leading academic and industrial partners in areas such as packaging, polymers, recycling, and design. These efforts explore a diverse range of technologies to enhance environmental sustainability, recognizing that a one-size-fits-all solution does not exist. Instead, we emphasize the development of a comprehensive toolbox of solutions.

Impact of process intensification and continuous processing

Process intensification likewise plays a crucial role in achieving sustainability in biopharmaceutical manufacturing. Enabling higher production rates using fewer resources and thus enhancing manufacturing efficiency significantly reduces environmental impact. This can be done by transitioning from standard fed-batch to intensified and fully closed continuous processes.

Both fed-batch processes and continuous processes can be used for mAb production. In a fed-batch bioprocess, mAbs are produced within a large-scale bioreactor (typically up to 2,000 L). After the cultivation phase, the product-containing cell culture fluid is separated from the cells and undergoes initial filtration. Subsequently, the clarified broth is processed through single-column capture chromatography, followed by a low-pH viral inactivation step. This intermediate product is then subjected to single-column polishing chromatography to further remove impurities, after which it undergoes sequential viral filtration and final filtration steps to yield the purified mAb product.

In contrast, a continuous bioprocess employs a smaller bioreactor (500–1,000-L scale) fitted with a perfusion system that enables continuous cultivation over extended periods. In this setup, the culture fluid is continuously harvested and directly filtered before entering a multi-column capture chromatography system. Following capture chromatography, the intermediate product stream undergoes continuous plug-flow low-pH viral inactivation. The product subsequently passes through multi-column polishing chromatography and continuous viral filtration, concluding with a final purification step using single-pass tangential flow filtration (SPTFF) to obtain the purified therapeutic mAbs with >99% purity.

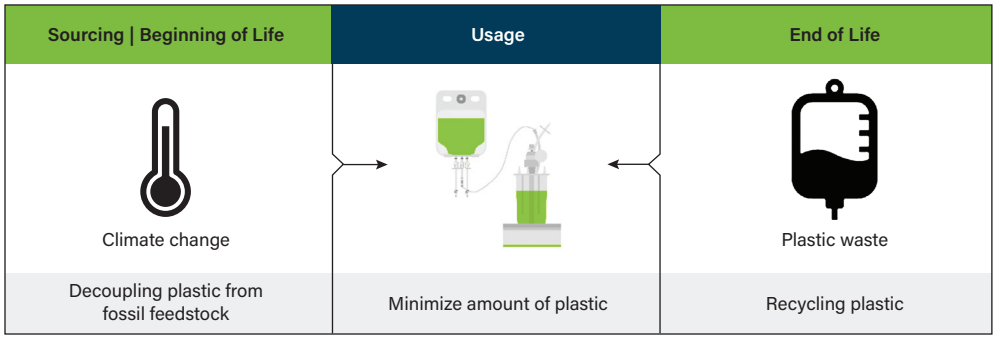
We have conducted an extensive analysis of the environmental impacts of such continuous processes, averaging industry values for critical process and facility parameters using BioSolve software. Figure 2 depicts the results of our comparison between intensified fed-batch and end-to-end continuous processes under the assumption of similar total annual throughput, highlighting the advantages of continuous processing. Continuous processing enhances process selectivity, resulting in:

- at least a 24% reduction in overall costs
- up to 51% reduction in the facility processing footprint taken up by process equipment
- up to 57% reduction in plastic waste
- up to 54% reduction in CO_2 emissions.

These findings underscore the alignment of economic and sustainability goals through the adoption of continuous processing *(4)*.

The impact of continuous processing on plastic waste reduction is further illustrated by the differing shares of cost and waste in fed-batch and continuous processes. For example, in fed-batch processes, filters constitute the dominant source of consumable waste and costs. In continuous processing, non-product contact bags represent the primary contributor to plastic waste, while filters still have the highest share of consumable costs. However, this trend changes as manufacturers move toward using concentrated buffers and in-line dilution and conditioning. Therefore, continuous processing generates less waste from product-contact consumables due to extended use.

A sensitivity analysis on critical process efficiency metrics was also performed. The results propose that recent improvements around titer, perfusion rate (expressed in vessel volumes per day [VVD]), and downstream processing (DSP) yield have resulted in significant reductions in plastic, water consumption, and CO_2 emissions. However, additional changes can still result in considerable environmental improvements. For example, an additional 50% increase in



◀ **Figure 1.** To improve the environmental sustainability of biopharmaceutical manufacturing, plastic usage must be minimized, and the way in which plastics are sourced and disposed of should also be considered. The direct climate impact of plastics is due to their CO_2 emissions from fossil fuels during the manufacturing stage.

titer, a 60% reduction in VVD, and a 10% increase in DSP yield would result in a 25% further reduction in emissions, a 20% further reduction in consumables waste, and a 10% further reduction in water usage, respectively. These values maintain process intensification as the most attractive option for continuing to reduce biomanufacturing environmental impacts.

Finally, considering an average value of 4.8 kg of CO_2 emissions per kg of plastics *(5)* used in the discussed manufacturing process, the analysis shows that on average, plastics contribute to less than 10% of the total facility CO_2 emissions of a state-of-the-art mAb production facility (capacity of 1,000–2,000 kg/yr). Consequently, plastics are not a major contributor to the total emissions of biomanufacturing. Nevertheless, the management of plastic waste is still an important issue. This analysis showed that, to address the largest source of plastic waste from intensified bioprocessing, efforts should be focused on prioritizing the development of recycling strategies for bags and plastic vessels.

It should be noted that these estimates are based on average values available to date, reported for different types of plastic from various sources. More detailed analysis using specific SUT plastic tools is expected to become available in the coming years.

Plastic circularity

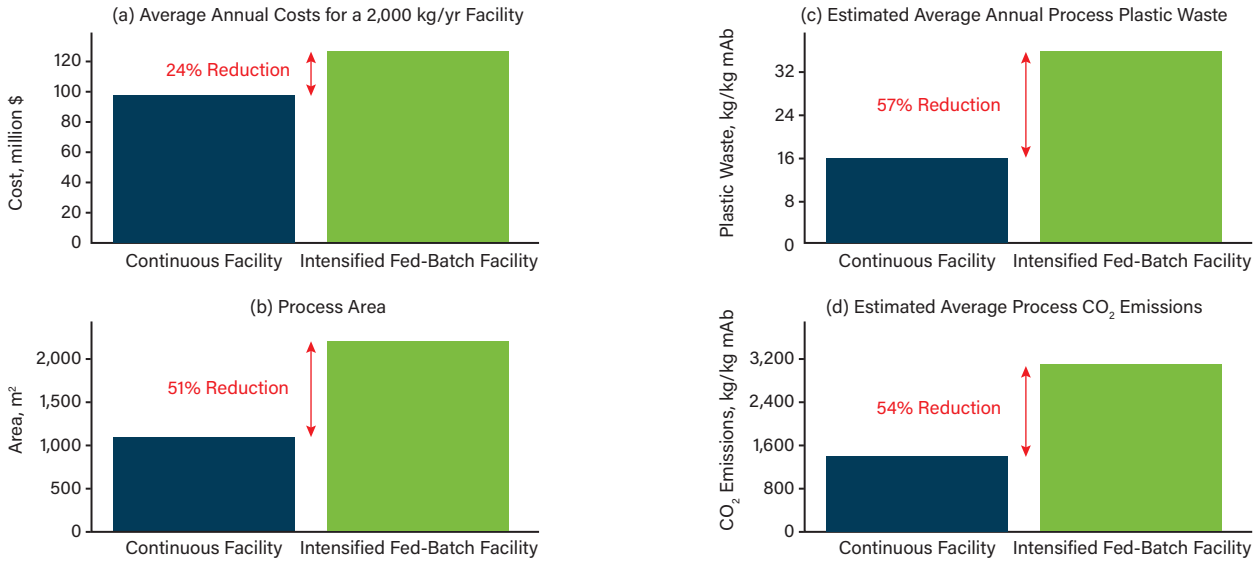
Achieving plastic circularity is a key industry imperative. Sartorius has been working on circulatory concepts encompassing the entire lifecycle of products and packaging. This includes the following steps:

1. *SUT design.* This step involves optimizing material selection, designing products for circularity and recycling, and exploring alternative feedstocks to decouple plastic production from fossil fuels and minimize environmental impact.
2. *SUT production.* During this step, measures are implemented to reduce scrap generation. Additionally, out-of-spec products are recycled internally.
3. *SUT usage.* Here, bioprocesses are designed to optimize resource consumption throughout the production process.
4. *SUT post-use processing.* The final step includes implementing strategies to divert products and packaging from landfills and incineration. Reusing SUTs, components, and packaging is considered whenever feasible. Collecting, sorting, and recycling plastics are also prioritized to reduce waste.

Figure 3 visually summarizes the SUT material conversion path, from feedstock to the product's end-of-life, and introduces some notions of plastic circularity that are discussed in this article.

Decoupling plastic from fossil feedstocks

Plastics are a diverse group of materials designed for widespread applications. Organic polymers (polyethylene [PE], polypropylene [PP], polyethylene terephthalate [PET], polylactic acid [PLA], etc.) are combined with additives — chemical compounds that safeguard polymers and enhance material performance, such as puncture resistance or ultraviolet (UV) light resistance — to form plastic materials. Historically, the production of plastic has heavily relied on

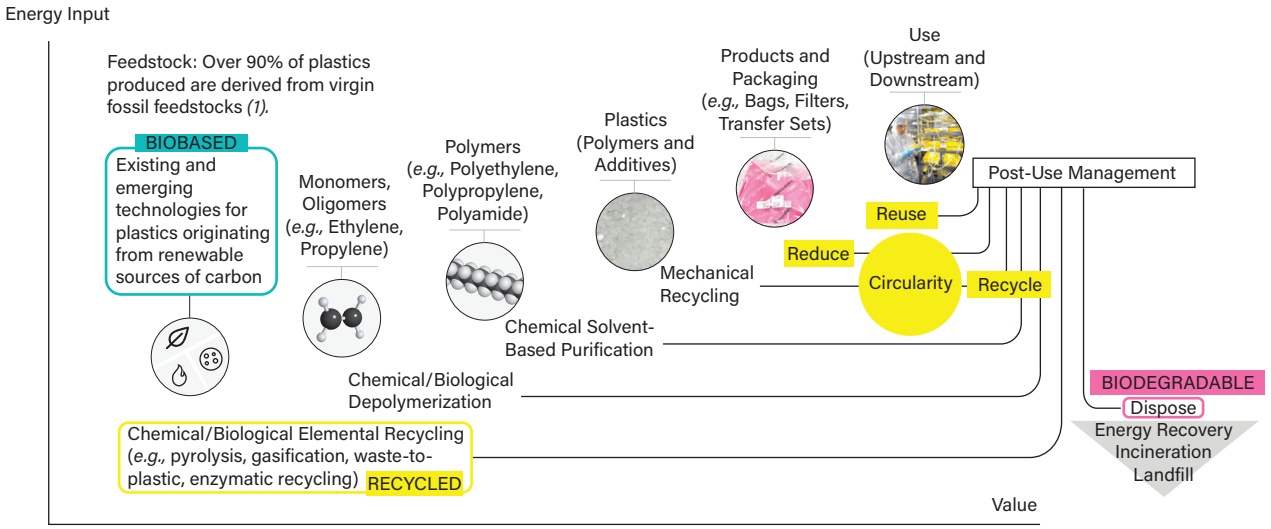


▲ **Figure 2.** The results of the economic and sustainability analysis are shown for a multiproduct bioprocessing facility with a 2,000 kg/yr capacity. The continuous and fed-batch facilities contain multiple lines with up to 1,000-L and 2,000-L bioreactors, respectively. Process intensification results in (a) a 24% reduction in cost, (b) a 51% reduction in equipment footprint, (c) a 57% reduction in plastic waste, and (d) a 54% reduction in CO_2 emissions.

fossil feedstocks. Over 90% of plastics currently used are derived from virgin fossil feedstocks. Efforts to decouple plastic from fossil feedstocks have evolved, with different approaches that use alternative feedstocks (*e.g.,* biomass, starches, carbon dioxide) emerging over time *(6–11)*.

Table 1 summarizes a comprehensive review of existing literature and a lifecycle analysis (LCA) *(12–15)* on alternative feedstocks for plastics production. This review indicates that currently, waste-based material — including biomass waste — is the most sustainable alternative for replacing fossil-based material. However, waste-based material is associated with a higher cost due to its low production quantity. The lack of maturity of these technologies makes predicting the scope of future solutions, such as microbial polymers and synthetic polymers from CO_2 capture, extremely difficult.

Biobased polymers — materials derived from renewable biomass feedstocks — are a potential alternative to fossil-



▲ **Figure 3.** The value chain and feedstock options for bioprocessing single-use technologies (SUTs) incorporate numerous material conversion strategies.

Table 1. The estimated environmental and economic impacts of alternative feedstocks are compared with those of average fossil-based feedstocks. The numbers represent relative ratios averaged over several studies based on different methodologies *(12–15)* and can change dramatically in the future.

Category	Impact Metric	Waste-Based	Food-Based	Fossil-Based	Potential Front Runner
Environmental Impacts	Normalized Greenhouse Gas Emissions	0.1–0.3	0.3–0.5	1	Waste-based
	Land Use (ha/ton)	Negligible	0.3–0.5	Negligible	
	Normalized Water Use	0.3	2–8	1	Waste-based
	Waste Management Impact	Positive (avoids landfill)	Neutral	Negative (landfill or incineration)	Waste-based
Economic Impacts	Normalized Feedstock Cost	0.05	0.25–1	1	Waste-based
	Normalized Production Cost	0.8–1.5	0.9–1.7	1	Fossil-based
	Normalized Market Price	1.3–2.1	1.4–2.5	1	Fossil-based
	Economic Viability	High (especially with waste fees/subsidies)	Moderate (dependent on subsidies/carbon pricing)	High (mature infrastructure, currently cheapest)	
	Investment (CapEx relative)	Moderate to High	Moderate to High	Low to Moderate	Fossil-based

based polymers. In addition to decoupling plastic production from fossil feedstock, biobased polymers can contribute to CO_2 consumption through carbon capture *(11)*, thereby helping mitigate climate change. It is typically preferable to utilize materials derived from waste streams (*e.g.,* wood chips, algae, used cooking oil) to address ethical concerns associated with the use of edible biomass.

Polymers, which describe materials derived specifically from renewable biomass waste streams, are also called biocircular polymers and may either have fossil-based counterparts (twin polymers) or be innovative polymers with unique properties. Implementing innovative biocircular polymers in healthcare applications requires a thorough qualification approach. Indeed, when selecting plastics for bioprocessing SUTs, it is essential to ensure that the material is fit for purpose, particularly regarding mechanical properties suited to the specific demands of the bioprocessing environment.

Additionally, considerations should include material compatibility, patient safety, bioprocess performance, regulatory compliance, the ability to withstand sterilization methods, and ensuring the plastic is free from harmful byproducts and maintains consistent impurity profiles. Batch-to-batch consistency and established change-control procedures are necessary to ensure that impurity profiles remain consistent and that harmful ingredients are absent for more than ten years (a common timeframe set by manufacturers to ensure consumable consistency from technology providers).

Twin polymers are identical to their fossil-based counterparts, allowing them to be used in healthcare applications without needing revalidation. Because twin polymers are indistinguishable, traceability is maintained through mass balance methods, offering a clear and accountable way to track biocircular feedstock usage and verify sustainability claims.

It is essential to distinguish biodegradable and biobased plastics, which are often confused due to the biopolymer generic designation (as "biopolymer" can refer to both types despite their differing environmental properties and decomposition processes). Indeed, biobased refers to the origin of the feedstock, whereas biodegradability refers to the breakdown of materials by microorganisms under specific conditions of temperature, time, relative humidity, and soil composition. It is also essential to distinguish biodegradability from compostability and oxo-degradability, as these terms have different meanings and implications. Furthermore, it is important to note that biodegradation is not considered a circular solution in the waste hierarchy since it is an end-of-life option and does not keep the material in the value chain.

Recycling technologies and post-use SUT management

The waste hierarchy — originally introduced by the European Union's Waste Framework Directive in 1975 — establishes a prioritized approach to waste management with the following order of preference:

1. *Prevention.* Reducing waste generation inherently prevents the need to determine how to dispose of the waste.
2. *Preparing for reuse.* Cleaning and repairing products can make them available for re-purposing, prolonging their disposal time.
3. *Recycling.* This encompasses transforming waste materials into new products or materials.
4. *Other recovery.* Recovering energy or resources from waste that cannot be recycled can maximize product usage.
5. *Disposal.* Disposing of waste that cannot be recovered or recycled in environmentally friendly ways should only be considered if levels 1–4 cannot be achieved.

Table 2 summarizes the different end-of-life options

Table 2. Here, end-of-life scenarios for mixed municipal plastic wastes based on existing technologies are compared. The estimates can change in the future as technologies evolve.

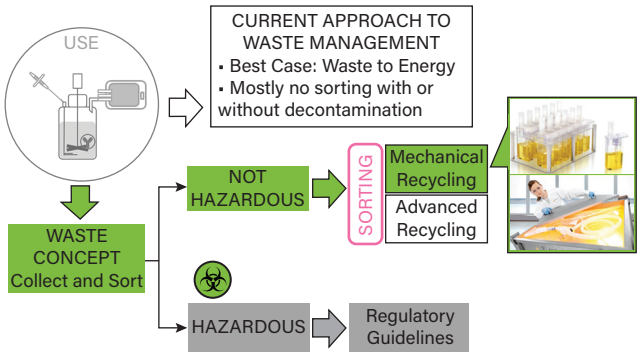
Recycling/Disposal Method	Environmental Impact (Climate/Emissions)	Energy Consumption	Cost Implications	Material Quality (Recyclate/Output)
Mechanical Recycling	Lowest emissions (baseline)	Lowest energy use (baseline)	Lowest overall cost	Moderate to high (depends on feedstock purity)
Chemical Recycling (Pyrolysis)	~50% higher emissions than mechanical recycling, but 50% lower than incineration	~40–60% higher energy use than mechanical recycling	~30–70% higher than mechanical recycling, varies by technology maturity	High-quality recyclate, suitable for high quality demand
Incineration (Energy Recovery)	Highest emissions (2× mechanical recycling)	~100–200% higher energy use than mechanical recycling	High capital & operational costs (~50–200% higher than recycling)	No recyclate; energy output only
Landfill Disposal	Moderate emissions, higher long-term risks	Minimal operational energy, but no recovery	Lowest immediate cost, potential long-term remediation costs	No recyclate; waste disposal only

based on environmental and economic impacts *(16–18)*. In the context of plastic recycling, the hierarchy dictates that mechanical recycling should be prioritized due to its lower energy intensity compared to other methods. However, mechanical recycling is currently limited in its applicability to certain types of plastics. Chemical recycling and conversion technologies are employed for plastics that are difficult to recycle mechanically. Conversion processes, while energy-intensive, produce recycled plastic with specifications comparable to virgin plastic, enabling the use of recycled content in healthcare applications with traceability via mass balance approaches.

The current approach to post-use SUT management primarily involves waste-to-energy processes. This approach often lacks proper sorting and decontamination procedures. Additionally, it does not address GHG emission problems and leads to a significant loss of the plastic's intrinsic value.

Sartorius Corporate Research is actively exploring innovative concepts for post-use SUT recycling, aiming to enhance circularity and reduce waste and carbon footprint (Figure 4). This involves:

- separating hazardous and non-hazardous SUT waste (sorting)
- recycling non-hazardous SUT components, such as Flexsafe® bags and Ambr® vessels, through mechanical processes (mechanical recycling)
- exploring advanced recycling technologies for single-use components that are difficult to recycle mechanically through chemical, mechanochemical, and other recycling procedures (advanced recycling).

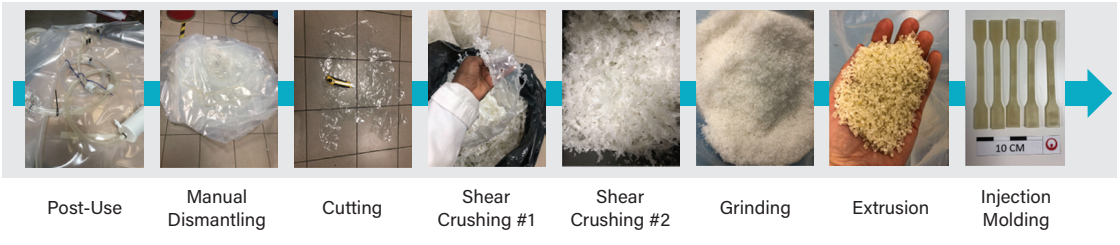


▲ **Figure 4.** Currently active recycling workflows for SUTs in Sartorius Corporate Research are shown.

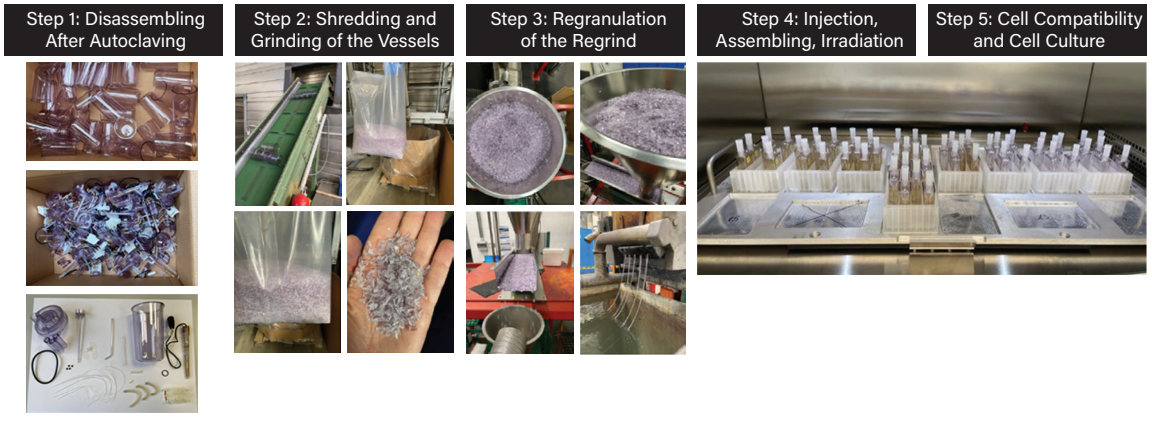
Mechanical recycling projects

Mechanical recycling is generally preferred among post-use SUT management solutions due to its favorable emission and economic profiles. However, concerns about the consistency of quality and material properties often impede its adoption. Therefore, Sartorius has implemented pilot projects to demonstrate the feasibility and benefits of mechanical recycling for SUT components for two major consumables. The first project, called R-Flexsafe *(19)*, is a bag film, which is the main component of buffer preparation and hold bags. The second project, R-Ambr *(20)*, is an automated, scaled-down bioreactor tool for research, process development, and manufacturing.

R-Flexsafe. After this material has been recycled (Figure 5), its properties exhibit comparable characteristics to



▶ **Figure 5.** The mechanical recycling of R-Flexsafe® includes several steps *(19)*.



▶ **Figure 6.** The different steps in the mechanical, closed-loop recycling of R-Ambr® are shown *(20)*.

virgin and existing low-density polyethylene (LDPE) recycling grades. It could be utilized in applications with performance requirements similar to those of virgin materials, such as films, bags, pipes and fittings, profiles, and flexible sheets.

R-Ambr. Figure 6 summarizes the related recycling steps for this material, the details of which can be found in Ref. 20. The cell growth profile in Figure 7 indicates that the recycling process, as implemented in this concept, does not adversely affect cell compatibility under typical cell culture conditions and that, therefore, the recycled material can be used in the exact same applications as the virgin material.

Collaboration for circularity

Whilst Sartorius has generated initial concepts of recycling plastics, achieving greater industry adoption of circularity in SUTs requires significant collaboration among raw material producers, technology providers, end users, and recycling partners. Such a collaborative framework for circularity begins with technology providers offering SUT products designed for circularity, collaborating with recycling partners to develop recycling processes, and utilizing recycled materials in SUT production when possible. It then includes end users collecting, decontaminating, and sorting SUT waste to increase material value (with the support of their waste management partner if needed) and using SUT products made from recycled materials when relevant. Finally, recycling partners must develop and implement recycling processes for SUT components, convert recycled materials into parts for SUT production, and collaborate with suppliers to ensure the quality of recycled materials.

It is envisaged that a regional hub network is required to collect and sort plastics, followed by processing and extrusion at regional centers to minimize shipping emissions. This framework is defined in Figure 8, where current collaboration discussions from the various groups are underway to execute regional pilot studies.

Moving forward

Process intensification, enabled by SUTs, has resulted in a significant reduction (up to 50%) in emissions and waste in the biomanufacturing industry. A combination of further process intensification efforts (*e.g.,* transitioning to end-to-end continuous processes with long durations) and designing

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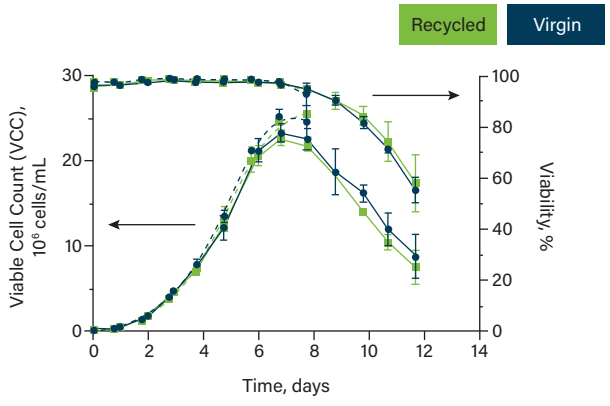
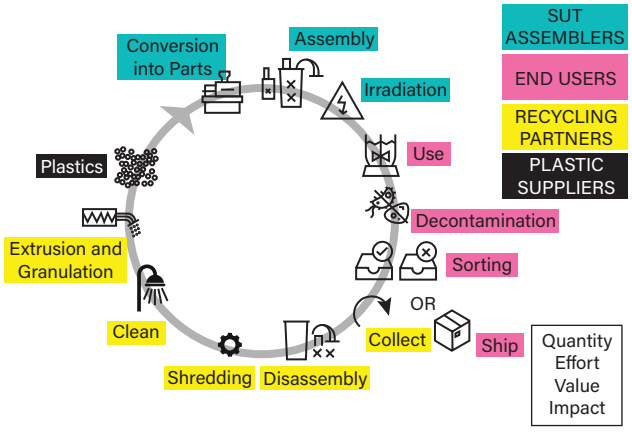


▲ **Figure 7.** Cell culture results (Stir Speed: 1,300 rpm; Temperature: 36.8°C; pH Upper Limit: 7.1; Dissolved Oxygen: 40%) of recycled Ambr, in comparison with the virgin control, indicate that recycling does not negatively affect cell compatibility *(20)*. The top curve represents viability, while the bottom represents VCC.



▲ **Figure 8.** A potential framework for the successful recycling of SUTs and cleaner biomanufacturing includes collaboration with technology providers, end users, and recycling partners.

SUTs with raw material circularity (including non-fossil feedstocks and plastic recycling) will continue to reduce the biomanufacturing industry's environmental impact.

Nevertheless, the foregoing analysis shows that process intensification and continuous processing are still the most economically viable and sustainable options. This not only results in further environmental impact reduction, but also in further reduction of therapeutic cost per dose. In addition, continuing to shrink the manufacturing footprint and capital required of the industry will enable regional manufacturing around the world and widen patient access to biologics and vaccines.

To continue to reduce the lifecycle of SUTs, our comparison demonstrates that investing in alternative feedstocks, such as biowaste-based polymers, is also advantageous. Most of the polymers used in SUTs today exist with biocircular feedstock options and can be implemented without revalidation.

For plastic waste management, the LCA shows that current mechanical recycling capabilities can provide a clear advantage over other approaches, such as landfills. We envision that mechanical recycling facilities will be located inside regional plastic sorting and processing centers and connected to the biotechnology and biopharmaceutical manufacturing hubs by a network of collectors. The plastic processing centers will then feed plastic extrusion facilities for intra-country plastic manufacturing, thus minimizing international raw material transit. When mechanical recycling is technically not possible, chemical recycling shows promise, particularly for handling plastics exposed to biological fluids. However, further investment is needed to improve the efficiency of this process and reduce its high-temperature burden. Solving this issue will further support expanding the circularity into manufacturing regional hubs over the next five years.

Finally, it's worth emphasizing that the plastic waste from therapeutic protein production contributes to a small portion of total direct emissions in biomanufacturing (less than 10%, assuming current mixed grid energy sources), and the most promising way to further reduce emissions is through continued process intensification. CEP

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