Bioproduction

Achieving environmental sustainability in bioprocessing

Advancing environmental sustainability in bioprocessing is an important and necessary step in achieving the pharmaceutical industry's goal of improving global health. In partnering with biopharma and contract development and manufacturing organizations (CDMOs), suppliers play a vital role in supporting their customers' sustainability goals.

The science behind the global climate environmental crisis is clear: climate change, ocean plastics, deforestation, loss of biodiversity, water scarcity, and waste effect have converged to create unprecedented global challenges for industry and humanity. Achieving sustainability goals has therefore become a key metric for companies in many leading sectors. In bioprocessing, this means working to understand and minimize the environmental impact of products and their packaging throughout a product's life cycle — from conception and early design to end-of-life.

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In a **recent webinar**, experts from Thermo Fisher Scientific, a global supplier of bioprocessing equipment and consumables, explored how to support the achievement of customers' sustainability goals through product innovation, particularly around single-use technologies (SUTs). Speakers for the event included:

- **Merete Miles, senior director**, Environmental Sustainability, Thermo Fisher Scientific
- **Adam Goldstein, senior director**, R&D Collaborations, Thermo Fisher Scientific

Designing bioprocessing consumables has become increasingly important in the single-use space as a way to address sustainability concerns. Single-use technologies, optimized with sustainability in mind, allow for more focus to be placed on water and energy reduction, closed connected systems and the reduction of footprint.

Designing more sustainable products for biomanufacturing

The pharmaceutical and bioprocessing industries have begun engaging in more concerted efforts to adopt sustainable practices to support their corporate sustainability goals, their processes' needs, and overall efficiencies. This push is crucial, as the complex operations and supply chains that typify the industry at large, coupled with the hurdles and costs that accompany new technology integration, can make reaching an organization's sustainability goals challenging.

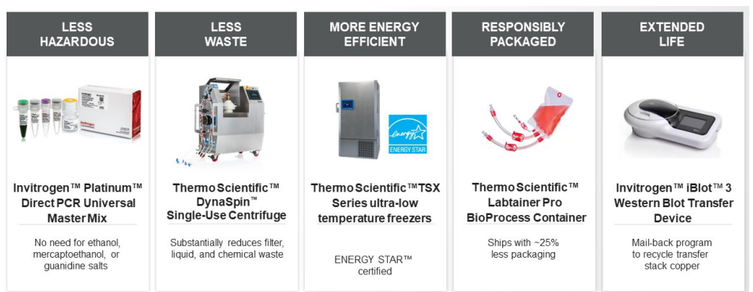
For some, the proliferation of SUTs in bioprocessing, particularly following the pandemic, may seem counterintuitive for bioprocessing organizations interested in promoting sustainable manufacturing. However, life cycle assessment (LCA) regarding SUTs has largely found that **these technologies**, leveraged with operational efficiency, have the potential to represent an improvement over more traditional systems such as stainless steel. Much of this difference can be attributed to the reduction in energy use in supporting SUT versus more permanent technologies that require more extensive cleaning procedures to be rendered safe for use in bioprocessing.

Incorporating materials and equipment optimized to lessen environmental impact in biomanufacturing is one of the key ways bioprocessing organizations can work to achieve their sustainability targets, advancing the efficiency of individual products, reducing the packaging required to transport them, establishing more regional supply chains, and promoting the recyclability of SUTs.

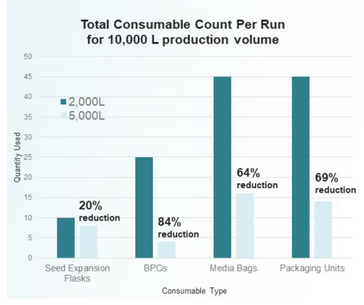
There are a number of effective strategies pharmaceutical companies can employ to achieve greater sustainability. Key among these is new equipment deployment, both to enable waste reduction and to drive process intensification. Thermo Fisher has recently launched two products, both SUTs, that represent a significant innovation in these areas: the Thermo Fisher™ DynaDrive™ Single-Use Bioreactor (S.U.B.) and the DynaSpin™ Single-Use Centrifuge.

DynaDrive™ Single-Use Bioreactor (S.U.B.)

The DynaDrive enables scalable, high-density cell culture with less hardware and consumables needed per run, owing to its scale-up and reduction in seed train expansions. The volumetric sizes at which the S.U.B. is offered, process intensification using the DynaDrive allows for reductions in seed scale-up steps, saving an average of 6 to 10 GMP manufacturing days per tech transfer. The efficiencies created by technologies like the DynaDrive are most impactful at large scales; ultimately, the DynaDrive can decrease the cost of production by 25 percent through a reduction in equipment, materials, consumables, and labor.



Sustainability in mind: Highlight of products developed by Thermo Fisher that offer sustainability benefits for bioprocessing.



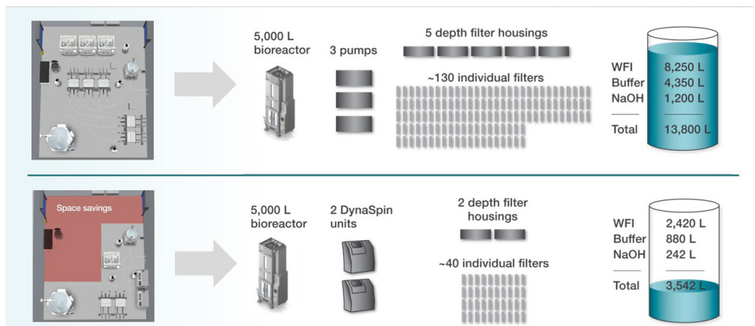
Traditional 2,000 L and DynaDrive 5,000 L seed trains compared by matching target production volume of 10,000 L (5x2K vs 2x5K). Transitioning to a 5,000 L Dynadrive supports reduction of consumables compared to traditional 2,000 L bioreactor for a 10,000 L run, which can result in cost savings.

Additionally, DynaDrive boasts significantly less packaging than traditional bioreactor systems, a 70 percent reduction, and a lower cost of capital requirements when compared to stainless steel. Other features, such as its built-in condenser system at 3,000 and 5,000 L, extend the life of the DynaDrive and reduce the quantity of exhaust filters needed, further streamlining efficiency and reducing environmental impact as a consequence. This, coupled with higher in-vessel turndown ratios, can reduce the number of bags loaded and unloaded, as well as the number of bioreactors needed overall in the facility. With product sizing available up to 5,000 L, mass transfer and mixing allows for the use of the same technology over a larger range of facility networks, simplifying process transfers and providing consistency from research and development to manufacturing.

DynaSpin™ Single-Use Centrifuge

The DynaSpin Single-Use Centrifuge is a technology that performs depth filtration and centrifugation during cell harvest, greatly simplifying this step and reducing its cost by approximately 25 percent. It also dramatically reduces the quantity of depth filters required, including costly buffers and cleaning agents to support them, which in turn helps reduce CO2, plastic, and chemical waste. This, in turn, has led to a commensurate reduction in costs – 40 percent lower per gram at the 5,000-liter scale.

Depth filtration traditionally consists of two filtration stages, one for primary filtration and a second to reach a process's defined purification parameters. In general, depth filters scale up well until large volumes force scaling out with huge numbers of depth filters to accommodate a process. This creates a burden on supply chains, as well as increased complexity in facility logistics and storage, increased cleanroom footprint requirements, significant buffer requirements and associated components, and increased hands-on labor during every step. The



The process optimization enabled by the DynaSpin maximizes operator savings in consumable and material usage, reduces cleanroom footprint and warehouse space, and ultimately lowers the risk to production.

DynaSpin centrifuge replaces the first stage of depth filtration with single-use centrifugation, directly reducing the quantity of required clarifying filters and creating harvest efficiency by allowing a singular step to separate out particulates. By decreasing the number of depth filters, DynaSpin reduces inventory and warehouse storage requirements as well as filter and buffer waste, enabling customers to accomplish what a normal two-stage depth filtration does at a reduced cost, footprint, and consumable usage.

For a 5,000-liter bioreactor process, for example, a typical harvest suite would require three pumps, five depth filter housings, and more than 130 individual filters. In this paradigm, operators are using roughly 14,000 liters of water for injection to conduct the process. In contrast, the same 5,000-liter bioreactor, supported by two DynaDrive systems, requires just two depth filter housings, roughly 40 filters, and, significantly, less than 4,000 liters of water for injection.

Employing cross-cutting strategies to reduce emissions

According to a report issued in October 2021, the biotechnology and pharmaceutical industry is the 25th-largest carbon-emitting industry in the world, and the sector's Scope 3 emissions are nearly five times larger than its Scope 1 and 2 emissions combined. Scope 1 emissions encompass those resulting from assets owned or controlled by a company, while Scope 2 emission are indirect emissions from the energy it purchases and utilizes. Scope 3 includes emissions not produced directly by a company or the assets owned and operated by them, but rather from indirect sources that populate its value chain more broadly, such as products purchased from suppliers. This is where supplier support for sustainability becomes crucial: by innovating their own products, optimizing their own supply chains, and prioritizing recycling and disposal strategies, suppliers can meaningfully transform Scope 3 emissions for their customers.

Thermo Fisher has been striving to optimize its supply chain to further reduce its carbon footprint. Transportation is a substantial source of emissions, and for most companies, among the top emissions sources targeted for immediate reduction. By leveraging an extensive in-region manufacturing network, Thermo Fisher helps its customers greatly reduce their Scope 3 transportation emissions. In a recent case study, a Thermo Fisher client was able to leverage its global single-use manufacturing network with more regional SUT warehouses, resulting in a CO_2 emissions reduction of roughly 1,300 metric tons per year. As one of the largest contributors to Scope 3 emissions, product transport is one of the key variables customers can address to reduce their overall environmental impact.

Partnering for sustainable success

There are myriad challenges biopharmaceutical companies face when trying to deliver lifesaving therapies, including operational complexity, financial pressures, forecasting uncertainty, and evolving technologies. This underscores the importance of a total life cycle management approach that drives circularity through the entire value chain, from product design to raw material sourcing to manufacturing, product delivery, and disposal. As such, Thermo Fisher is working on end-to-end solutions to promote sustainability by deploying innovative equipment, optimizing supply chains, and refining processes.

Thermo Fisher is collaborating across the industry to drive end-to-end sustainability for bioprocessing through a number of key partnerships. Its collaboration with BioForum, for example, focuses on reducing carbon footprint across the bioprocessing value chain, as well as embedding circular design, harmonizing industry response to regulations. Other collaborations with industry associations like the Bio-Process Systems Alliance (BPSA) and the International Society for Pharmacoepidemiology (ISPE) are geared toward education, sharing best practices, exploring alternative solutions to lessening environmental impact, and identifying key partnerships to develop novel solutions.

Achieving sustainability targets through supplier expertise and innovation

In order to further its commitment to environmental sustainability, Thermo Fisher has established a number of ambitious external targets. These include a targeted 50 percent reduction in emissions by 2030 compared to 2018, as well as the additional goal of helping its own suppliers achieve net zero by 2050. As part of this initiative, it has also committed to preserving freshwater resources and managing waste. By 2024, Thermo Fisher plans to assess water usage for water-intensive manufacturing facilities in water-scarce areas, and to have 30 of its manufacturing and warehouse sites zero-waste certified by 2025. These targets have been validated by the Science Based Targets Initiative, a partnership between CDP (formerly the Carbon Disclosure Project), the United Nations Global Compact, World Resources Institute (WRI), and the Worldwide Fund for Nature (WWF).

Thermo Fisher is also working to move away from fossil fuel as a power source. Currently, it has 150 sites powered by renewable electricity through the purchase of renewable energy certificates in China, India, and South Africa. It has also added more than 900,000-megawatt hours of clean energy to the grid through power purchasing agreements, enabling all current U.S. sites to operate on 100 percent renewable electricity by 2026. Thermo Fisher continues to work to achieve the same transition for its sites around the world, working with local governments to pursue options that will enable this parity. Beyond investing in existing renewable energy sources, Thermo Fisher has established projects in Oklahoma focused on wind energy and in Texas aimed at new solar energy capacity.

Ultimately, biopharmaceutical companies should be able to rely on suppliers to provide expertise and solutions tailored to their sustainability targets. Identifying suppliers with their own aggressive sustainability goals will be increasingly important for the industry and partnering with those that can curb their Scope 3 emissions through comprehensive, complementary targets is core to this value proposition. By focusing on initiatives aimed at waste reduction, energy efficiency, and manufacturing practices focused on circularity, coupled with closed and intensified processes, suppliers can help transform the bioprocessing landscape globally for a more sustainable future.

About Thermo Fisher Scientific

Thermo Fisher Scientific Inc. (NYSE: TMO) is a leading supplier of scientific products, with annual revenue exceeding $25 billion. Whether our customers are accelerating life science research, solving complex analytical challenges, improving patient diagnostics and therapies, or increasing productivity in their laboratories, we are here to support them. Our global team of more than 75,000 colleagues delivers an unrivaled combination of innovative technologies, purchasing convenience, and pharmaceutical services through our industry-leading brands, including Thermo Scientific, Applied Biosystems, Invitrogen, Fisher Scientific, Unity Lab Services, and Patheon. For more information, please visit thermofisher.com

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