

BioProcess Insight

How can bioprocessing professionals evolve their manufacturing for greater flexibility and efficiency?

Introduction

The evolution of the bioprocessing industry is defined by two converging trends: increasing product complexity and the demand for manufacturing flexibility. Traditional stainless steel systems, though reliable and proven, are increasingly misaligned with the needs of today's biomanufacturers. Large-scale stainless steel facilities demand significant capital investment, extensive cleaning validation, and rigid infrastructure, making them less adaptable to multi-product pipelines or process intensification strategies.

To stay competitive, bioprocessing professionals must shift their mindset from fixed, large-volume infrastructure toward modular, scalable systems that can quickly adjust to evolving demands. Single-use technologies (SUT) make this evolution achievable, offering the tools to build adaptive facilities, reduce turnaround times, and optimize every stage of production from process development through commercial manufacturing.



1. Rethink facility design: build for flexibility and modularity

A key step in evolving toward single-use adoption is reimagining facility layouts. Instead of purpose-built stainless steel suites segmented by open systems and extensive piping, SUT-enabled “ballroom” configurations allow for closed system processing across unit operations. This approach helps simplify GMP compliance, reduces the need for classified cleanrooms, and enhances space utilization. It also enables faster facility builds and simpler tech transfers, helping process engineers and MSAT teams adapt quickly to new molecules or modalities.

For example, with next-generation single-use bioreactors, single-use facilities can achieve comparable production capacity to stainless systems with significantly lower net present cost (NPC) and shorter commissioning timelines, positioning them as an agile alternative for both new builds and hybrid retrofits.

2. Standardize and scale processes intelligently

A smooth transition to single-use manufacturing requires alignment between development, scale-up, and production. Standardizing process parameters - such as mixing, gas flow, and agitation - helps ensure consistent performance across scales and sites.

Modern single-use bioreactors and mixers are designed to mirror the hydrodynamic and mass transfer performance of traditional stainless systems, offering equivalent control of oxygenation, shear forces, and nutrient delivery. With optimized mixing and gas exchange efficiency, single-use systems can support intensified processes and high cell densities while maintaining product quality and batch-to-batch consistency. Utilizing the same film for consumables (e.g., bioreactor bags) across upstream and downstream also helps to reduce variability.

For process development scientists, this means improved scalability and reproducibility, enabling faster tech transfer and process validation while reducing the need for custom engineering at each step.

3. Adopt a hybrid approach to manage risk and transition smoothly

Full conversion to single-use technology doesn't have to happen overnight. Many manufacturers are finding success with hybrid facilities that pair existing stainless infrastructure with SUT-based unit operations. This phased strategy allows teams to adopt SUT where it supports the most value for their circumstances, such as in seed trains, buffer prep, or downstream clarification, while continuing to leverage existing assets.

Implementing hybrid workflows helps teams validate SUT performance, build operator confidence, and establish data-driven evidence of efficiency gains before full-scale adoption. Over time, as production demands evolve, these hybrid facilities

can transition easily into fully single-use environments with minimal disruption.

4. Leverage automation and continuous improvement

SUT adoption can modernize control strategies. Advanced sensors, automated sampling, and integrated process analytics available in next-generation SUT platforms helps provide real-time visibility into performance metrics such as oxygen transfer, pH stability, and nutrient consumption.

Continuous monitoring enables adaptive control loops and more predictive maintenance, key for MSAT teams responsible for optimizing productivity and limit downtime. Furthermore, single-use systems facilitate rapid iteration and continuous improvement, allowing process engineers to implement new technologies without the lengthy revalidation cycles associated with stainless systems.



5. Prioritize sustainability and waste reduction smoothly

Sustainability is an integral part of the single-use evolution. While stainless steel systems consume vast quantities of water, chemicals, and energy for cleaning and sterilization, single-use workflows supports eliminating these requirements.

This shift can dramatically lower facility utility demands and carbon footprint. Studies have shown that single-use operations significantly reduce water consumption and energy usage while helping to reduce waste generation through optimized material use and recycling initiatives.

Beyond environmental benefits, these efficiencies also translate to tangible operational cost savings - particularly in labor, maintenance, and utilities - while improving facility throughput and responsiveness to production needs.

Leading the next phase of biomanufacturing

The next generation of bioprocessing leaders will be those who see change not as disruption, but as opportunity. By strategically incorporating single-use technologies, biomanufacturers stand to gain accelerated time to market for life-saving therapies, complexity reduction, and lower total cost of ownership.

References

1. <https://documents.thermofisher.com/TFS-Assets/BPD/Reference-Materials/single-use-vs-stainless-steel-white-paper.pdf>



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