

How Single-use Technology is Transforming the Future of Biomanufacturing

| SUMMARY

Since its initial introduction in the late 1990s, single-use technology has been a transformational force enabling the future of biomanufacturing. In this article, we explore the impact of single-use technology, the major problems it addresses, and how it's shaping the future.

| INTRODUCTION

Widespread use of single-use technology (SUT) has transformed the biopharmaceutical sector. Modern biomanufacturing is now dependent on SUT for flexibility, efficiency, and scalability.¹ Emerging technologies such as cell and gene therapies (CGT) stand to benefit considerably, as standard stainless-steel facilities can impede speed and innovation.² These facilities are becoming too costly to build to serve a small patient population, lacking the flexibility required to easily adjust to different manufacturing requirements.

| BIOPHARMA TRANSITION TO SUT: REASONS 101

Prior to the introduction of single-use technology, stainless-steel bioreactors and fixed infrastructure dominated biopharmaceutical production.³ While effective in producing large volumes of a single product (blockbusters), these systems have several limitations including: long build and validation times (meaning investment decisions being made earlier), high upfront capital expenditure (CAPEX), elevated operational costs (OPEX) driven by the initial and ongoing validation requirements to demonstrate equipment performance, cleanability, and sterility. Then once in operation, the turnaround time between batches is considerable, due to the cleaning and sterilization processes required between runs. These systems have a high rate of resource consumption (water, energy, chemicals), all generating a large volume of liquid waste. Additionally, the systems have limited scope for reconfiguration, require costly and time-consuming reengineering and revalidation, create a large footprint, and present challenges in end-of-life disposal and sustainability.⁴



Single-use technologies reduce initial CAPEX by eliminating the need for the installation of permanent infrastructure supporting high-capacity utilities such as WFI and clean-steam generation, while also lowering OPEX through reduced maintenance, validation, training, and downtime.⁵ They eliminate batch-to-batch and product-to-product contamination risk (meaning one facility can support a portfolio of products), allowing for rapid turnaround and less resource consumption (e.g., 85% less water).⁶ While they do create plastic waste, SUTs are modular and space-efficient, making them ideal for multi-product, decentralized operations with the potential for recyclable plastics or thermal energy recovery, providing benefits over stainless-steel scrapping at the end of life.⁷

| KEY INDUSTRY CHALLENGES SUT IS SOLVING

Single-use technology eliminates prolonged turnaround times and allows for flexible configuration of facilities, enabling rapid start-up and higher facility utilization. In turn, this enables production to accommodate more niche or even personalized products, often addressing unmet needs in the treatment of chronic illnesses while helping to reduce high capital start-up and operational costs.

Long Downtimes from Cleaning and Validation

To ensure no batch-to-batch contamination, traditional stainless-steel facilities must undergo stringent cleaning in place (CIP) and sterilization in place (SIP) validation. In routine use, these CIP/SIP operations might take several days and require QC laboratory testing to release the equipment for use; holding facilities dormant while waiting on testing results, slowing manufacturing schedules, and increasing expenses as equipment and facilities are idle. Single-use, sterile systems eliminate the need for these CIP/SIP steps, minimizing turnaround times and allowing for quicker batch transitions and high facility utilization, ultimately leading to more products being produced.⁸

High Capital and Operational Costs

Building and maintaining stainless steel infrastructure is capital-intensive, requiring hundreds of millions of dollars in initial expenditure and ongoing costs associated with maintenance and validation. All of these costs must be committed early in the clinical trials process if you are to capture maximum revenue before patent expiry. Operational costs such as energy, cleaning chemicals, and personnel add to the cost. Single-use equipment significantly cuts start-up costs to the high tens or low hundreds of millions as well as enabling that investment to be made later in the clinical trials cycle. Once in production, expenses are controlled by reducing infrastructure needs and operational overheads.¹⁰

Inflexible Manufacturing for Emerging Therapies

Emerging medicines, particularly in precision medicine, require highly flexible production methods. Stainless-steel facilities are great for standard processes at large scale > 2,000 L, such as producing commercial quantities of monoclonal antibodies serving a wide patient population, but they lack scope for process flexibility. In contrast, SUT offers versatility and rapid reconfiguration, making it perfect for multi-product facilities and clinical manufacture of tailored treatments.⁹

Scalability Issues in Cell and Gene Therapy (CGT)

Relatively smaller batch sizes and significant yield unpredictability in cell and gene therapy treatments can pose distinct scaling issues. Traditional infrastructure struggles to be flexible enough to meet these demands. Single-use platforms offer smaller, concurrent production streams (scale-out as opposed to scale-up) that better meet the demands of CGT manufacturing. This adaptability lowers bottlenecks and speeds up clinical development schedules.¹¹

INNOVATIONS IN SUT: WHAT'S NEXT?

The continued growth of single-use technologies is pushing the frontiers of what is feasible in biomanufacturing, lowering costs, speeding time to market, and serving smaller patient populations to address unmet needs. Innovations need to address not just efficiency and cost, but also allow for greater and wider access to life-enhancing and often, life-saving drugs.

Automated, Closed Mixing Solutions

Sensors are important for closed-system processing because they enable automation and allow engineers and scientists to monitor the system in a noninvasive way. Parameters such as pressure, flow, conductivity, and temperature can now be monitored continuously using new in-line and at-line noninvasive sensors. Solutions like the Oceo Rover from FUJIFILM Biosciences exemplify a trend towards fully-closed and automated processing.¹² Oceo Rover automates hydration management in a fully-closed system, reducing human procedures, processing time, and contamination hazards. Such advancements point to a future in which biomanufacturing is faster, safer, and more repeatable.

Expanding Process Analytical Technology (PAT)

Quality by Design (QbD) sets and defines the parameters a process needs to stay within to produce a product that meets the specifications set for it. Process Analytical Technology (PAT) is enabling automated biomanufacturing. It monitors production processes in real time to ensure they are consistent, safe, and compliant with regulatory requirements by controlling Critical Process Parameters and Critical Quality Attributes, defined in the QbD process.

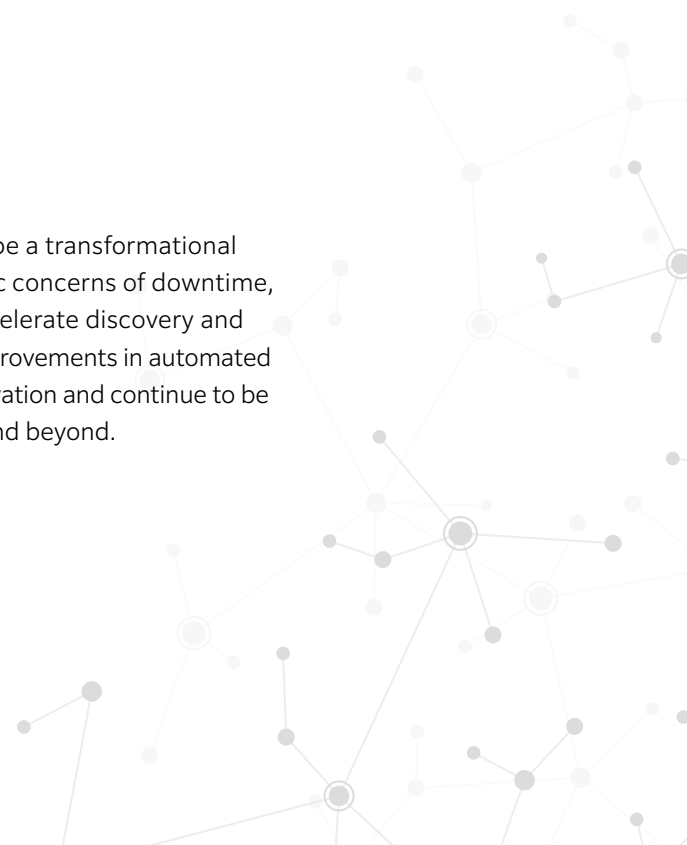
Integration with Digital and Smart Manufacturing

As Industry 4.0 principles gain traction in life sciences, SUT is becoming more integrated with digital monitoring, real-time analytics, and predictive maintenance systems.¹³ These advancements guarantee that manufacturing processes are both efficient and data-driven, helping businesses to retain quality and compliance in increasingly complicated regulatory contexts.

PAT tools, such as in-line spectroscopy, advanced sensors, and data-driven control algorithms are increasingly integrated into SUTs to provide feedback that enables corrective or optimal actions during production. PAT is making batch-to-batch variability or failure a thing of the past by conducting continuous quality verification rather than end-point testing.

CONCLUSION

Single-use technology is driving manufacturing forward as it continues to be a transformational force influencing the future of biomanufacturing. By addressing the chronic concerns of downtime, inflexibility, cost, and scalability, SUT enables biopharma businesses to accelerate discovery and deliver life-changing medications to more patients faster. With continued improvements in automated closed systems and digital integration, single-use platforms will support innovation and continue to be integral to biopharmaceutical manufacturing throughout the next decade and beyond.



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