

Sustainability of single use technology in the manufacturing of biologics



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Abstract

The biopharmaceutical industries are dominated by stainless steel systems for the commercial manufacturing of biologics and biosimilars due to its proven reliability and scalability. The integration of Single use systems was retarded due to concerns over extractability, leachability, scale up and operational equivalence. However, the Single use systems have gathered momentum in biopharma industries by offering pre-sterilized, disposable, and aseptic components which can further reduce cost, cross contamination risk, increased production, and shorter turnover times. These benefits have gained widespread adoption of these technologies in upstream and downstream bioprocessing, from vaccine research to monoclonal antibody development.

Keywords: Single Use Technology, sustainability, biologics, biosimilars, biopharmaceuticals, , stainless steel, flexibility.

1. Introduction

Single Use Technologies (SUT) also known as Single Use System (SUS) are disposable bioprocessing components such as filter, tubing, connectors, clamps, bags, buffer containers, and bioreactors. (1)

Biologics are medicines whose active drug substance is produced by a living organism using techniques like recombinant DNA technology with regulated gene expression. (2) Over past two decades, SUS have revolutionized manufacturing of biologics and gained momentum in biopharmaceutical industries. Particularly in the manufacturing of modern modalities such as monoclonal antibodies, viral vectors, vaccines, gene therapies and mRNA therapeutics. Compared to the traditional approach which rely on stainless steel equipment and bioreactors, is expensive and demands high maintenance for re-use. The primary disadvantages of traditional manufacturing are the limited level of flexibility, which requires separate facilities for each manufacturing step or drug product, as well as the high time and man power in preparing equipment for readiness. Requalification of the reused bioprocessing equipment comes after resource-intensive clean-in-place (CIP) and sterilize-in-place (SIP) operations, which take a lot of time and tie up important operational resources. (1,3)

2. Advantages:

Modern SUT promises reduced cost, lowers risk of cross contamination and increased productivity and improves quality products. Therefore, these benefits have led them widespread adoption in biopharmaceutical industries. (4)

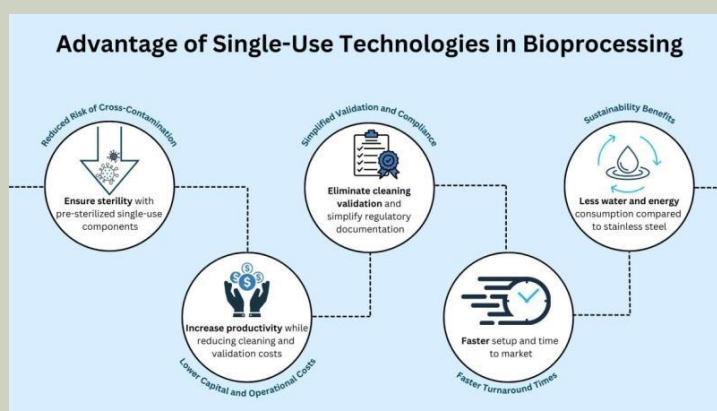


Figure 1. Advantage of Single Use Technology (6)

- (i) **Cross-contamination risk minimized:** One of the major issues in the manufacturing of biologics is cross contamination between batches and products. (5) The conventional system involves rigorous cleaning and sterilization between batches, creating possibilities of contamination. Single use systems eliminate this concern by offering pre-sterilized and disposable components preventing product carry over and microbial contamination. (6)
- (ii) **Cost reduction:** Traditional bioprocessing facilities require expensive stainless-steel infrastructure along with extensive cleaning and maintenance. Implementing SUS significantly reduce costs and resources for complex production stages like cleaning (CIP) and sterilization (SIP). (5) Capital and operational expenditure like direct labor costs for installation as well as costs for water and cleaning chemicals can be minimized. Furthermore, the facilities do not require cleaning and sterilization, which in turn accelerates batches turnovers resulting in overall productivity and lowering operational cost. (7)
- (iii) **Simplified Validation and Compliance:** Regulatory compliance is an essential requirement in biopharmaceutical manufacturing. (7) In order to meet current Good Manufacturing Practices (cGMP) conventional stainless-steel system need extensive cleaning validation, detailed documentation, and repeated testing. In contrast, a single-use system reduces validation requirements and simplifies regulatory compliance. Furthermore, materials used in single-use equipment follows very high regulation standards with different kinds of certificates and studies, for example, extractables and leachable studies, certificates, including BSE, TSE, Bis-Phenol-A, phthalates and melamine etc. These systems support consistent product quality while meeting the requirements of regulatory authorities and standards such as the FDA, USP, and ISO. (6)
- (iv) **Faster turnover times:** The requirement for thorough cleaning and sterilization of stainless-steel systems is essential for producing contamination-free products, leading to increased expenses for manufacturers. (6) Conversely, single-use systems, which are pre-sterilized and disposable, remove the need for lengthy turnaround processes and help to

reduce production delays. As a result, the adoption of single-use technology boosts productivity and decreases both costs and process complexity. (5)

- (v) **Sustainability benefits:** SUS significantly reduce the consumption of energy, water, and media. (7) Traditional stainless-steel systems requires large amount of energy to heat and sterilize equipment during manufacturing and rely heavily on utilities like purified water, water for injection (WFI), compressed air and steam etc. (3)

On the other hand, single-use assemblies have been demonstrated to significantly decrease media consumption and reduction in water usage when compared to plants utilizing steel equipment. (8) Overall, the average decrease in the carbon footprint which encompasses reductions in water, energy, chemicals, and more was found in comparison to stainless steel. (5,7)

In terms of sustainability, SUS offers more advantages at the end of their lifecycle. Most SUS are manufactured from high grade polymers that can be recycled into other plastics or alternatively be incinerated to release their stored chemical energy for electricity or heat generation. These features enhance resource efficiency and support more sustainable manufacturing practices while maintaining operational flexibility. (8)

3. Challenges and solution

Despite their benefits, SUS also pose environmental challenges, especially concerning plastic waste management. Large amounts of plastic waste are produced by laboratories and bioprocessing facilities, primarily from single-use products like tubes, petri dishes, and disposable culture vessels, which are usually made of petroleum-based polymers like polystyrene. (8)

Another method of waste management is incineration, which results in the release of carbon dioxide that had been sequestered underground in fossil fuels, thus contributing to climate change. To mitigate this problem, the industry is increasingly pursuing sustainable alternatives. One viable solution is the adoption of biodegradable materials, including polylactic acid (PLA), a renewable polymer obtained from plant sources such as corn starch. Although its use in bioprocessing is still in its infancy, PLA significantly reduces environmental impact relative to petroleum-derived plastics. (9)

The adoption of circular economy principles, including the recycling and repurposing of single-use components, has the potential to greatly mitigate the adverse environmental effects linked to SUT.(10) Studies suggest that single use bioreactors lead to a significant reduction in water and energy consumption in facilities when compared to stainless steel bioreactors.(11)Nonetheless, the disposal of SUS raises critical concerns regarding waste generation and potential environmental impacts.(12) Life cycle assessments evaluating single use bioreactors and stainless steel bioreactors have revealed that the environmental impacts of both systems are largely dependent on manufacturing conditions and disposal practices.(13,14)Furthermore, substantial progress is being achieved in enhancing the sustainability of SUT, addressing factors from materials to packaging, as well as regional manufacturing and distribution.(15)

4. Conclusion

Despite the ongoing concerns regarding plastic waste and the disposal of products at the end of their lifecycle, single-use systems provide a persuasive argument for adopting more flexible and sustainable manufacturing methods when considered in a holistic context, which includes energy requirements, carbon footprints, and water consumption. This review suggests that the sustainability profile of contemporary biopharmaceutical production could be significantly enhanced without compromising quality or scalability by effectively integrating single-use technologies with advancements in recyclable materials and waste management.

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