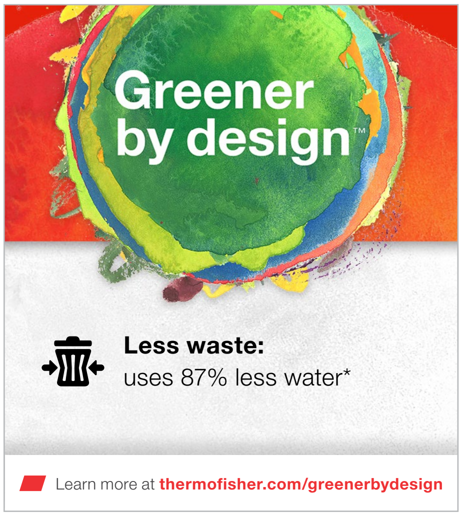
Single-use bioprocessing systems



Introduction

We are committed to designing our products with the environment in mind. This fact sheet provides the rationale behind the environmental claim that single-use bioprocessing systems use fewer resources compared to conventional bioprocessing systems.

Bioprocessing systems using single-use technologies (SUTs) offer tremendous advantages to users at process stages from buffer and media preparation through filling and shipment, and from laboratory-scale to large-scale production. However, the need for waste disposal at end-of-life has called the environmental sustainability of SUTs into question. As a result, several life cycle assessments (LCAs) have been conducted to investigate and characterize the environmental impact of SUTs over the life cycle from sourcing to end-of-life [1-5]. The consensus in these published reports, summarized below, is that conventional fixed systems have a higher environmental impact, at all process scales examined, than single-use systems.

Product description

Thermo Scientific™ single-use bioprocessing systems have transformed the cell culture industry— allowing for quick, economical, and scalable production. Used at every production stage—from buffer and media preparation through filling and shipment, and from small- to large-scale production, single-use systems can be adapted to virtually any process.

The benefits of single-use systems include:

- **Scalable**—well suited for use from benchtop to production scale processes.
- **Readily integrated**—compatible with a variety of high-performance systems for all steps in the production of therapeutic biologics.
- **Operational**—reduces the risk of cross-contamination. The elimination of cleaning in place (CIP) and sterilization in place (SIP) systems reduces water consumption as well as setup, maintenance, and validation times, enabling increased output.
- **Economic**—helps reduce capital investment and labor costs, leading to a reduction in production costs.
- **Strategic**—lowers investment costs by enabling shorter time to market and reduction of risk in the early stage of the product development cycle.

*For a commercial MAb process at 3 x 2,000 L scale (Sinclair et al. 2008) [3]

Green feature

Less waste

Several LCAs have been conducted for monoclonal antibody production at scales of 100 L to 2,000 L using single-use and conventional fixed systems [1–5]. These studies have evaluated the impacts not only during use and end-of-life, but also include impacts related to sourcing raw materials and manufacturing the units (Table 2). Factors included in the LCAs summarized here focused on areas that are affected by choosing disposable equipment such as raw materials, facility, utilities, consumables, and labor. These studies, however, did not account for potential differences in product yield resulting from the choice of process technology. It also did not include general cleaning, garment cleaning and/or disposal, or shared consumables such as small-scale culture equipment, weigh boats, pipette tips, gloves, etc. Traditional systems were assumed to have a 10-year lifetime, after which 25% was assumed to be reused while the remainder is recycled (90%) or landfilled (10%), while the single-use items were assumed to be incinerated without energy recovery (or nonhazardous waste sent to landfill) [2,3]. The difference between fixed and single-use processes is higher at small (100 L) scale compared to large scale (2,000 L) [1], so the 2,000 L scale has been used as a conservative representation of a "typical" process.

The results of these LCA studies have demonstrated that single-use systems use less water and energy, and have a lower overall environmental impact compared to conventional fixed systems. The high environmental impact of fixed systems is driven by water usage and the energy consumption required for cleaning and sterilization processes (process water, steam, and the water for injection still) during the use-phase of the product life cycle (Figure 1; Tables 1, 2) [1–5]. In contrast, single-use systems are sterilized by irradiation, reducing or eliminating the need for large quantities of process water, steam and water for injection, and the energy associated with those processes. For a typical process, single-use systems reduce water consumption by 87%, energy consumption by up to 29% (for a facility that can also take advantage of the reduced facility footprint associated with SUT), and CO_2 emissions by 25% (Tables 1,2). This translates to utility savings at the facility compared to conventional systems. [3,7].

While environmentally favorable at all other stages, single-use systems do have a greater impact than fixed systems at end-of-life because most components are disposed through hazardous waste incineration or through landfill disposal of non-hazardous waste [6,7]. Although this impact is small compared to the benefits discussed (Figure 1), there is an opportunity to further reduce this unfavorable impact of single-use systems through incineration with energy recovery or other more sustainable waste streams, if available to your institution. Various options for disposal and future opportunities have been summarized by the bio-process systems alliance [8]. These include landfill (untreated, treated, or with grinding), recycling, incineration (with and without energy recovery), and pyrolysis.

For production of a monoclonal antibody (full process train) at 2,000 L scale, as much as 300,000 L (~80,000 gallon) of water could be saved using single-use systems [1]. This is equivalent to 16,000 5-gallon water cooler bottles, or more than the average annual water usage for two people [9]. Reducing water and energy usage by using single-use systems helps to minimize not only utility costs, but also our customers' footprints. This is a win for our customers and the planet.

Table 1. Water and energy consumption for a typical process (commercial MAb production at 3 x 2,000 L scale) [3].

	Water consumption (L)	Energy consumption (kWh)
Fixed	104,524	14,451
Single-use	13,532	9,697
Difference	**-87%**	**-29%**

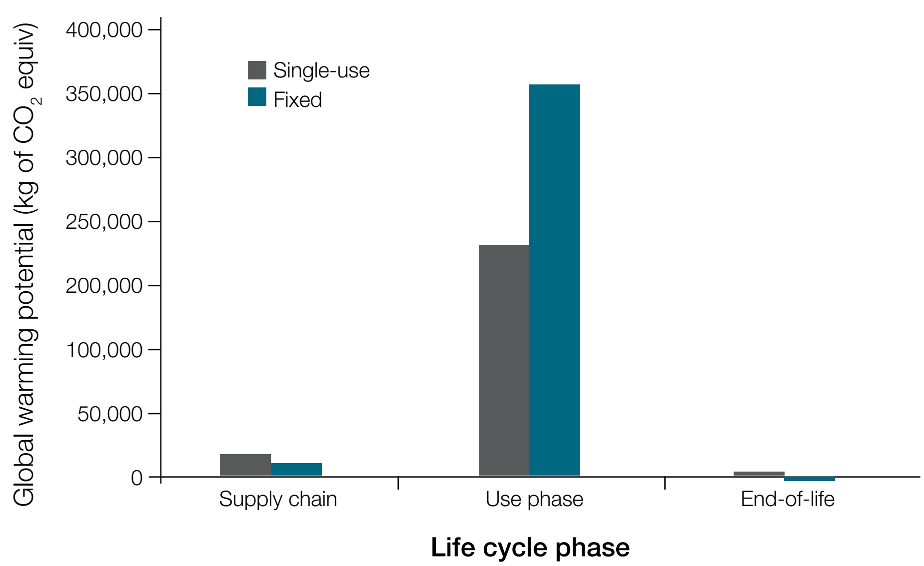


Figure 1. Global warming potential (GWP, as kg of CO_2 equivalents) of a typical process (commercial MAb at 2,000 L scale) grouped by life cycle stage [2].

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Table 2. Summary of difference in CO_2 emissions (per batch for a typical process) for single-use compared to fixed systems. Differences in values are relative to the fixed system facility [3].

Source	Difference (%)
Sterilization-in-place	-0.3
Cleaning-in-place	-0.6
Transporting plastic	0.1
Pumping water and wastewater	0.0
Steel fabrication (amortized per batch)**	-4.0
Plastic polymerization	0.4
Plastic extrusion	0.3
Water for injection still	-18.7
Cleanroom energy	0.0
Incinerating plastic	5.0
Workers driving to work	-7.7
Total difference in CO_2 emissions per batch	**-25.5**

** Amortization of stainless steel components over standard 8 years in BioSolve.

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