

Application of Single-Use Technologies (SUT) in Biosimilar Development

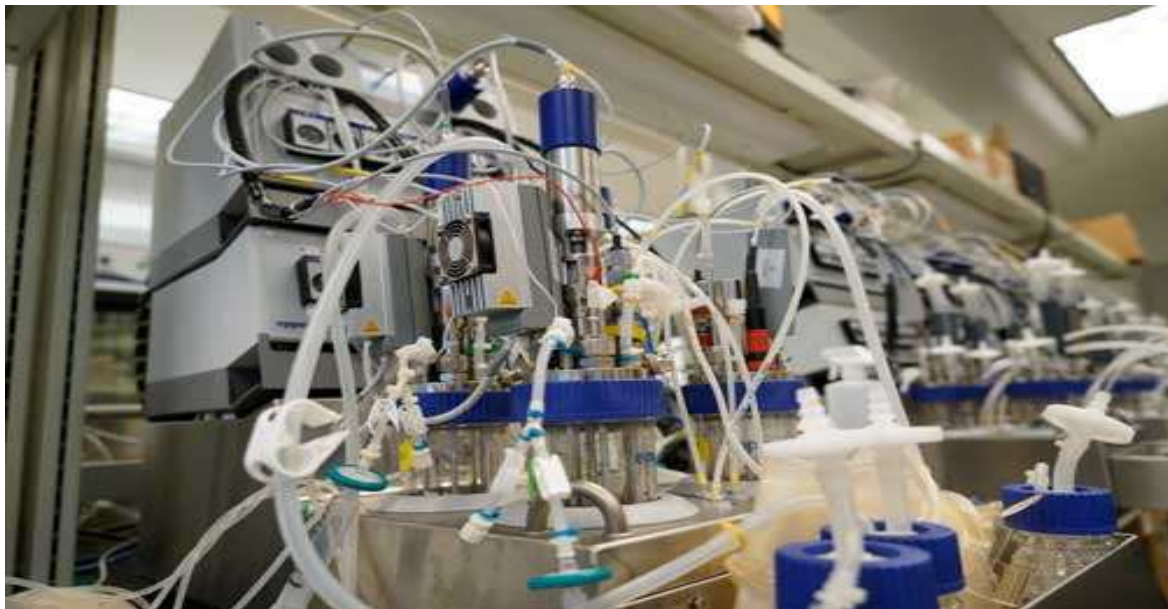
The current processing paradigm of large manufacturing facilities dedicated to single-product production is no longer an effective approach for best manufacturing practices. Additionally, in recent years, patents on several blockbuster biologics have expired, which means leading pharmaceutical companies can no longer charge a premium for these products.

The subsequent launch of biosimilar drugs, which can be sold at a lower cost, has put pressure on manufacturers to lower production spending in order to stay competitive.

Single-use systems are ideal for multi-product manufacturing facilities, especially where process steps may differ. They eliminate contamination crossover, change out time, and downtime for cleaning and sterilization between batches and products. Therapeutic developers are increasing their use of single-use systems for clinical batches, and many will continue at production scale as batch sizes become smaller.

Benefit: Single Use System

Primary savings benefit of single-use systems for biosimilar development is the reduced cost for process development and clinical trials. By changing out pre sterilized single-use bags between product batches, manufacturers can eliminate the risk of inter-batch contamination from more difficult to manage in-house sterilization processes. Single-use systems also have applications in formulating and filling operations, moving purified biosimilar drug substances to the formation container.



Single-use technologies offer savings in cleaning expense, especially purified water and WFI usage and have demonstrated greater safety without endangering environmental efforts compared to stainless-steel systems. By implementing single-use systems, manufacturers can avoid issues related to cross contamination between batches and

products. Cross contamination is a risk with all bioprocessing equipment that is reused, including piping, tanks, mixers, and bioreactors. Cleaning validation for such equipment is expensive and time-consuming.

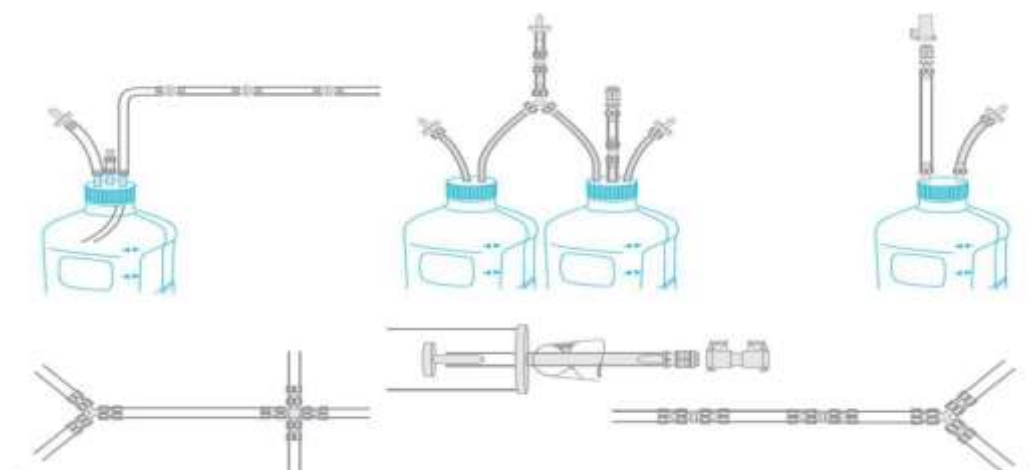
Single-use systems reduce costs associated with cleaning, maintenance, and assembly, minimize operator exposure, and free facility resources for other activities. Eliminating user-managed cleaning and sterilization reduces the need for a utility system and piping within a facility, leading to faster facility build time and lower capital cost. Establishing a single-use-enhanced facility takes about half to a quarter of the time that it takes to install a stainless-steel facility.

Single-Use System Pro's & Con's

Technical	Traditional Stainless Steel Technology	Single Use Technology
Product Change over Time	Slower	Faster
Flexibility to change	Painful	Easy
Campaign Turnaround times	Slower	Faster
Water Usage/Waste Water	High	Low
Solid waste Disposal	Less	More
Leachable/Extractable validation	Small	High
Facility Size	Large	Smaller
CIP	Complex	Simpler
SIP	Complex	Simpler
Sustainability	Low	High

A solution toward Single Use Assemblies

Ami polymer offers wide range of gamma irradiated single use assemblies for various critical applications in biopharmaceuticals. These are range from simple tubing with connector to complex manifold with several joint/connection. All the assemblies are manufactured and packed in Class 7 certified clean room. We cover the whole upstream and downstream bioprocess, ranging from laboratory scale and pilot plant scale to production scale. Few applications of upstream and downstream production in Biopharmaceutical industries where Ami polymer supplying assemblies listed below:



- Buffer and media transfer (feeds, the addition of base/acid, antifoam, growth medium, and other liquids),
- Collecting samples with zero risk of contamination assemblies,
- Media filtration assemblies,
- Inoculation assemblies,
- Removal of liquids from bioprocess assemblies,
- Carboy/bottle assemblies for cell culture,
- Product Filtration assemblies,
- Filter manifold assemblies and
- Peristaltic pump tube manifold assemblies.

