



# Empowering Customer Success Through Assurance of Single-Use Supply

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# Empowering customer success through assurance of single-use supply

Single-use technology (SUT) has come a long way in the last 20 years. Early on, biopharma and biotech embraced it, primarily in process development and early-phase clinical trials; but in recent years, the industry has seen higher adoption of SUT in cGMP manufacturing due to the many benefits it offers, such as shorter turnover time as well as reduced capital investment in equipment. The flexibility of SUT also allows for a more fit-for-purpose product that meets the needs of each manufacturer's unique process.

The urgent need for a vaccine to combat the current SARS-CoV-2 pandemic further strengthens the argument for implementing SUT at a larger scale. Ramping up production to the volumes required for global vaccine distribution would be considerably slower with traditional

stainless steel, since the timeline for building a greenfield stainless steel site from scratch is anywhere from two to five years, not including time for validation. Conversely, building and equipping a fully validated single-use facility can be done in a fraction of the time and up-front capital investment.

Yet, the rapid growth of SUT is not without its own challenges, and maintaining assurance of single-use supply is of major importance to biopharmaceutical drug and vaccine developers. That is why Thermo Fisher Scientific employs a combinatorial strategy that utilizes standardization, global capacity expansion, and quality harmonization processes to ensure manufacturers have consistent access to high-quality products.

## Securing our foundation of supply

With more manufacturers looking to adopt SUT in a cGMP environment, the demand for product availability has increased significantly. To continue successful SUT adoption while avoiding supply shortages in the future, two steps are critical. First, SUT suppliers must establish an integrated and robust supply chain that services manufacturers well into the future. And second, suppliers and manufacturers need to collaborate and develop forecasting mechanisms that enable proper resource and capacity planning. It is everyone's responsibility to work together to prevent any interruptions in the supply network that could lead to delays in SUT production or, worse, to drug shortages.

BioProcess Containers (BPCs) and fluid transfer assemblies (FTAs) from Thermo Fisher are critical components in today's bioprocessing industry, both upstream and downstream. The BPCs, which come in multiple shapes and sizes from 50 mL in 2D to 10,000 L in 3D, comply with the rigorous industry quality standards for the production of life-saving therapeutics and vaccines. To meet our supplier obligation described above and to ensure BPC and FTA availability, Thermo Fisher has gone beyond just securing safety stock and raw material inventory. We are the first and only supplier in the industry

to qualify a second supplier for our leading films—Thermo Scientific™ Aegis™ 5-14 and CX5-14 films—which strengthens our ability to provide film even when certain scenarios challenge our supply. However, this is only a portion of the effort we have made to secure our SUT supply.

## Unlock the value of standardization

SUT's ability to increase flexibility and productivity is a major advantage in today's rapidly changing biomanufacturing landscape. And while its benefits have long been known, adoption of SUT in large-scale cGMP manufacturing is only recently picking up speed, which is not surprising in an industry historically averse to change. As a result, there is now a growing pool of suppliers in this market that offer a variety of tubing, fittings, and connectors. Manufacturers have been able to take advantage of the numerous options by using them to build the most appropriate SUT system design, based on the unique needs of their product and process as well as the quality of the components.

While this flexibility in design allows for fit-for-purpose SUT products, there is considerable risk in relying on the supply chains of multiple suppliers. Therefore, remaining a reliable supplier in our industry means limiting the standard components we offer as part of our BPC or FTA assembly, while still giving manufacturers the flexibility to build a fit-for-purpose product.

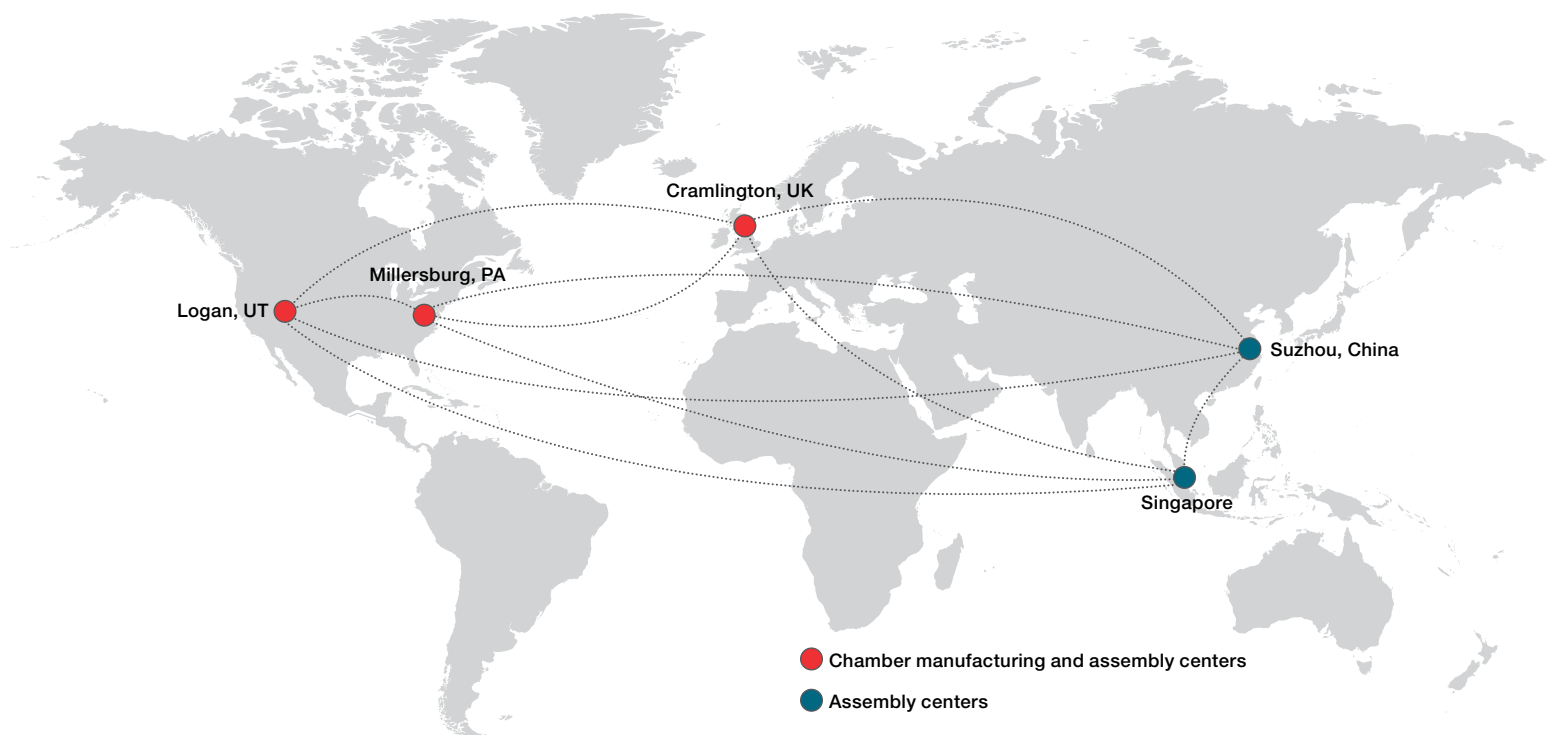
That is why we have launched a global standard component library (GSCL) comprised of the most commonly used filters, connectors, tubing, and more from many different suppliers in the industry. We encourage manufacturers to build their BPC and FTA assemblies using these components, as they have already been tested, validated, and stocked.

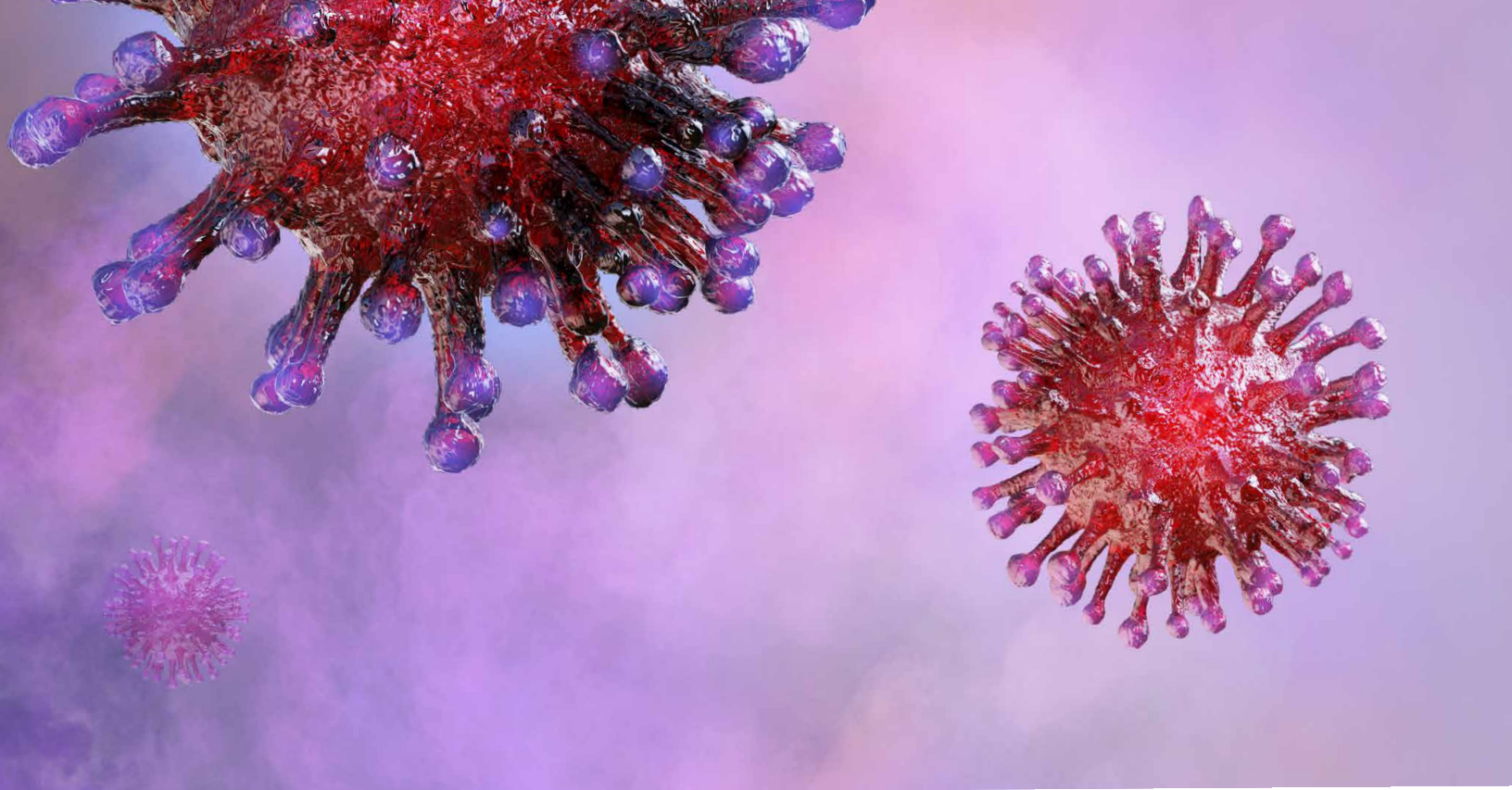
We currently have a network for five assembly sites for BPC and FTA manufacturing and assembly. For those that have qualified multiple Thermo Fisher manufacturing sites, they can have the BPC or FTA built at each one, knowing the components will be identical and available. Seeing the advantage of maintaining fewer drawings and ordering standardized products, manufacturers are already embracing the GSCL. As the demand for SUT in large-scale cGMP manufacturing increases, so does Thermo Fisher's commitment to investing in its future—and our customers' future—by also expanding our SUT manufacturing network.

## A reliable infrastructure of SUT supply

At the core of SUT supply continuity and control is a strong, single-use equipment supply chain. Thermo Fisher realized in 2019 that its manufacturing network would not be able to sustain continuous growing demand in SUT with the available capacity in Logan, UT; Millersburg, PA; and Cramlington, UK. That is when we began to expand our existing SUT manufacturing network, adding more than 100,000 square feet of total cleanroom space while also adding SUT assembly centers in Singapore and Suzhou, China to support the growing Asian markets. This effort exemplifies our long-term commitment when it comes to the reliable SUT supply chain manufacturers require and expect.

With more capacity across the globe, it is important our processes and people remain aligned with our goals. That is why we have harmonized our quality systems and processes, providing true redundancy in manufacturing through the assurance and availability of high-quality products. Combined with the GSCL, this harmonization gives manufacturers the ability to qualify multiple manufacturing sites knowing that, regardless of where their product is produced, it will always meet the same quality and manufacturing standards.





## A forward-thinking strategy for the future of pharma

As pharmaceutical companies began to answer the call for SARS-CoV-2 vaccines in 2020, we saw the impact of when a deficient supply of critical raw materials meets a high demand for quick scale-up of life-saving medications. Producing the number of doses for each phase of the vaccines' rollout required strategic thinking, world-class expertise, and industry collaboration. The same is necessary to circumvent SUT supply shortages in the future, especially as we see an increased demand for flexible facilities utilizing it. Countries that want to speed up SARS-CoV-2 vaccination distribution may even begin building their own local manufacturing sites with single-use systems, further driving the growth of SUT.

The global SARS-CoV-2 response, combined with the rising adoption of SUT, means suppliers must make substantial efforts to meet the moment for SUT supply. Thermo Fisher's strategy is the result of a proactive approach that began years ago when we saw what was not only an emerging problem, but also a new opportunity to serve our customers. As you consider the future of your product, make sure your supplier is equipped with an SUT supply strategy that empowers you by securing the single-use products you need now, and well into the future.

Find out more at [thermofisher.com/flexiblecontainment](https://thermofisher.com/flexiblecontainment)

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