



Single-use flexible containment

# Building a robust manufacturing network

The way forward in single-use  
supply assurance

# Creating a reliable and harmonized global supply chain for single-use consumables

## Fast-tracking supply chain resiliency

A resilient supply chain for single-use technologies (SUTs) is critical to helping ensure biopharmaceutical manufacturers are able to meet their key operational business goals. Suppliers have been challenged with unprecedented high demand for single-use consumables coupled with ongoing shortages of manufacturing capacity and raw materials.

To meet these challenges head-on, Thermo Fisher Scientific has implemented a multi-tiered strategy to improve the resiliency of our supply chain that utilizes standardization, global capacity expansion, and quality harmonization processes to help ensure manufacturers have consistent access to high-quality products.

A critical component of this overarching strategy is aimed at maximizing the efficiency of new and existing manufacturing capacity through the creation of a harmonized global manufacturing network. Our manufacturing network utilizes a standardized approach to SUT design and a harmonized manufacturing process to produce SUT products of consistent quality, form, fit, and function no matter where they are built. Our network approach is the way forward to help assure single-use supply.

We are committed to finding new solutions to optimize the way we deliver single-use products to our customers around the globe. These standardization efforts are designed with the goal of providing shorter lead times while consistently meeting or exceeding industry quality standards.

## Enabling the network

### Single-use global network enablement and redundancy of supply

The creation of the SUT manufacturing network is part of our global strategy to help provide our customers with a more responsive supply chain for Thermo Scientific™ BioProcess Containers (BPCs) and fluid transfer assemblies (FTAs).

This SUT manufacturing network allows for more efficient capacity utilization through established manufacturing redundancies with the capability to transfer demand across the network to meet complex customer demand signals. A core strength in the application of open-architecture design principles to support customer-specific configurations is maintained but balanced with the option for standardized components and raw materials, pre-qualified and stocked for use across our network.

We anticipate that this novel approach to single-use manufacturing will help mitigate supply chain risk and enable Thermo Fisher to provide a more efficient and more sustainable SUT supply chain.

## Key elements to building an efficient network



### Expansion

We will increase our manufacturing capacity by nearly 2.5x by the end of 2022



### Standardization

We've implemented a design strategy that leverages the benefits of standardized components and raw materials for optimal network manufacturing



### Harmonization

We've aligned our critical businesses and manufacturing processes to help enable consistent manufacture of our high-quality products across our network



### Enablement

We're operationalizing our network strategy to transform the way we produce your products, including an option for enabling your current single-sited products for network manufacture

~200,000 ft<sup>2</sup> of cleanroom space  
across our global SUT manufacturing network

● **Networked SUT sites**

**Chamber manufacturing  
and final assembly locations:**

- Logan, Utah
- Cramlington, United Kingdom
- Nashville, Tennessee

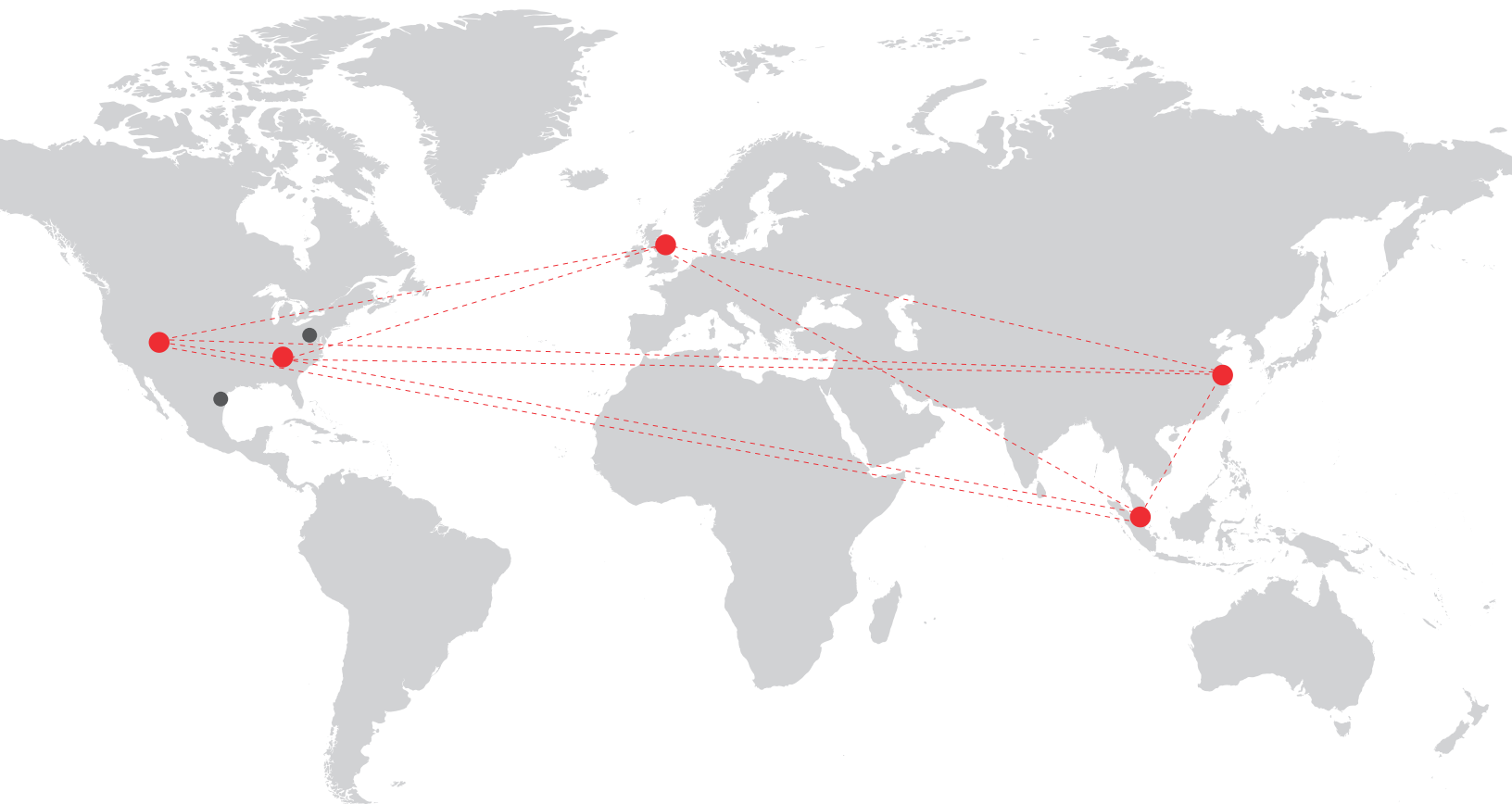
**Final assembly locations:**

- Joo Koon, Singapore
- Suzhou, China\*

● **Future networked sites**

The sites listed below are currently under evaluation to be incorporated into the SUT manufacturing network in the future:

- Millersburg, Pennsylvania
- Matamoros, Mexico



\* Finished goods will not be exported from China.

# Standardization and harmonization

## Network standardization

### Offering customers the flexibility to configure products to fit their specific process

With a virtually unlimited design space for SUTs resulting from the combination of thousands of potential components from hundreds of suppliers, the issue of supply chain security becomes a significant area of risk in terms of business continuity, cost containment, and lead time. Standardizing at the component level allows us to invest additional resources into securing the materials that are widely used. By implementing key standardization and harmonization initiatives, we've taken strides to address customer challenges with a focus on building a resilient supply chain network while maintaining flexibility of design.

## Global standard component library

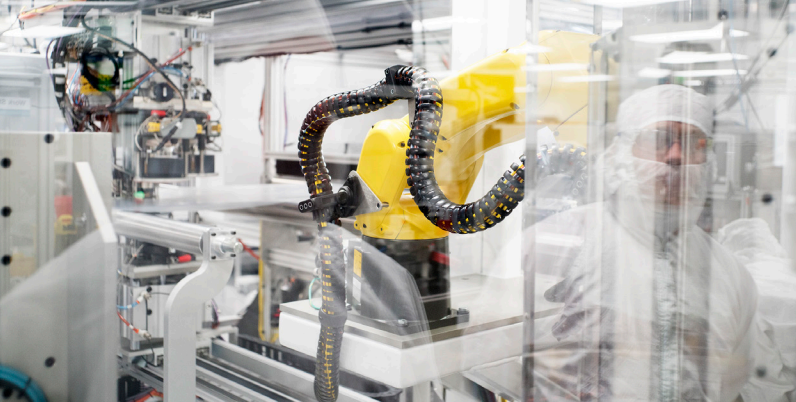
To help enable reliability in our industry, we are optimizing the design space around the standard component options we offer for network manufacture while preserving the flexibility to build complex, custom designs. To this end, we've created the global standard component library (GSCL) for use in the design of single-use products that are optimized for network manufacture, use pre-qualified components, have standard claims, and are stocked within the network. The GSCL encompasses our most widely used components, which have been carefully selected based on their broad applicability and their universal relevance.

Within this library, we've included one of the market leading Thermo Scientific™ Aegis™5-14 and CX5-14 film platforms and a large variety of commonly used connectors, tubing, filtration devices, sensors, fittings, clamps, and closures. We will continue to maintain an unparalleled ability to create highly customized SUT designs for the most complex applications. However, through standardization, we offer customers the option of choosing designs that offer our highest level of supply assurance.

### GSCL key characteristics:

- Broadly applicable
- Qualified for network manufacture
- Stocked within network
- Enables creation of assemble-to-order (ATO) network designs
- Carries consistent, standard claims, including sterility, and endotoxin-, bioburden-, and particulate matter-free





## Network harmonization

The creation of a manufacturing network is dependent on true manufacturing redundancy, with the ability to seamlessly shift demand to efficiently utilize available capacity. To that end, each facility within our SUT network has been harmonized with respect to product attributes, manufacturing processes, and quality management systems (QMSs) to ensure equivalence in product form, fit, and function. We've harmonized our manufacturing network, systems, and processes to ensure that no matter where a BPC or FTA is manufactured, the product meets the same quality and manufacturing standards. From product design procedures, claims, and certification of analysis (COA) to labeling and packaging, you should expect to see the same high-quality product produced to the same high standards regardless of its site of manufacture.

This adjustment in BPC manufacturing approach strips away waste traditionally associated with highly customized product designs, leveraging our global standard components to delay the point at which customization is applied. Shifting the BPC manufacturing paradigm toward late-stage product customization moves complexity as far downstream in manufacturing as possible. This allows us to provide the same customized product while also minimizing lead times. Purpose-built equipment and processes, leveraging standard product components, minimize manufacturing waste.

## Irradiation site network

A robust network of irradiation suppliers is critical to ensuring consistent and efficient sterilization of our single-use products. Our global manufacturing network leverages a partner network of irradiation suppliers across three continents, near our manufacturing sites and strategically located near regional biotech hubs. Each of our network sites benefits from a minimum of two in-region qualified irradiation suppliers.

## The value of multi-site qualification

Multi-site qualification allows you to take advantage of the benefits of network manufacture for your custom-designed products. All current and future standard catalog items are eligible for network manufacture by default. However, new and existing custom designs will require site acceptance and customer approval prior to network manufacture. Please contact your representative to learn how we can support your move to network manufacture with our current, shortest network lead times and supply assurance level.

**Table 1. Alignment of critical business processes to support quality and consistency across the SUT manufacturing network.**

Product	Manufacturing	Quality
<ul style="list-style-type: none"> <li>• Product claims</li> <li>• Product numbering</li> <li>• Packaging</li> <li>• Labeling</li> <li>• Specifications</li> <li>• Drawings</li> <li>• COA</li> <li>• Irradiation dose</li> </ul>	<ul style="list-style-type: none"> <li>• ISO 7 cleanroom–certified and maintained per ISO 14644</li> <li>• Environmental conditions</li> <li>• Manufacturing processes</li> <li>• Production planning</li> <li>• Approved suppliers</li> <li>• Operator training</li> <li>• Enterprise resource planning (ERP) system</li> </ul>	<ul style="list-style-type: none"> <li>• QMSs</li> <li>• Quality inspection</li> <li>• Document control and records</li> <li>• Corrective and preventative actions</li> <li>• Compliant management</li> <li>• Component qualification</li> </ul>

## Global single-use manufacturing

The biopharmaceuticals market has been rapidly adopting SUTs to reduce risk and improve operational efficiencies. Thermo Fisher has been investing in capacity and innovation across all of our portfolios, including flexible containment, single-use bioprocessing equipment, and rigid containment solutions. These portfolios have proven to be robust and scalable from laboratory to cGMP production applications.

### Flexible containment

- Logan, Utah
- Millersburg, Pennsylvania
- Nashville, Tennessee
- Cramlington, United Kingdom
- Suzhou, China
- Joo Koon, Singapore
- Matamoros, Mexico

### Rigid containment

- Miami, Oklahoma
- Rochester, New York
- Roskilde, Denmark
- Suzhou, China

### Equipment and automation

- Santa Clara, California
- Leicester, United Kingdom

### Related resources

Watch these videos to learn more about how we are expanding our global single-use manufacturing network:



Global manufacturing capabilities overview



Logan, UT, and Millersburg, PA



Cramlington, UK



Suzhou, China

We are committed to supporting our customers by providing a single-use flexible containment manufacturing infrastructure and a reliable supply chain for operations. Contact us to talk about your single-use flexible containment needs.

[Request more information](#)

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

**thermo** scientific

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