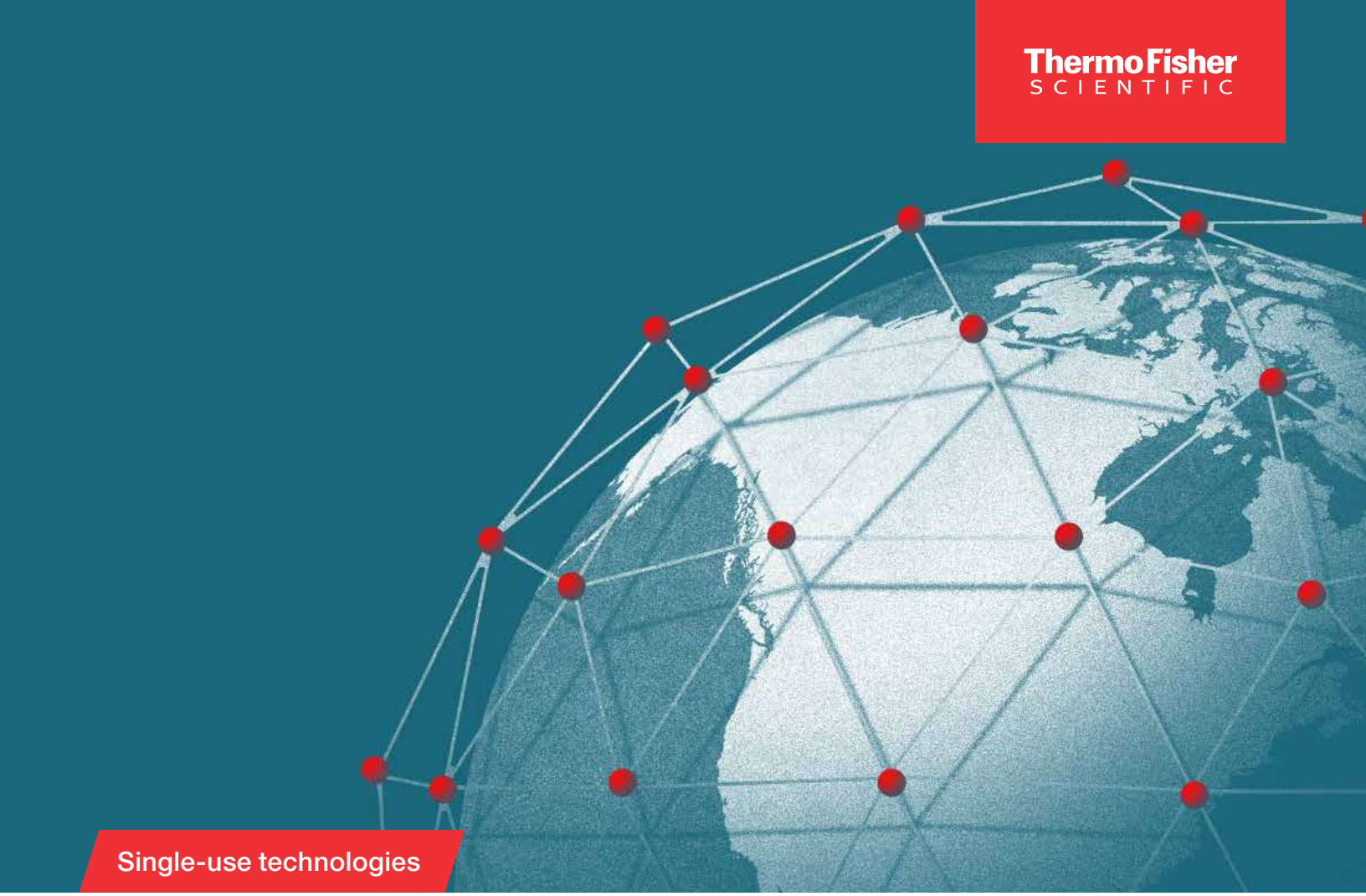

Single-use technologies

A collaborative path to single-use supply assurance

Improving your supply chain management

Source: Thermo Fisher Scientific

Supply chain management is of critical strategic importance to any biopharmaceutical company. Locking in the supply to support crucial production components in a landscape beset with unprecedented demand will require cross-functional, collaborative solutions from the industry's biggest players.

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Today, the entire single-use supply chain is under severe strain, driven largely by the disruptions, risks, and long lead times caused by the ongoing SARS-CoV-2 virus crisis. Addressing supply chain disruptions in both the short and long term requires comprehensive planning strategies and collaborations. Thermo Fisher Scientific, a global leader in providing technology solutions for the life sciences industry, and Sanofi, a multinational company focused on human health, have jointly recognized the value of collaborative partnership in bridging shared supply chain challenges. In response to today's market landscape, Thermo Fisher and Sanofi have worked to create a relationship that supports both companies' long-term supply chain goals.

In a recent webinar, "A Collaborative Path to Single-Use Supply Assurance," professionals from Thermo Fisher and Sanofi explored ways in which pharmaceutical companies and their suppliers can mitigate the challenges that define the current life sciences landscape.

As part of the webinar, the speakers explored how Thermo Fisher and Sanofi are working toward creating redundancy of supply through a multi-tiered strategy; Thermo Fisher is focused on more than doubling manufacturing capacity by the end of 2022 when compared to pre-virus crisis levels.

Speakers for the event included:

- Prateek Gadhoke, Global Head of Specialty Care Procurement, Sanofi
- Christine Callahan, Vice President, Global Supply Chain, Life Sciences and BioProduction Groups, Thermo Fisher Scientific
- Mike Ellis, Director, Commercial Programs, Single-Use Technologies, Thermo Fisher Scientific

Some of the key approaches employed as part of this effort have included:

- Implementing a design strategy
- Leveraging benefits of standardization by decreasing the overall number of stock kept units (SKUs) in raw material components by driving a global standard component library
- Harmonizing critical business and manufacturing processes to help ensure consistency and form fit and function, regardless of where products are within the global network
- Enabling a global network strategy to transform the way these companies manufacture products for customers

Evolving procurement and supply chain management internally is especially important for companies in the bioprocessing space. The vulnerability inherent to manufacturing, handling, and shipping biopharmaceuticals has spurred a surge of companies looking to increase safety stock and initiate product builds. Building the right supply and demand–planning relationships with key vendors is core to helping ensure this supply assurance. As companies across the space work to scale up their supply, maintaining collaboration and connectivity is key to guaranteeing that capacity is experienced across the sector, its customer base, and ultimately, patient populations.

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Creating optionality through collaboration

There are very strong trends that can be observed both globally and regionally when it comes to pharmaceutical supply chains. As the virus crisis began closing off borders and subsequent transportation issues exacerbated global supply chain issues, many companies began exploring shorter, more regional supply solutions to counteract shortages and long lead times. Shortening the supply chain also has positive implications for costs, which has become increasingly important as demand has ramped up and the cost of materials, supplies, and transport has ballooned commensurately. Reimagining the supply chain to address costs, stability, and lead times is key to achieving both short- and long-term supply resiliency.

Creating optionality and extending the industry's demand horizons through forecasting, capacity planning, and increased raw materials capabilities represent some of the biggest hurdles to achieving resiliency. The key tenets to surmounting these challenges—expansion, standardization, harmonization, enablement, stabilization, and optimization—are all necessary to achieving Thermo Fisher's envisioned expansion. To more than double its footprint in 2022, the company will first focus its efforts on harmonization, aligning its critical business, manufacturing, and quality assurance processes. As Thermo Fisher works to transform its manufacturing organization into a global network, it is enabling stabilization through the strategic transfer of demand throughout the network, as well as optimization aided by customer collaborations that facilitate product conversions from single-site to network manufacturing.

By the end of 2022, Thermo Fisher's approach to its expansion will make it the largest single-use manufacturing organization in the world, with six regional assembly sites: two in Logan, Utah; one in Nashville, Tennessee; one in Cramlington, England; another in Suzhou, China; and one in Singapore. The company will also have two sterilization sites for each assembly site; five networked sites, including three Centers of Excellence for chamber manufacturing; two film manufacturing sites in Japan and North America; and expansions to its non-networked sites in Millersburg, Pennsylvania, and Matamoros, Mexico. Thermo Fisher has invested more than $400 million in these expansions.

Supply planning: challenges and opportunities

Historically, demand signals within the industry have been highly transactional, facilitated by relatively short lead times. The virus crisis has shifted that paradigm immensely, and single-use technology suppliers like Thermo Fisher have been forced to adapt, particularly through closer collaboration and connection to customers and suppliers alike. Planning for demand now requires looking well beyond the purchase orders currently in queue. Thermo Fisher forecasts its customers' demand 12, 18, and even 24 months in the future.

While achieving a perfect forecast is nearly impossible, establishing a solid one starts with gaining insight into suppliers' overall capacity. As a Thermo Fisher customer, Sanofi has embraced a forward-thinking strategy regarding supply planning, with a goal of performing demand forecasting as far out as three to five years. In response to SARS-CoV-2, the company introduced a "crisis control tower" structure less than two years ago to achieve greater vertical organization. With a network of roughly 10 internal manufacturing sites, a large Contract Manufacturing Organization (CMO) network, and a mix of drug substance, drug product, packaging, labeling, and distribution operations, Sanofi's business practices represent a comprehensive, end-to-end supply chain. The vertical orientation the company has implemented, with localized planning at the site level, has helped Sanofi better engage with life sciences partners such as Thermo Fisher and give more accurate demand signals.

When working to establish a reliable forecast, Sanofi engages in routine business reviews, often on a quarterly basis, to revise its short-, medium-, and long-term planning horizon. Today, the company is working at getting more advanced, integrated business planning processes in place, particularly in procurement, for which the demand signals are critical in the current landscape. Its supply chain team is also working to standardize how Sanofi communicates its forecast consistently and in ways that reduce the workload for local manufacturing sites, regional networks of manufacturing sites, and its global business units in specialty care and vaccines, which experience a heavy overlap between their process supply bases.

Standardization doesn't have to include a highly advanced electronic data interface (EDI) connection; a routine, coordinated check-in with the right people who can speak on behalf of a global consolidation process is one of the foundational tools to achieving standardization. For the majority of organizations that do not possess fully integrated Enterprise Resource Planning (ERP) Material Requirements Planning (MRP) interfaces, it is even more critical to engage in higher-level business discussions with key supply base and sciences partners, such as Thermo Fisher, to discuss business trajectories for key brands in the commercial space, as well as launches and other core activities.

Launches are one example of the potential instability inherent to forecasting. Sanofi has approximately 17 launches planned for the next five years, and the variables that attend those launches, from clinical manufacturing to process performance qualification (PPQ) to commercial launch, engender uncertainty when it comes to long-term demand planning. Consequently, its supply forecasting strategy will be heavily dependent on trying to quantify that uncertainty. This planning will require more than an EDI—establishing partnerships and consolidating information in ways that give organizations like Sanofi and Thermo Fisher a more holistic understanding of long-term supply constraints will be crucial to their success.

Solving supply chain issues through increased capacity

Access to raw materials is a critical point of risk in a supply chain. A pharmaceutical company in Sanofi's position may not possess the same "visibility" when it comes to assessing sourcing that a supplier like Thermo Fisher may have; for suppliers, affording customers feedback on which components are more accessible than others, as well as predictions on how that may change and when, is important to maintaining supply chain resiliency.

That optionality becomes particularly important when working to maintain legacy operations. As opposed to the new capacity currently being built out around vaccine processes, legacy processes often cannot be changed on the fly and require an approach that emphasizes early demand planning and optionality. While historically, single-use has grown around a single source for a given component, many suppliers, including Thermo Fisher, are working toward qualifying alternative sources, thereby enabling greater optionality and transparency, paving the way for more standard components and more qualified sources for those components.

In the short term, Thermo Fisher is working to increase optionality through its new, networked manufacturing sites. As new sites come online—Suzhou opened in early 2021, Singapore in mid 2021, and Nashville is planned to open in 2022—Thermo Fisher will continue to offer customers co-located near a site access to that new capacity. In the long term, Thermo Fisher is positioned to level-load its capacity across this global network, improving on-time, in-full (OTIF) rates and reducing lead times.

Expanding this capacity and helping customers understand its reach is one element of ensuring resiliency. Another factor is creating supply redundancies, whether through validating more supply sources or generating more capacity. Central to this is a quality strategy that accounts for varying levels of validation, from localized requirements at the site level to global change control requirements necessary to standing up new sites. Prioritizing that capacity activation in the face of time and resource constraints is a challenging proposition, and integrating newly acquired business units in ways that facilitate networked connectivity is equally critical. Establishing a globally accepted quality management system is the key to achieving not only level-load capacity, but also to building an interconnected regionalized network with primary sites and backup secondary sites for every customer.

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Achieving standardization for the future

There are varying levels of standardization that are possible within the pharmaceuticals space—from a structure in which component manufacturers fully standardize and commodify single-use technologies across the board to a more company-level approach, with components supplied by the same vendor but employed across various sites. Drawing a line in the sand and beginning the process of standardizing a company's component libraries may be a prudent strategy for many organizations, as it allows for a more gradual approach.

Since their inception, single-use technologies have been highly customized, with bespoke SKUs for custom processes. This paradigm has created a slew of different assemblies, each customized to perform the same function. By evaluating processes from the outset to establish standardized components, companies can start to push back against the challenges caused by these bespoke technologies in the wake of supply constraints. Thermo Fisher has performed extensive analyses of the most used components in its final assemblies, and has built a database, the Global Standard Component Library, to give its customers more latitude in evaluating and modifying their processes.

Thermo Fisher plans to deploy the Global Standard Component Library across its manufacturing network and have those standard components available at each of its assembly sites. As a living document, the library allows for multiple vendors of key components to be built into the specifications through collaboration with customers, and enables Thermo Fisher to de-risk single sourcing at the component level while building out a very robust design space for its customers. In addition, the library can be used to develop long-term horizon forecasts and secure key components from suppliers around the world.

Learn more at **thermofisher.com/flexiblecontainment**