

# **Enter the Age** of Modular Manufacturing

**Thermo Fisher Scientific's** standardized, modularized system provides individual building blocks that can be arranged in a customized fashion, while easing supply chain pressure.

Throughout the COVID-19 pandemic, Thermo Fisher Scientific has worked to ensure robust supply chains for customers. But the company has also been busy developing further novel solutions and strategies, including modularization, that offers many benefits to biopharma

customers. Rob Hendrix, Manager, Systems Design Engineering at Thermo Fisher Scientific, tells us more about these exciting developments.

### What is your role?

I work on single use and system design within the Bioprocess Collaboration Center. I am part of the Thermo Fisher Innovation Team and my primary role concerns modularization strategies and how to achieve more economical manufacturing efficiencies for customers at commercial scales. To really make an impact in this area, you must look at the process requirements and systems for manufacture, and also evaluate the impact of business decisions that affect investment in this area and de-risk both process and business-based factors.

How do standardized, modularized systems benefit supply chains? Modularization, at its core, allows us to use

the minimum chain of single-use manifolds at a high volume, whilst retaining the maximum number of degrees of freedom in your process design. Modularization may involve a little loss of efficiency during the unit operation optimization process, but this is more than made up for later on. As a business case, these small shifts in efficiency can ultimately have a significant impact. Modularization allows the same component (stock item) to be used for multiple unit operations within a multi-unit operation end to end process. This single component with multiple different

uses design philosophy solves several challenges that affect supply chain management, as it is based on ordering of a smaller subset of materials compared with custom processes. It promotes manufacturing robustness through the stocking of common materials within multiple manufacturing

suites, allows standardized deployment across multiple manufacturing sites, and decreases the risk of supply shortages for individual stock items.

Standardization of the manifolds offered through our mAb Process Playbook Modular Manifold Library allows the designer to seamlessly piece together their unit operations regardless of polymeric construction materials. It's our equivalent of building blocks ! Building blocks always connect regardless of which piece you have. Our components are also designed to remove the potential for errors, which might normally arise when stacking various process steps together or trying to transition between polymeric materials of construction to meet other mechanical requirements within a given process.

Modularization through standardized subcomponents helps to also build additional levels of human factor engineering into a manufacturing

design to further reduce manufacturing errors. One of the underestimated benefits of this type of modularization strategy is that it transitions the manufacturing mindset away from one of custom every time but "right-first-time" to one of "right-first-time" with a never changing connection process. This allows for specialization of operator tasks around a repeated subset of operations and thus an observable drastic reduction in errors associated with uniqueness.

## Why should manufacturers think about modularization early in the life cycle of a molecule?

Modularization via standard manifolds is a design approach that brings efficiencies at all scales but increases drastically as a firm moves toward commercial scale manufacturing. It is of utmost importance that clients transfer this philosophy into their development in the early stages of a molecule's lifecycle.

One of the pitfalls of many organizations is that the development drives information and process requirements in a one directional workflow from Development to Commercial. However, this can lead to over optimization toward unit operation specific yields and an end-to-end workflow design that does not translate efficiently at a commercial scale when manufacturability of the process is considered.

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To help clients adopt this design approach at earlier process scales within the development

pathway the modular manifold library is designed to offer the same engineering and design strategy starting from the bench top and then transitioning the whole way through commercial scale components. Maintaining the same components and design approach through the life cycle of the molecule from development to commercialization offers additional efficiency potentials for a firm including earlier troubleshooting and evaluation of engineering performance of the molecule with the subcomponents and polymers as well as an easier pathway to other manufacturing efficiencies such as batch record standardization and templating. This inherent combination of flexibility and efficiency is something not seen in customized, single-use processes.

#### What are the risks?

Our studies have shown that adopting the standardized modular approach does not increase errors associated with connections.

Foremost, modularization of an end-

to-end manufacturing process introduces a small increase in the total number of process connections within each unit operation. While the actual number of connection

the number of connection points within the process boundary. To further evaluate the potential impact of this connection, an increased statistical analysis was performed that evaluated the elevated connections within multiple same 2000L liter scale processes. This

analysis demonstrated that at a

unit operations has been shown in other publications to not be large this accepted increase in the number of connections runs counter current to the accepted design ethos of minimizing 98 percent success criteria the processes whether modularized or designed with fully custom and minimal connection single use manifolds behave statistically the same. This analysis was published by Thermo Fisher in a white paper titled Analysis of engineering manufacturing risk utilizing a modularized and standardized single-use manifold design approach.

What are the upsides? Our standardized, modularized system provides individual building blocks that can be arranged in a customized fashion. This reduces the need to turn to a custom solution since the customization can be achieved by just rearranging the pieces. These building blocks, by their very nature, remain constant, which simplifies supply and stocking. Standardization, therefore, leads to supply chain resilience by reducing the number of unique stock items required. There are also other benefits; for example, it can significantly reduce process design, as well as



address the complexities of component management, all without limiting process capability. It also simplifies upfront design time, resulting in time- and cost-savings for manufacturers. We believe

that using a consistent approach to design increases manufacturing success rate because it allows companies to focus on increasing production instead of managing complexity – highly valuable in terms of saving time and cost.

Adoption of this system is straightforward and requires very little change in company operating practices. Ultimately, its adoption should reduce the administrative burden of purchasing and stocking.

# Why partner with Thermo Fisher Scientific?

We are the ideal partner to collaborate within this field for several reasons. We have put a great deal of resources into developing our modularization options and strategy, particularly during the pandemic, and we have designed a system that simplifies, de-clutters, and improves supply chain performance. We also have a trusted and experienced presence worldwide and can deliver these subcomponents reliably.

Our innovation in this area is a great example of how Thermo Fisher Scientific works at its best. We actively seek opportunities to work together with our clients. We believe in establishing a trusted partnership led by collaboration and open communication to evaluate, assess, and plan, while finding the appropriate solutions early in your journey.. Through this philosophy, we keep evolving and growing alongside our clients. It is exciting to see how this system will be deployed across the industry - and where it will take biopharma manufacturing in the future.