



How does early process design impact the robustness of your supply chain?

Source: Thermo Fisher Scientific

More than ever, biomanufacturers are seeking support to quickly and efficiently produce a wide variety of therapies to meet the growing population's needs. Striving to enable and complement our customers' goals, we have leveraged our multidivisional, end-to-end workflow strategies to provide a highly flexible, standard, single-use technologies offering: the mAb Process Playbook. While production facility layouts may vary across internal and external networks. The included products are designed to address unit operations regardless of infrastructure, enabling more consistency and simpler technology transfers.

In a recent webinar, “How does early process design impact the robustness of your supply chain?”, our experts discuss how early design and early process design can impact the robustness of your supply chain within your organization. Thermo Fisher Scientific has compiled a library of standard and multifunctional products in the mAb Process Playbook. This resource will help to optimize your network supply chain by using a minimal number of unique manifolds to address diverse unit operations requirements. The theme is helping our customers truly optimize their manufacturing facility. To ground the conversation, we begin with the questions: (1) what is optimized manufacturing for a pharmaceutical organization and (2) how can the framework deliver the highest quality product that helps improve material availability, the least manufacturing risk, and the lowest cost?

The objective of this webinar is broken up into two interconnected biopharmaceutical manufacturing goals: minimization of the unique material catalog and optimization of batch output. The challenge of material proliferation has become a significant hidden problem impacting costs, lead times, service levels, and profitability. Optimized manufacturing strategies strive to mitigate these issues.

Strategies

1. Optimizing material catalog

- Objective: create a standard material catalog that helps improve material availability, reduces lead times, increases agility, and lowers cost
- Process: industry invests very little time here

2. Optimizing manufacturing batch output

- Objective: Help generate the greatest yield of drug supply with the fewest manufacturing batches
- Process: the industry spends a substantial amount of time here

Current design approaches allow SKU proliferation to occur specifically with single-use technologies and specialty chemicals. Process design for a specific manufacturing campaign is a particular challenge for CDMO companies that interface with multiple clients and have multiple processes running within their facility each year. From this one sees SKU proliferation develop as a part of the normal process design. With this structure, design practices are leading to more risk associated with the supply chain.

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What causes SKU proliferation of single-use technologies?

1. New modality workflows are developed using highly customized processes which promote complexity
2. Innovation in single-use tried-to-mimic stainless steel—component by component, new technology emerged to replace its fixed/reusable counterpart
3. Strict change management inhibits improvements—processes that are validated have limited ability to change with advances in technology or market supply

Originally in the biotech industry, based on the newness of single-use technology and the patient demand, highly engineered stainless steel custom facilities were designed for specific products without a lot of options. These process designs were highly customized and specific to each company depending on the type of molecule they were producing. As the industry has matured and indications have increased, the focus has shifted toward a demand for increased production with higher efficiency and quality to improve titers and product yields. The need for single-use technology started coming into the frame and becoming more and more practical for companies to adopt. Working within a highly regulated environment, this is not something where a company can simply make a change to a different technology. This is something that requires rigorous change management and regulatory approval in conjunction with employing change controls to ensure that process and product impact are being considered before any changes are made.

Using multiple single-use 2,000-liter bioreactors instead of a 20,000-liter stainless steel bioreactor allows companies to manage a whole portfolio of

products within their pipeline. This has the added benefit of streamlined changeover and cross-contamination management, where multiple products can be managed in a much more fluid manner. Not only this, but there is a huge push in the industry for single-use technology due to the engineering benefits from a facility design standpoint. Thermo Fisher Scientific can start using sterile raw materials that are closed, allowing us to simplify our facility design with unidirectional flow elements, high classification in ISO certification, and flexibility that stainless steel systems do not offer. From the start of facility design, even without knowing the process, customers can design around a platform or co-develop process design with facility design to shorten the overall lead time with facility construction. This allows the manufacturer to start producing batches sooner, decreasing the time it takes to deliver critical medicines to patients in need.

What causes SKU proliferation of chemicals?

1. Lack of integrated, unified infrastructure
 - Independent teams across sites accommodating clients' unique material requests and trying to meet tight deadlines
 - Lack of a centralized database or catalog
 - CDMO vs. client-owned—clients own or control their exclusive material resulting in material duplications
 - Lack of centralized catalog management
2. Technical regulations can drive raw material proliferation
3. Varying product phases can have varying specifications and testing
4. Post pandemic supply chain shortages

When looking at SKU proliferation of chemicals, we identified four key drivers that have resulted in us having a very large, redundant, and complex chemical portfolio. We have independent teams across our different sites working closely with clients trying to accommodate all their unique material requests, and at the same time working to meet tight deadlines. What often happens is each of these client teams is pulling together the same material but using different SKU numbers based on the specific client that is receiving the material. The lack of a centralized database to easily identify existing materials that would help avoid creating new specifications and new SKU numbers accordingly drives SKU proliferation of chemicals even further. Very often, clients will request to have their own specific materials stored in our warehouse. However, with numerous clients all requesting the same storage arrangement, we may end up, for example, with forty clients' sodium chlorides that are very similar products, with the exception of a unique SKU inspection number for each SKU. This creates redundancy and complexity that makes it more difficult to manage and find areas where SKUs can be consolidated.

Another driving factor is supply chain shortages, not at all unique to our industry, which poses direct impacts and challenges to customers. What we have observed, especially since the SARS-CoV-2 pandemic, are knee-jerk reactions and post pandemic supply chain shortages. One option for dealing with the challenges is to consolidate SKUs that reflect the same base material, which is listed as numerically separate to uphold client specificity; this option allows for greater supply chain resiliency and stockpiling within the warehouse.

Effects of material proliferation on supply chain efficiency

1. Creating new material

- More time spent on specification creation
- More time and costs auditing suppliers

2. Procurement and purchase

- More materials and SLAs to manage
- More administration and paperwork
- Less leverage to negotiate better pricing and services
- More challenges managing MOQ
- Less visibility for buyers
- More time and effort on master data
- Less agility to respond to changes

3. Transportation

- More carriers to manage and schedule
- More paperwork
- Less leverage to negotiate better pricing and service
- Less visibility for logistics
- More difficult to track carrier performance
- More time and effort on master data
- Less agility to respond to changes

4. Receiving

- More receiving activity
- More systems and reporting, and reporting transactions
- More difficult to track vendor reliability
- More time and effort on master data
- Less agility to respond to changes

5. Test materials

- Higher testing costs of smaller batches
- More time and effort in tracking materials
- Longer lead times and less agility
- More difficult to track third-party testing quality

6. Warehouse

- More bin locations to manage
- More warehouse space and costs
- More time and costs to 'put away' and 'pick' with more transportation wasted
- Longer lead times, less agility
- More time and costs to cycle count/track

7. Inventory

- More time and effort to develop an inventory and resourcing strategy
- More difficult to manage inventory targets (safety stock, cycle stock)
- Less excess and obsolescence

SKU proliferation is impactful based on the costs and risks associated with how a company manages their supply chain business. Our goal is to help mitigate the impact of SKU proliferation in your organization, and we do this using modular SKUs to maintain the same design degree of freedom and customization needed to support your process. Regardless of the process that you are designing, many of the SKUs are already available and stocked on the shelf,

ready to meet your needs. Our modular catalog allows us to create standardized yet flexible strategy, which allows for cost optimization and protects against supply chain shortages.

We heard you, our customers, and we responded:

- 550 new modularized standard SKUs
- Bioreactor and mixer bioprocess containers and fluid transfer assemblies

Allowing you to:

- Maintain design customization capability
- Create high-volume and low-volume SKU designs
- Generate non modality specific SKUs
- Help enable additional efficiency strategies for technology transfers and multi product operations

Process-liquid benefits from modularization

Choosing standard options simplifies your process and reduces the number of resources required to deliver chemicals and process liquids to your customers based on their

individual needs. With standard, packaged chemicals you can reduce complexity and help protect consistent access to supplies.

Water for injection	Trusted weights	Nuisance buffers	Chromatography buffers	Concentrates
<ul style="list-style-type: none">• Purchase catalog water for injection (WFI) off the shelf• Reduce internal testing requirements• Reduce footprint required for WFI equipment• Source for WFI overflow capacity	<ul style="list-style-type: none">• Outsourcing weigh and dispense workflow• Chemicals delivered in standardized package configurations• Chemicals delivered in precise, predetermined unit volume• Ready for introduction to your process	<ul style="list-style-type: none">• Maintaining stock of nuisance buffers reduces the need for ad hoc batch creation• Can reduce steps involved with handling and mixing caustics and corrosives• Improve planning and maximize resources by outsourcing nuisance buffers	<ul style="list-style-type: none">• Outsourcing can simplify operations such as material planning, equipment scheduling, sampling testing, and mixing and hydration• Receiving ready-to-use buffers tested to agreed-upon specifications can reduce variability and help lead to fewer failures	<ul style="list-style-type: none">• Using in-line dilution allows standardization around common concentrated stock solutions to make a majority of buffers• Using common stock solutions reduces the number of buffer containers required, leading to less material handling, less inventory, fewer samples and tests, fewer process connections, and less packaging to discard



In closing

Across all the various examples and formats, we can offer warehouse and delivery services that work to reduce the amount of warehouse space and the number of pallets that you require, while streamlining warehouse operations in support of cost savings. We can take some of the excess and obsolete inventory that adds up due to SKU proliferation and simplify the process while managing the supply chain.

With more biomanufacturers adopting single-use technologies (SUT), we remain focused on the rapid delivery of high-quality products. Our standardized SUT workflow solution is backed by an industry-leading network of harmonized global SUT manufacturing sites with production redundancy. A robust supply chain of reliable, off-the-shelf components helps you rest assured during operations.

Our mAb Process Playbook helps simplify your workflows and, in turn, produce therapies for patients more efficiently.

 Learn more at thermofisher.com/mabprocessplaybook
and thermofisher.com/simplifybufferprep

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