

SOLUTIONS TO MANAGING SUPPLY CHAIN DISRUPTION

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THE RISE OF SINGLE-USE IN BIOPROCESSING

The bioprocessing market has experienced tremendous demand in the last few years because of an aging world population and the COVID-19 pandemic. To address the needs of this growing demand for biopharmaceuticals, significant investments have been made in the production of biologics through capacity expansion projects to scale existing production facilities and build new facilities.

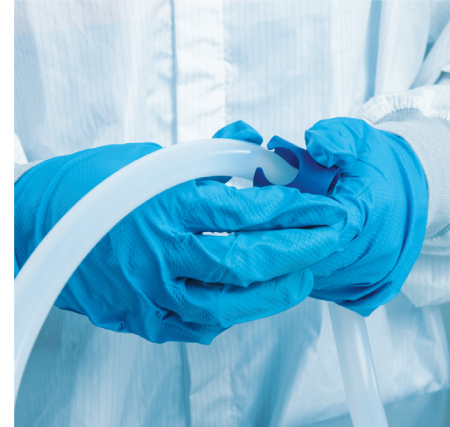


As the advantages of implementing single use products for biopharmaceutical manufacturing are well understood, manufacturers have become increasingly reliant on suppliers of single use products. This reliability has led to substantial growth in the adoption of single use products to address the ever-growing challenges of scalability, patient safety and time-to-market. Similarly, because of this growing demand for single use products, existing and new suppliers alike have invested in manufacturing capacity expansion projects.

Yet, with investment by single use suppliers in capacity expansion to meet the growing demand of the bioprocessing market, supply chains everywhere are under constant disruption. Factors contributing to the disruption include forecasting due to uncertainty in demand, increased costs for transportation, labor, raw materials, staffing shortages and port congestion. What has become clear is to meet growing demand, the single use supply chain must evolve to overcome today's challenges.

UNDERSTANDING KEY CHALLENGES

The challenges presented in the last few years are concordant to both single use suppliers and biopharmaceutical manufacturers. Suppliers and manufacturers are increasingly interconnected across many countries and time zones. To ensure strong interconnectedness remains, and the challenges of today do not remain the challenges of tomorrow, suppliers and manufacturers need to work more closely together to minimize supply chain uncertainty.



While no two supply chains are created equal, it is critically important that every supplier understands their key supply chain challenges and inherently manages the risks. Through a deeper understanding of the current operating environment, a supplier can establish requirements, identify pain points to create value, and evolve for the future. After careful planning and communication, the team at **Carolina Components Group (CCG)** performed an operations and supply chain analysis to understand key challenges facing the organization. As a result of this analysis, the team identified several opportunities that could be acted upon in the short term to provide better service to our customers.

THE OPPORTUNITIES IDENTIFIED INCLUDED:

- ◆ Supplier capacity for critical processes
- ◆ Transportation costs
- ◆ Quality control of finished single use products
- ◆ Supplier capacity for critical components

Upon establishing the opportunities, the team mapped solutions in which the opportunities could be addressed, ranked the proposed solutions, and set a course to implement those solutions that were selected.

IMPLEMENTING SOLUTIONS

At the onset of the operations and supply chain analysis, the team's stated requirement was improved speed, quality, and service. This requirement guided the team throughout the process to ensure the solutions implemented provided value in at least one of these areas.

SUPPLIER CAPACITY FOR CRITICAL PROCESSES

Inherent to providing a sterilized single use product is the need for sterilization services. During the analysis, the team identified supplier capacity for sterilization services as a key challenge facing CCG. Not only is this a key challenge for CCG, but also for other critical single use product suppliers. While new methods of sterilization are evolving, the primary method used for sterilization of single use products is gamma irradiation. Recently, demand for gamma irradiation services has outpaced capacity, creating

a constraint on this critical process step in supplying single use products. To mitigate this risk, CCG validated two different suppliers for gamma irradiation sterilization services as well as multiple facilities throughout the US. Additionally, CCG secured contracted capacity, so that weekly sterilization service is guaranteed. In doing so, CCG can utilize both suppliers, as necessary, to ensure on time delivery of gamma sterilized single use products with dependable lead times.

TRANSPORTATION COSTS/QUALITY CONTROL OF FINISHED SINGLE USE PRODUCTS

With the rising costs of transportation, availability of drivers and sheer amount of goods being transported, the team identified transportation costs and quality control of finished single use products as a key challenge. Specifically, ensuring packaging, such as boxes, tape and poly bags, of sterilized single use products remains integral, is critically important. Often, suppliers will utilize edge protectors, "do not stack" cones, and other methods to minimize damage during transport with their respective freight suppliers. While no definitive amount of packaging is foolproof, taking appropriate steps during transportation and handling will greatly reduce the risk of packaging failure. CCG uses many of these same methods

to minimize packaging failure, but also implemented a fleet of dedicated CCG trucks for transportation and shipment to and from sterilization suppliers and biopharmaceutical manufacturers. CCG's goal is to minimize the number of "product touches" throughout the process. All product, palletized for gamma, returns in the same configuration with the same wrapping on the same pallet. Moreover, the palletized product avoids going through a depot or being reloaded onto several different trucks. As a result, CCG has been able to improve lead times, reduce costs due to packaging failures during transportation and improve quality of finished single use products.

SUPPLIER CAPACITY FOR CRITICAL COMPONENTS

As demand for assembled single use products grew in the last few years, so too has demand for the components used in the finished products. Polymeric components such as fittings, gaskets, clamps, tubing, and others have extended lead times and increased costs due to raw material availability and labor. As a result, quality defects found with packaging, labeling, particulates, and performance all increased. Additionally, without these critically important components, finished single use products were unable to be implemented in biologics processes, putting manufacturers and more importantly,

patients, at risk. To address critical component availability, CCG made an investment to vertically integrate manufacturing for polymeric components that are widely used in finished single use products. This investment includes multi-cavitation tooling, manufacturing automation and stocking of raw materials and finished inventory. Available under the FlowLinX brand, CCG has significantly reduced lead times and improved quality for finished single use products, while supporting other single use product suppliers for their critical component needs.



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LOOKING AHEAD

With the rise of single use products used in biopharmaceutical manufacturing, demand has outpaced capacity and created significant challenges throughout the single use product supply chain.

While traditional supply chain strategies have worked to mitigate risk in the past, single use component suppliers need to evolve with the changing landscape and gain a deeper understanding of their specific challenges through analysis. To reduce risk and remain agile, biopharmaceutical manufacturers suffering from supply chain disruption should partner with a single use supplier who understands key challenges, implements solutions to address those challenges and ensures world class speed, quality, and service.



CCG Truck Fleet