FEATURES

# Reimagining the Global Pharmaceutical Supply Chain

Reimagining the global pharmaceutical supply chain to address current issues is essential for ensuring that patients and providers have access to the care and supplies they need.

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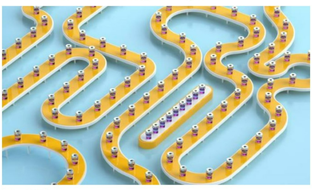

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November 14, 2022 - Workforce optimization, compliance challenges, and supply chain disruptions are all issues that plague the global pharmaceutical supply chain – an essential part of the healthcare system. Because global pharmaceutical supply chain issues have become more evident over the course of the COVID-19 pandemic, modern manufacturing companies equipped with the right solutions are quickly adapting their business approach to alleviate the burden of these common issues.

As Franco Stevanato, Executive Chairman of the Stevanato Group, told *PharmaNewsIntelligence* during a recent visit to the United States Technology Excellence Center in Boston, Massachusetts, most people around the world experience the same illnesses regardless of geological location. This poses the question: why is medicine across continents handled so differently?

Although the Italian-based company provides industry members with drug containment, drug delivery, and diagnostic solutions designed to preserve the integrity of the drugs, the Boston facility is primarily focused on testing drug containment systems. In an exclusive interview, *PharmaNewsIntelligence* got a first look inside the laboratory used to analyze these drug containment systems and streamline the drug development process.

## COMMON ISSUES IN THE PHARMACEUTICAL SUPPLY CHAIN

"Supply chain resiliency and robustness are still the largest challenges for pharmaceutical manufacturers and their customers. As a result, companies are looking for reliable ways to reduce and mitigate supply chain risk, including having more proximate suppliers, issuing long-term supply contracts, and diversifying the sourcing to ensure redundancy and business continuity," highlighted Riccardo Butta, President of the Americas, Stevanato Group.

### Materials

One of the prominent issues within the pharmaceutical supply chain is access to materials. Often, a limited quantity of resources — whether they are natural or artificial — can cause bottlenecks in the pharmaceutical supply chain.

Supply chain shortages are not restricted to the **pharmaceutical industry**; they can impact all industries. Recent examples of supply chain shortages, such as the **contrast dye** and **helium shortage**, shed light on common supply hitches that continue to threaten the healthcare industry.

"For supply chains to work smoothly, materials must be available for every process stage. Currently, in the pharma supply chain, a common problem is having access to components that are essential for the development cycle, such as drug containment systems," continued Butta.

While some of these shortages may not have a solution, others may be addressed through flexibility and fostering professional relationships. Butta told *PharmaNewsIntelligence* that having multiple suppliers helps their organization manage supply chain issues more easily.

"Instead of depending on one supplier only for a specific component, the Stevanato Group goes out to two, three, or four suppliers," revealed Butta, providing an example of how many vaccine distributors functioned similarly throughout the COVID-19 pandemic.

According to a survey conducted by **McKinsey and Company**, 93% of supply chain executives intend to make their supply chains more flexible, agile, and resilient. The survey also found that 60% of healthcare industry leaders had regionalized their supply chains throughout the COVID pandemic.

### Capacity

In addition to issues regarding materials, Butta shared that one "major problem is capacity. Because the market is growing at rates that weren't expected a couple of years ago, bringing the capacity up takes time."

According to an insight report by **Fortune Business Insights**, the United States pharmacy market was valued at $534.21 billion in 2020 but is projected to grow to $861.67 billion by 2028. This value is even more remarkable when looking at the global market. With the current and projected growth, manufacturers and pharmaceutical companies are struggling to keep up.

Capacity issues bleed past the manufacturing portion of the supply chain and into distribution. Many retail pharmacies, responsible for distributing medications to patients, are overworked and understaffed.

According to an **article** published in the New York Times in February 2022, approximately 166,337 pharmacy technician positions opened in 2021, 21,100 more than in 2020. Despite efforts by larger retail pharmacies to expand their workforce, roughly 74% of **pharmacists** still believe they have insufficient time for patient care and clinical duties.

### Regulation

In addition to the issues mentioned above with the pharmaceutical supply chain, global regulation may pose some potential concerns. With each country having its own regulatory guidelines, multinational pharmaceutical companies must adhere to the policies of all the countries they supply.

Butta commented, "Global regulation is a challenge within all manufacturing supply chains, as global supply chains are more complex than ever. Global regulation is known to cause delays in supply chains, which is why we work daily to control the complete manufacturing process. This allows us to be involved in every step of the cycle and be flexible and resilient with any issues that may arise."

A comprehensive understanding of pharmaceutical regulations in each country, such as the FDA approval process in the US, is necessary for pharmaceutical companies to mitigate any preemptive delays in the supply chain. This is especially important when manufacturing and distributing products to address public health risks, such as COVID-19 vaccines.

### The Delivery Process

Beyond issues of material shortages and capacity, Butta explained, "a large bottleneck within manufacturing supply chains is the delivery process. This bottleneck can be caused by various issues, from packaging shortages to price spikes and site holdups. Improved tracking methods and supply chain robustness would help identify delays in the delivery process, which can be addressed so the goods can get to the provider faster and more efficiently."

Delays in the delivery process are multifaceted and often require a multipronged approach that addresses material, capacity, and regulatory issues. For companies with a global reach, these issues are amplified as the supply chain tends to be longer, requiring shipping and tracking supplies across different countries.

## STREAMLINING THE SUPPLY CHAIN

As Butta mentioned, the complex delivery process can prevent smooth transitions from the manufacturer to the supplier to the patient. Many believe that the best way to minimize bottlenecks in the pharmaceutical supply chain is to streamline and consolidate the process.

### Manufacturing

One thing that the Stevanato Group is doing to streamline and shorten the supply chain is to control a large majority of the drug containment process. The company can manufacture glassware, test containment systems, monitor syringe flow, and perform various other physical tests. Essentially, they cover all drug production processes except for filling.

One significant benefit to this approach is that any issues caught early on can be resolved, resulting in cost savings. Rather than a company discovering that its containment system is inadequate during the filling process, companies will be able to conduct all its testing in one facility. The Stevanato Group works closely with customers throughout the process to ensure that any issues are communicated and addressed with minimal delays.

"To address manufacturing issues, a company must be flexible and quick to react through a thorough data-driven root cause investigation to guarantee that the proper solutions are implemented. In the development of its project lifecycle, the Stevanato Group applies a quality-by-design approach and closely monitors every stage of execution to ensure no hiccups within the process. Because of our engineering expertise and ownership of the manufacturing process technology, we can guarantee a reliable and consistent output for our products," added Butta.

As Butta mentioned, expertise works alongside technology. Having high-tech devices provides an advantage for manufacturers, but it is nothing without the team and expertise needed to use them and analyze their results. In addition to having expertise, an interdisciplinary team brings value to a company, as having multiple backgrounds working toward a common goal can provide the company with a well-rounded understanding of its product and any potential issues that may arise.

Butta also shared that having specific devices that reduce complexity and shorten the supply chain has proven to help minimize issues. "The Stevanato Group is working to develop new products and increase capacity for its patented EZ-Fill solutions — pre-sterilized and ready-to-use vials (EZ-fill vials) that help reduce complexity and shorten the supply chain. The Stevanato Group's EZ-Fill platform offers increased flexibility, faster time to market, enhanced quality, and lowers the total cost of ownership for customers. By being an end-to-end partner for customers throughout the pharmaceutical value chain, the Stevanato Group also provides more visibility into the cycle," shared Butta.

### Regulation

While having one universal regulatory system would be ideal for global pharmaceutical manufacturers, it is unlikely to happen in the near future. To work around regulatory issues and the delays they cause in the supply chain, the Stevanato Group, like many others, has developed a process to ensure that its internal regulatory measures are comparable to all government regulations to address the issues of different regulatory actions.

Butta explained, "the Stevanato Group has standardized its processes and policies to the applicable regulations and international standards. This allows us to supply goods and services characterized by high reliability and effectiveness, guaranteeing a consistent quality of care across the board."

The impact of issues in the pharmaceutical supply chain is not contained to pharmaceutical manufacturers or suppliers — they trickle down to patients, pharmacists, and other frontline healthcare providers.

While always there, these issues and their impacts were amplified and highlighted by the COVID-19 pandemic. Left unaddressed, delays and shortages in the pharmaceutical supply chain will adversely impact patients, providers, payers, and the entirety of the healthcare industry, reducing access and driving up costs of essential healthcare services.

*Editor's Note: Portions of this report have been revised for clarity and attribution.*

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