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Article

Overcome Global Medicine Shortages With Innovative Manufacturing

Source: FUJIFILM Diosynth Biotechnologies

As demand for biologic medications continues to grow, global shortages loom large over developers seeking to provide a reliable supply to patients in need. In 2022, multiple factors contributed to widespread medicine supply disruptions, including the COVID-19 pandemic, geopolitical tensions, inflation, energy prices, export bans, and consumer stockpiling.¹ In the European Union, 29 member countries reported experiencing medicine shortages. The UK faced a hormone replacement therapy (HRT) shortage while the US struggled to maintain ibuprofen stocks and ADHD treatments. Health authorities in Mexico, Asia, and Australia all reported similar difficulties.¹

The manufacture of pharmaceuticals is typically highly concentrated, and with a relatively small number of facilities and suppliers, compared to existing and latent demand, any disruption, such as ongoing regulatory obstacles and raw material shortages, could spiral into a global matter. By nature, biologics production processes have high quality requirements and small margins for error. As injectable medicines, they are more susceptible to manufacturing challenges than their small molecule counterparts. To prevent disruptions to their production, some manufacturers are investing in innovative strategies to build more resilient supply chains, mitigate risk, and prevent potential shortages.

Thoughtful Tactics To Meet Market Demand

In a 2020 report by [Bain & Company](#)², researchers outlined the following key strategies to improve global supply chain resilience for the pharmaceutical industry:

- **Redundancy:** building capacity buffers into production networks to help develop an agile manufacturing ecosystem with backup supply
- **Adaptability:** designing a modular approach to manufacturing enables companies to shift production to other sites as needed. Digitization and automation further increase adaptability and the speed at which firms can address disruption.

- **Predictability:** implementing tools to predict fluctuation and risks that share real-time demand and stock data
- **Empowerment:** strengthening problem-solving capabilities and entrusting local organizations to make decisions that prioritize business continuity

Evolving Offerings to Ensure Efficiency and Flexibility

At FUJIFILM Diosynth Biotechnologies (FDB), we offer large-scale cell culture manufacturing capacity at an existing facility in Hillerød, Denmark, and in 2025 we will bring online our new, state-of-the-art cell culture facility in Holly Springs, NC. Each location was strategically selected to ensure geopolitical and climatic stability as well as offering manufacturing services located near major patient populations. Leveraging our modular approach to capacity expansions allows us to offer a high degree of flexibility for our clients and enables efficient tech transfer should the need arise to move processes from one facility to another based on their portfolio needs.

This modular approach also permits us to ramp up production at unprecedented speed by making our facilities readily expandable for customers who require additional capacity to accommodate growing demand forecasts. Modular facilities streamline production lead times by efficiently manufacturing a single product on multiple lines and achieving higher material throughput. This efficiency is one of the strategies FDB offers to minimize the risk of biological medication shortages.

Continuous manufacturing is another critical component of our strategy to reduce medicine shortages. A continuous biomanufacturing platform leverages small, easily deployable facilities and affords developers the option of easy-to-modulate capacity, a lower cost of goods, and more efficient, sustainable processes. This approach has grown increasingly appealing across the industry in recent years for its ability to generate large amounts of material with small ecological footprints.

Continuous is used as an alternative to large-scale manufacturing and can be especially valuable in cases where the initial demand forecast doesn't justify a large up-front investment but where there is potential for demand to increase over time. In these cases, increasing process run times meets increased production needs as opposed to scaling up. For supply chain concerns, continuous manufacturing is an agile solution that can provide a backup supply. If a client needs to respond to demand fluctuations, these platforms can be assembled quickly and used to produce buffer capacity to support large-scale manufacturing programs. FDB developed MaruX™, our continuous manufacturing platform that has demonstrated the ability to run successfully at 500 L scale in a proof of concept run. Going forward, this capability will be a part of our new single-use good manufacturing practice (GMP) facilities as they are constructed.

The Bottom Line

As biopharmaceutical shortages continue to be a concern across the globe, consider how working with a flexible, innovative manufacturing partner can help you alleviate these challenges. If faced with uncertain demand forecasts, a contract development and manufacturing organization (CDMO) that offers a modular approach to manufacturing as well as the ability to shift between continuous and large-scale manufacturing as needed will help you mitigate production disruptions and ensure patient access to your therapeutic.

References

1. Bishen, S., Spina, A. (2023, February 20). *Why are there medicine shortages and what is the solution?* World Economic Forum. <https://www.weforum.org/agenda/2023/02/why-is-world-experiencing-medicine-shortages-and-how-can-the-generics-industry-address-supply-challenges/>
2. Lesmeister, F., Kwasniok, T., Peters, D. (2020, December 4). *A strategy to make pharma supply chains more resilient.* Bain. <https://www.bain.com/insights/a-strategy-to-make-pharma-supply-chains-more-resilient/>

About FDB

FDB is a global CDMO operating in Europe and North America with integrated platforms to meet client demands and deliver medicines to patients faster. FDB has capabilities not only with drug substance manufacturing but also with finished goods manufacturing on both sides of the Atlantic, allowing a customer to work with a single provider for their end-to-end manufacturing needs. To learn more about their CDMO offerings, [contact the FDB team](#).