

## Navigating the New Normal

# Biomanufacturing Goes Local

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The pandemic has spared no industry. As fast-food chains have sought to drive business through chicken sandwich wars, Burger King's release of its chicken sandwich was delayed in Michigan due to a shortage of pickle jars. While the writers of this article would certainly like to know if the pickles will help Burger King's sandwich reign superior, Burger King's inability to get pickles due to canning jar shortages from the pandemic exhibits how companies across industries are now having to grapple with making their supply chains more resilient and more controlled to maintain a competitive edge.

The life sciences industry knows this well and perhaps learned this lesson the hardest way during the pandemic when overseas supply shipments were delayed or, worse, when overseas manufacturing facilities were shut down because of government-mandated quarantines. While Massachusetts has continually ranked as a top location for the life sciences industry due in part to its proximity to world class teaching hospitals and educational institutions, it has not been a hotbed of manufacturing with most biotech companies in the area relying on third-party contract manufacturers, including in Asia and Europe. While having suppliers who focus on one aspect — say, pickle jars — of the manufacturing process who then rely on others for necessary materials affords flexibility

and choice, it can also result in missing links in the chain and can multiply the opportunities for errors, setbacks and delays. This became most acutely evident during the COVID-19 pandemic when the U.S. government utilized its Defense Production Act of 1950 authority to commandeer manufacturing facilities and lines to produce COVID-19 vaccines for the U.S. market, forcing suppliers to send their biotech customers delay notifications for production of their novel biologics for cancer and other serious diseases. Producing novel biologics is, unfortunately, not so easy to pick up and relocate, especially during a pandemic and even moreso when there are not enough domestic producers to begin with. As the life sciences industry continues to rapidly grow, life sciences clusters in Greater Boston are growing and expanding into the next phase: biomanufacturing onsite and building their own self-sustaining supply operations.

### **Rise of Biomanufacturing**

Biomanufacturing uses living biological systems to create biological materials for use in medicines, industrial applications and food and beverage. In the life sciences sector, biomanufacturing produces the ingredients that will eventually become a final biological drug product that treats disease. Unlike conventional drugs which are manufactured based on a chemical recipe, biological materials are complex and difficult to handle. So what is the problem? The production of these biological materials requires precision, a controlled environment, and takes time. Oftentimes, these drugs are not manufactured fast enough to beat out the overseas competition, or, more importantly, to meet the needs of those who need it.

While the pandemic has accelerated the widespread use and public appreciation of biologics, the challenge with biomanufacturing is bringing finished drugs to the patient in an efficient manner. This challenge has been underscored by the pandemic. The need to develop a vaccine, and quickly, called attention to the critical role of supply

chain in the life sciences industry and highlighted the current shortage of U.S. biomanufacturing facilities. Shortages of medicines, medical supplies, and manufacturing capacity, and the difficulty in obtaining the same, as a result of various governmental restrictions, required companies to pivot, sometimes at the direction of the U.S. government under the Defense Production Act, and has driven government investment in vaccines and the facilities needed to produce them. As a result, increasing demand has driven a rising interest in biomanufacturing facility startups in the U.S. to increase domestic life-saving drug production.

### **Biomanufacturing in the United States**

Developing a significant biomanufacturing presence in the U.S. will require an assortment of factors, such as economic influence and a talented workforce. Companies are looking to the established life sciences hubs in the U.S. as they provide a strong foundation with rich resources and considerable investments in research and development.

Fueled by universities, venture capital firms, and teaching hospitals, the life sciences clusters in Massachusetts, for instance, have largely focused on office and laboratory setup and research and development. Cities like Boston and Cambridge have consistently seen low vacancy rates and commercial rents have only increased. In order to adapt to increasing demands, the life sciences community expansion has reached the suburbs of Lexington (MA), Watertown (MA) and Waltham (MA). While Boston and Cambridge have long been homes to research and development, expansion to Lexington, Watertown, and Waltham will continue to allow for biomanufacturing to incubate and flourish. We predict that other clusters will see similar growth as biomanufacturing continues to expand domestically.

As previously mentioned, the weaknesses in the supply chain were evident. Life sciences companies, as well as those in other industries, saw shortages in supplies and materials for production causing

disruptions in development even before the pandemic but later exacerbated by the pandemic. These disruptions have led to new strategies to combat and minimize any future disruptions. One notable strategy being companies controlling their own supply chains. With the development of new technologies, such as the messenger RNA and other curative therapies, companies will want the development and materials to facilitate such development close at hand. And, with the potential of biomanufacturing facilities being in-house or a short drive from the research and development capitals across the U.S., biomanufacturing startups and life sciences clusters can position themselves to collaborate or to build the capabilities needed in-house to address this critical biomanufacturing need.

Another attractive attribute of developing biomanufacturing facilities in the U.S. is that domestic biotech companies will be able to more easily control and oversee the current good manufacturing practices (cGMPs) required by the U.S. Food and Drug Administration for biologics. With biomanufacturing facilities in the U.S., companies can easily monitor and audit their processes and ensure compliance with cGMPs that help to ensure the quality, safety and efficacy of the drugs and therapies produced.

Life science clusters are in a position to capitalize on the various limitations imposed by the pandemic and the shift toward domestic manufacturing of therapies and medical technologies, leveraging top-tier talent pools. Creating smaller networks outside of Boston and Cambridge that work in tandem with the research and development facilities, for example, or building in-house biomanufacturing operations to self-sustain research and development needs, will enable Massachusetts and other life sciences clusters across the country to support and maintain manufacturing capabilities.

## Conclusion

While the pandemic has certainly highlighted the vulnerabilities of the supply chain, it has also highlighted an opportunity for the domestic production, whether in-house or through new startups, for the manufacturing of biologics. We predict that we will continue to see the domestic expansion of biomanufacturing in proximity to all life sciences clusters, decreasing domestic developers' dependence on biomanufacturing facilities around the world.

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