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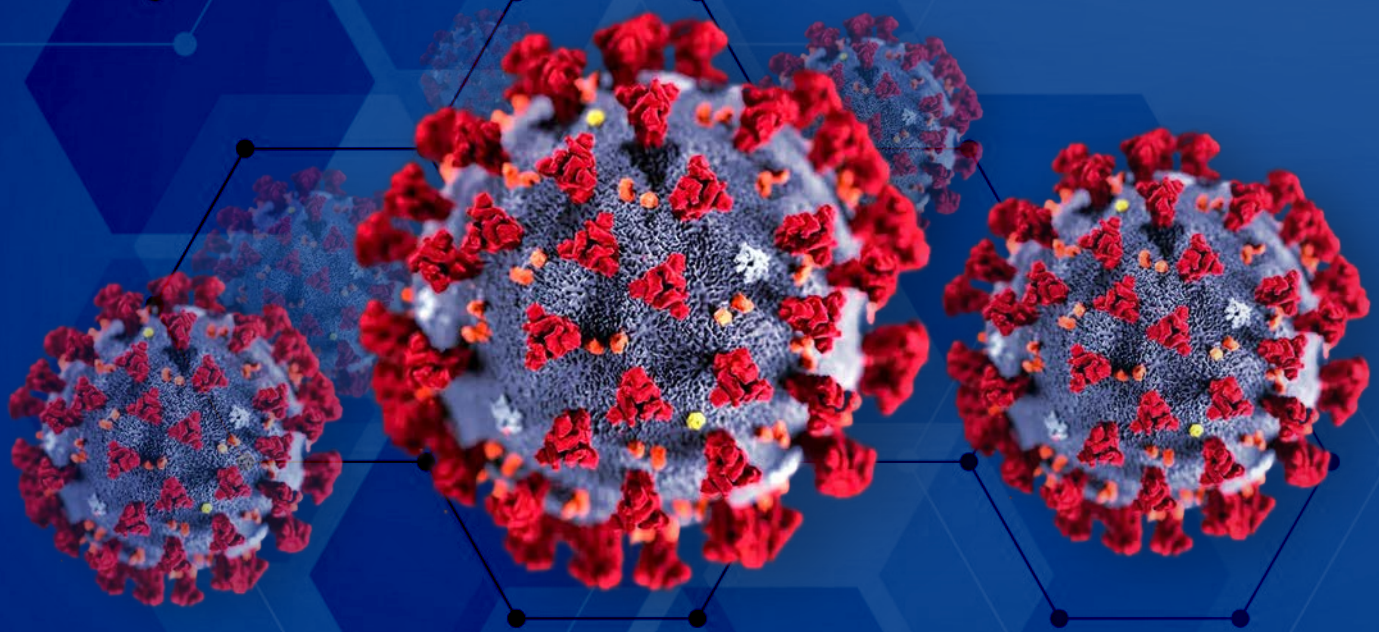
COVID-19 Pandemic has Exposed the Risks of Reliance on Foreign Markets for Critical Drug Components



COVID-19 Pandemic has Exposed the Risks of Reliance on Foreign Markets for Critical Drug Components

by **Anshul Mangal**, CEO | Project Farma

Background

The recent COVID-19 pandemic has brought the world to a standstill. The required quarantine and social distancing guidelines have disrupted the global supply chain for many industries, but most critically, the drug manufacturing industry. Following the outbreak, the world is facing an unprecedented shortage of critical supplies, materials and drugs across the life science industries

Factory slowdowns and government enforced lock-downs around the world have forced drug manufacturing facilities to stop exporting due to shortage (Sah 2020). The response and roadblocks the industry is experiencing during this outbreak is evidence that the industry is not prepared to rapidly respond to a pandemic.

The pandemic has exposed the risks of outsourcing the manufacturing and production of critical drug materials to foreign markets. China is currently the biggest producer and exporter of active pharmaceutical ingredients (API) by volume, they were also the country that was hit first and the hardest at the start of the outbreak causing a country wide shut down. According to the FDA, 13% of brand and generic active pharmaceutical ingredient (API) manufacturers are based in China. However, they do not know which materials, and how much of them, are not being imported to the US making it difficult to understand where to anticipate gaps in domestic supplies.

The US has been over-reliant on other countries to provide the critical components we need to make drugs. If other countries are in a shortage of raw materials and APIs, as they are currently, they will not be able or willing to export these materials to the US. Foreign factories being shut down or banned from exporting due to the pandemic affect the global supply chain and have caused a domestic shortage, with the FDA identifying its first drug shortage earlier this year (Corridon 2020).

FDA data also shows that of the world's facilities that manufacture Essential Medicines, deemed essential by the World Health Organization (WHO), only 21% are based in the US. While major US pharmaceutical companies do not anticipate any immediate shortages, these various reports reveal the vulnerability the US is subject to when the global pharmaceutical supply chain is destabilized. This pandemic has additionally highlighted the importance of having emergency preparedness plans in place if a partner, foreign or domestic, is no longer able to deliver.

Other challenges brought by COVID-19 has made it difficult to conduct clinical trials. Companies that provide clinical development have acknowledged their roadblocks to safely conducting trials. In general, our overburdened healthcare system and social distancing policies are creating a challenging landscape for the life science industry, and over-reliance on foreign markets are now exasperated in an already difficult environment.

How Project Farma Can Help

The U.S. pharmaceutical companies must make efforts to be able to manufacture these materials on domestic soil. Project Farma can help you evaluate the availability and capacity of your existing organization. We can model different financial scenarios and determine the best approach when speed to market is critical. We can lead scale up or scale out of your existing domestic manufacturing facilities or build new ones to increase capacity and ensure a robust supply. We can also help select and manage CDMOs, external manufacturing partners and vendors.

In light of the COVID-19 outbreak, we must pivot to become self-reliant for critical raw materials and APIs. Project Farma can manage and direct the production of such lifesaving materials in a safe and timely manner. Now more than ever, we need to scale back our reliance on imported materials and implement new strategies to overcome the challenges we currently face.

To increase the quality of relief responses, manufacturing facilities need to adapt and pivot to be:

- Modular and flexible
- Capable of efficiently running multiple processes
- Compliant for the clinical or commercial manufacturing of several products

Project Farma has experience leading cGMP facility builds for small molecule, large molecules including biologics, vaccines and advanced therapies ranging in size from 5000 sq. ft. to over 500,000 sq. ft. using cutting-edge modular, flexible, emerging bioreactor and single-use technologies.

We have also created therapy-specific task forces to:

- leverage industry best practices real-time for
- enable speed and efficiency for drug development for
- ensure safety and compliance to
- properly and swiftly respond to

our partners and other companies designing and manufacturing vaccines and cures for the Coronavirus.

There is a clear need for the US to decrease reliance on foreign markets for critical materials and supplies to address the current and future pandemic. We need to work together as an industry to resolve any shortages of raw materials, supplies and drugs. Project Farma is here to help and is actively working to scale-up and scale-out manufacturing during this critical period.

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Sources

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3. Sah, S 2020, Impact of COVID-19 on pharma supply chains <https://www.expresspharma.in/covid19-updates/impact-of-covid-on-pharma-supply-chains/>

About Project Farma

We provide biomanufacturing strategy and execution to startup and established pharmaceutical companies, advanced therapy companies, academia, hospitals, financial institutions, CROs/CMOs, and medical device companies. Our services include turnkey capital projects and facility builds; owner's representation; project management; validation; quality, regulatory and compliance; engineering and automation, reliability and compliance and more. We are committed to helping advance manufacturing to achieve operational excellence and accelerate speed to market for next-generation medicines.

Contributing Author

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