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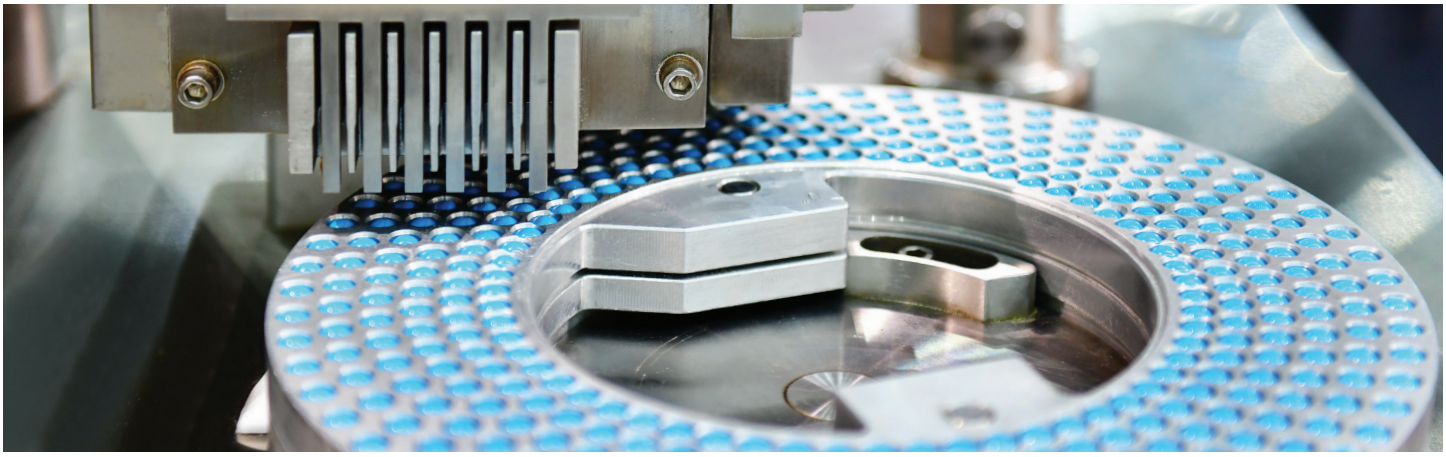
WHITE PAPER

Anticipated New Phase In U.S. Manufacturing

With the COVID-19 crisis, global insecurities have never been more apparent and are leading to a push to onshore pharmaceutical manufacturing.



People are all adjusting to a new normal that COVID-19 has brought to business operations, including social distancing by limiting interactions with peers and colleagues. These temporary changes to business operations have redefined how people work and interact on a day-to-day level, with work-from-home policies being enacted out of the abundance of caution and only mission-critical staff members allowed to work in manufacturing and production environments.

The collective effect of these changes has disrupted the markets, with organization leaders reevaluating where and how we operate from a risk perspective. With the rise in availability of low-cost labor and access to growing populations in Asia in the last 30 years, manufacturing plants across all industries are offshoring, primarily to China and India. Free-trade policies with no restrictions on imports and exports internationally have resulted in the overwhelming majority of Active Pharmaceutical Ingredients (API) being sourced from outside of the United States, making the supply chain vulnerable to geopolitical risks.

The Congressional Research Service estimates with independent research that China supplies 30% of U.S. medical personal protective equipment (PPE). An immediate shortage is occurring of PPE consumables available for first responders and medical team professionals responding to the COVID-19 crisis. Within the coming weeks and months, we will begin to see reduced availabilities of critical pharmaceutical products as countries of origin limit exports to protect their own populations. The end result will likely be a loss of visibility and control of the United States manufacturing base. In response to the pandemic, United States manufacturers are increasing production of medical supplies to combat COVID-19. While the pandemic has exposed public health and economic vulnerabilities in the United States, there are signs that those same vulnerabilities will not be repeated, that we will see a restructuring and retooling of pharmaceutical and medical device supply chains not seen since World War II. Once the COVID-19 pandemic is behind us, it will be hard to imagine pharmaceutical and other critical manufacturing sectors remaining offshore and vulnerable to geopolitical risks.

A New Phase of the American Manufacturing Base

In the wake of COVID-19, it will be more likely that we will see a rebirth of United States manufacturing in the form of onshoring of pharmaceutical and other critical manufacturing back to the United States as a national risk reduction measure. While global insecurities may freeze capital investment and API production offshore for the short term, individual companies may decide on their own after performing risk reviews of their supply chain to make the decisions to remove the manufacturing footprint from countries vulnerable to these risks.

Secondly, we may see the federal government make changes to national foreign policy to mandate onshoring of a portion of pharmaceutical or other critical manufacturing sectors as a matter of national security. In the wake of the COVID-19 response, many Americans will debate the increased level of risk to the collective health and economic welfare and may expect changes to reduce the risk to pharmaceutical and medical device supply chains to prevent a medical supply shortage or delay from happening again.

Just as the Department of Homeland Security has categorized critical infrastructure in response to the COVID-19 pandemic, an examination of the source of the critical manufacturing sector will get underway as the United States reaches the back side of the curve of infections.

This is the time for debate and discussion as the United States determines which manufacturing sector verticals are deemed critical to American public health and economic welfare and should be categorized as critical manufacturing infrastructure by the Department of Homeland Security. It will also have to be determined what tax, legislative or foreign policy changes will be necessary to move manufacturing of pharmaceutical and medical device and consumables back to the United States.

All-of-the-Above Approach

Tariffs have reduced the profitability of manufacturing in China, and as a result of tariffs, many companies will consider other countries in the region with available low-cost labor as alternatives to China before onshoring manufacturing capacity to the U.S. Therefore, it will take more than current tariffs on Chinese exports and existing corporate tax incentives to onshore critical manufacturing capacity — given this manufacturing base is entirely private investments.

Mandating that veterans hospitals procure their medical supplies in the United States would result in a positive increase in American manufacturing capacity and would be a good place to start. However, this would make a small dent in the estimated 80% of APIs that are sourced from India and China. Additional federal incentives will be needed so that United States firms considering alternatives to China return to the United States instead of relocating to other countries where low-cost labor is available and where the same vulnerabilities to the supply chain exist.

There are signs that onshoring U.S. pharmaceutical manufacturing capabilities is getting the attention of the highest levels of the federal government. Earlier this year, three Democrats in the U.S. Senate signed on to legislation from Republican Sen. Marco Rubio of Florida that would support lessening supply chain dependence on offshore sources. And a report last year from the U.S.-China Economic and Security Review Commission told Congress that U.S. dependence on drugs and API from offshore sources presents both national security and economic risks. Among the commission's recommendations is requiring federally funded health systems to purchase their pharmaceuticals from U.S. production facilities or facilities that comply with U.S. health and safety standards.

Benefits of Onshoring

A long-term benefit to American companies of onshoring is the protection of intellectual property (IP). Many countries around the world require U.S. and Western firms to hire local or government-owned engineering companies who partner to deliver Front End Planning (FEP) engineering, which includes site selection activities, preliminary cost estimating and conceptual engineering packages. This partnering is usually required by law, which includes a knowledge transfer of industry best practices that American and Western firms invested in over decades in the form of training of project teams, membership fees of associations who maintain industry standards, and costs associated with developing and automating processes to deploy real estate, engineering and procurement teams around the world.

This knowledge transfer of industry best practices is considered the cost of doing business and results in a standardization of practices within the manufacturing industry. However, China has built structural controls over the knowledge transfer process that coordinates design, environmental permitting and customs inspections of highly specialized imported process equipment at ports of entry for the coordinated collection of intellectual property. This coordinated approach for the collection of IP, the crown jewels of American innovation and technology, will continue long after COVID-19 has run its course or been otherwise contained through the introduction of a vaccine and treatments. The onshoring of American pharmaceutical and other manufacturing capacity deemed critical for national defense will have two benefits to the welfare of the American people. First, it will significantly reduce the vulnerability of the health and economic welfare to disruptions caused by future pandemics, as the FDA has warned of the potential pharmaceutical impact with COVID-19. Secondly, onshoring of American manufacturing will eliminate the systematic collection of intellectual property — the crown jewels of American innovation.

Owners can prepare for the potential onshoring of APIs and other critical manufacturing by seeking industry partners who can support them confidentially through the pre-development and site selection process. With experience on your side, the process will yield multiple sites for consideration with the greatest incentives available. Evaluating sites based on primary cost drivers like utilities, labor and site development costs is critical to justify the business case of onshoring manufacturing capacity.

Furthermore, it is crucial to make an unbiased decision for site selection based on predetermined business case criteria. Thorough site selection research and business case analysis provide for full integration into FEP engineering services for confidentiality and speed to market.

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