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White Paper

Strengthening The Drug Manufacturing Supply Chain During Extraordinary Times

The Covid-19 pandemic placed unprecedented strain on the biopharmaceutical supply chain as the accelerated development of drugs and vaccines drove a surge in demand for raw materials. This demand outstripped the global manufacturing capacity of the entire supply chain resulting in shortages that were compounded by pandemic-driven challenges in logistics and staffing.

By March of 2020, we had determined that the global need for vaccines and therapeutics to combat the Covid-19 pandemic, in addition to the already expansive pipeline of non-Covid-related therapeutics, would require us to implement a substantial increase in our manufacturing capacity for the raw materials, assemblies, and technologies used by our customers.

Within the last two years, we initiated an ambitious multi-year expansion strategy aimed at increasing supply security through improving the resilience of our manufacturing operations. The fundamental principles of this strategy included investing in expansions to fuel sustainable growth, increasing regional redundancy of manufacturing capabilities, and streamlining logistics. Execution of this strategy was combined with projects to maximize output at existing locations and internal structural changes to improve the efficiencies of our operations through collaboration and transparency, both internally and with customers.

Increasing Output by Optimizing Existing Operations

The increases in global demand for raw materials and products required adding new manufacturing capacity to our global network. As we accelerated those expansion efforts, we also initiated projects that could be quickly acted on to increase output by unlocking underutilized capacity.

Maximizing output at our sites required precise alignment and a strong focus on resources to ensure a high level of collaboration among internal teams with a high degree of transparency. To achieve this, we used a multi-pronged approach which included the initiatives highlighted in **Figure 1**:

- Investment in a supply chain "control tower" and data insights platform to provide an in-depth view into supply plans, raw materials, and delivery dates and enhance predictably and transparency of demand that had not been forecasted.
- Realign resources within our integrated supply chain operations to deepen senior operations focus for each product line.
- Reassign resources and enlist third-party consultants to support our own operational excellence experts at major manufacturing sites to holistically review processes and identify opportunities to unlock additional output and adjust systems for efficiency gains.
- Investment in additional machinery to support production and optimization of all technology and processes. We also streamlined testing and production requirements.

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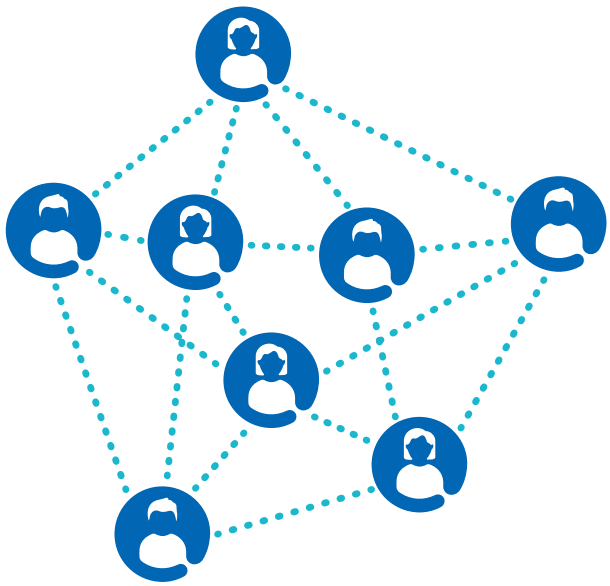

Figure 1. Output from existing sites was optimized by aligning and focusing resources for robust collaboration and transparency.

These initiatives better positioned us to continue supplying materials for critical vaccines and therapeutics and other lifesaving and life-enhancing biotherapeutics.

As we increased manufacturing capacity, we worked closely with customers to align priorities and ensure support for key projects; ongoing dialogue and bidirectional transparency was essential. These collaborations led to better forecasting which guided more informed manufacturing requirements for our sites.

This level of transparency enabled us to proactively work with our raw material suppliers to establish accurate supply agreements and maintenance of safety stock at our manufacturing locations, both of which help mitigate risks to the supply chain and increase business continuity for customers. Demand forecasting in close collaboration with our customers created the foundation for improvements in:

- Delivery metrics
- Decision making for capacity investment and expansion
- Capacity constraints and supply disruptions

Figure 2 highlights key initiatives focused on deepening customer collaboration and increasing transparency.

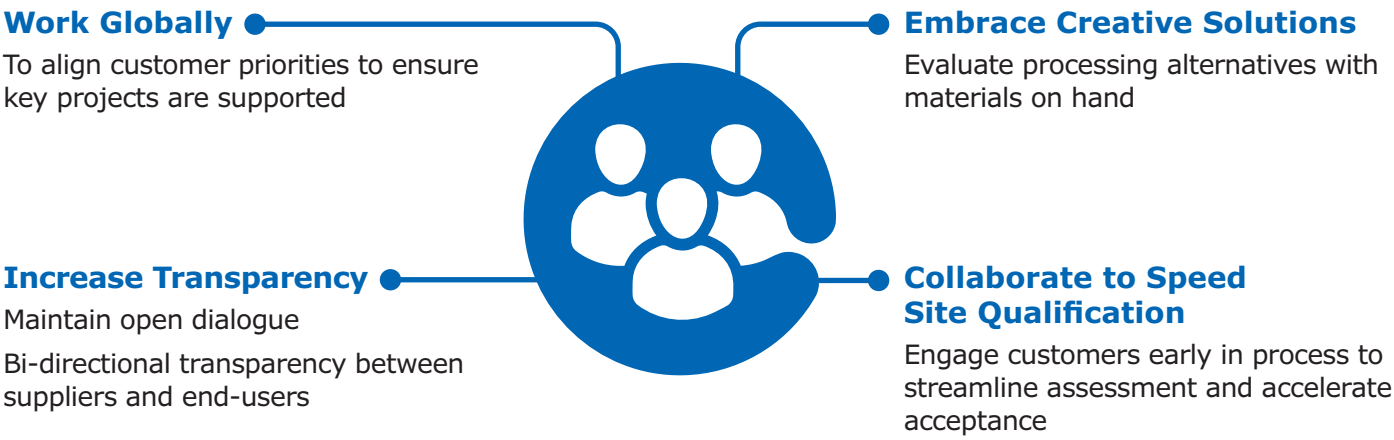

Figure 2. Initiatives focused on deepening customer collaboration and increasing transparency.

Increasing Global Capacity

The global pandemic emphasized the need for suppliers within the biopharmaceutical supply chain to increase security and strengthen resilience. At the start of the pandemic, our long-range expansion plans included multiple projects to add manufacturing capacity and capabilities worldwide to improve regional proximity to our customers. Recognizing that our pre-pandemic plans would not be sufficient to meet the increased demand for products and that we needed to act quickly to expand manufacturing capacity, the first phases of our expansion strategy focused on projects that would most rapidly add manufacturing capacity.

To achieve the early rapid expansions, we took a phased approach based on first accelerating the completion of on-going expansion projects and looking at our existing framework to quickly launch new capacity projects. With these early initiatives underway, the next phase involved bringing timelines forward and increasing the scope of planned projects. We refocused our investment program goals to develop the roadmap to achieve the tenets of our long-term supply security strategy informed by the lessons of the global pandemic.

The first new project was the expansion of our Danvers, Massachusetts single-use facility. Conceived in March 2020 and approved in April 2020, this expansion was completed in eight months, doubling our single-use assembly capacity. At the start of the pandemic, single-use assembly line expansion activities had already been underway at our production site in Wuxi, China. Our team completed the first phase of this expansion six months ahead of schedule. Simultaneously, we began expanding our Jaffrey, New Hampshire filter manufacturing facility and adding new manufacturing lines within the existing footprint of the site, a project originally planned for late 2022.

A key focus of our supply security strategy is to increase our global manufacturing redundancy by adding capacity and capabilities worldwide. This regional approach places our manufacturing facilities in closer proximity to our customers while also streamlining logistics. For example, in March 2021, we announced our intention to accelerate expansion plans in Europe for single-use products. While this expansion was previously planned, we brought the timeline forward and, at the same time, increased the scope and scale of the project to include more manufacturing capabilities. We also used a multi-phased approach to enable rapid, incremental capacity increases. We recently announced plans to add a single-use manufacturing center to our Wuxi, China campus and a new filter manufacturing facility in Blarney, Ireland, further strengthening our redundancy and supply security as both new sites will manufacture the entire portfolio of products **(Figure 3)**.

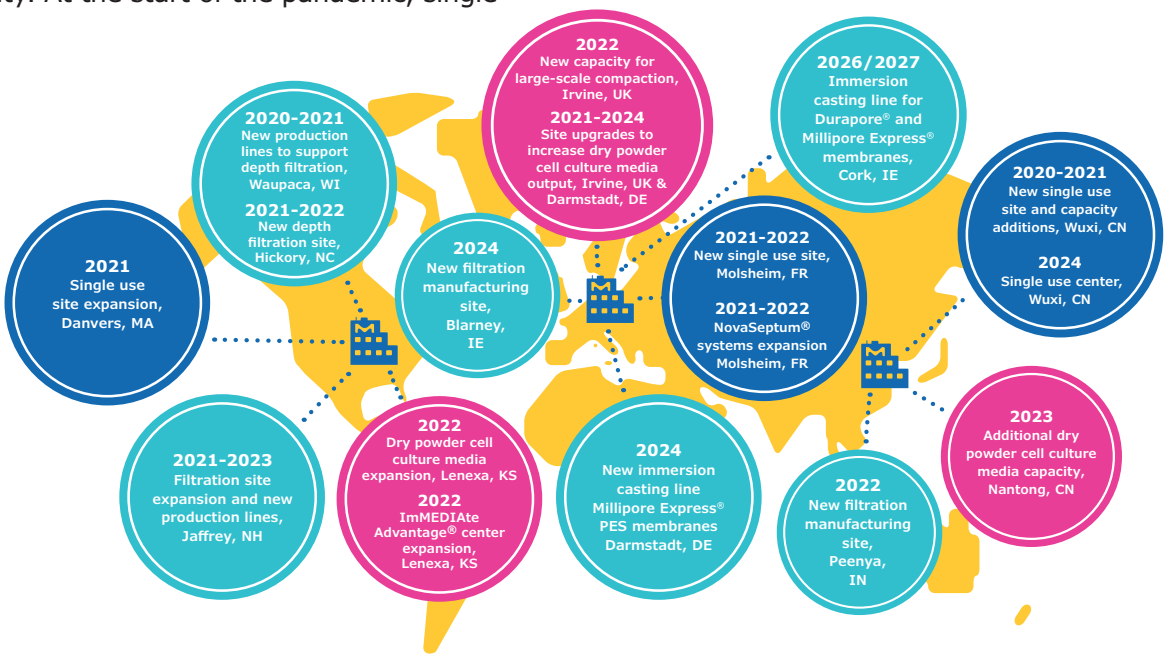

Figure 3. Global capacity expansions of our biopharmaceutical manufacturing sites.

As we expanded global capacity, we wanted to ensure that the benefit of the expansion would be available to customers as quickly as possible. We saw an opportunity to collaborate with customers to streamline the site qualification process and enable them to benefit more quickly from the new capacity.

Together, we developed a program to ensure customers can access the information to understand a change in a manufacturing site, have confidence that it has been qualified, and have sufficient data to show that there has been no change to the product.

The Way Forward

The recent pandemic has impacted countless aspects of how the biopharmaceutical industry operates. From social distancing requirements for employees, to the unprecedented speed of vaccine development, change is the new normal. In response, suppliers to the industry have had to further strengthen supply chains to not only support the unprecedented mobilization of resources against the virus, but also ensure that the robustness and resilience is in place to protect against future crises.

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