

HOW TO ADAPT EFFICIENTLY TO A NEW ERA OF SUPPLY CHAIN MANUFACTURING

Source: Ajinomoto Bio-Pharma Services

By Stephen Aiken, Director of Supply Chain Management and Allison Jackson, Procurement Manager at Ajinomoto Bio-Pharma Services

Prior to the COVID-19 pandemic, the drug manufacturing supply chain was relatively stable and lead times were manageable. However, when COVID-19 hit globally in March of 2020, supply chains across sectors suffered major impediments. Suddenly, vendors were missing shipping and delivery commitments and demonstrating previously unseen inconsistencies. These struggles were caused by the sudden surge in demand brought on by government rated orders, a result of the Defense Production Act invoked to ensure manufacturers prioritized orders dedicated to the production of COVID-19 related vaccines and therapies.

In response to these newfound obstacles, contract development and manufacturing organizations (CDMOs) and their vendors began to implement necessary risk-mitigation activities, including shifting their focus to multi-sourcing efforts and operating with higher raw material inventory to mitigate delays. Across the entire supply chain – from suppliers to manufacturers to pharmaceutical companies – there is now a greater demand for transparency and collaboration. Pharma executives are calling for more detailed insight into their manufacturer's supply chain viability. Though the supply chain continues to change, risk aversion strategies and supply chain mapping are helping to create more robust and resilient networks. As you consider how your own company's manufacturing needs are evolving, start by exploring the strategies and partnerships that can bolster your manufacturing process and consistently satisfy timeline goals in this new climate.

Taking Stock of the COVID-19 Impact

The global lockdowns and restrictions of COVID-19 led to a domino effect of disruptions and modifications to the supply chain. CDMOs could no longer

rely on their suppliers' proposed lead times or shipping and delivery dates. Faced with new variables, they were forced to pivot to alternate strategies, including a greater focus on multi-sourcing and more robust supplier relationship management.

Frequently throughout this period, manufacturers had to grapple with international COVID-19 policies and lockdown procedures that impacted production schedules. As a result, raw material manufacturers began to consider both insourcing and onshoring while also identifying ways to improve transparency between international partners. Across the supply chain, there was now a greater emphasis on collaboration and more thorough traceability for each component.

Though COVID-19 has now receded to a more manageable state, manufacturers continue to combat its impact. Many are facing lead times of one to two years, while vendors still miss shipping and delivery dates as they work through massive order backlogs. On a global scale, supply chains remain burdened with transit delays due to congestion at ports, largely caused by the increase in consumer purchasing triggered during the pandemic. Furthermore, raw material inventory continues to

be an issue. As they attempt to meet the immediate needs of their clients, vendors are keeping certain materials on manual allocation to help cover demand and keep drug manufacturers operational. Many pharma companies are asking CDMOs to hold larger raw material inventories to reduce risks caused by unpredictable lead times and to ensure coverage. Unfortunately, this process can tie up cash flow and requires careful inventory management. And finally, though restrictions have eased and in-person meetings have resumed, face-to-face time with suppliers remains less frequent as companies work to ensure employee safety and maintain visitation policies that account for local transmission rates.

To combat some of these struggles, raw material manufacturers are launching capacity expansion programs that invest heavily in new construction and added production lines to meet demand. That said, the construction and validation processes will take time, and it could be years before manufacturing settles into its new normal. When considering your product's new or ongoing manufacturing process, the following priorities should be top of mind.

Identifying Resilient and Reliable Partnerships

The call for greater transparency across the supply chain has led pharma executives to ask more thorough questions at every stage of their collaboration process with a manufacturing partner. These are some of the crucial inquiries that can make a partnership more fruitful and less risk prone:

- How much inventory do you have available on-site?
- What are you doing to ensure supply chain continuity and minimal disruption?
- When will your inventory be returned to pre-pandemic levels?
- What actions are you taking to mitigate risk?
- When will lead times start to normalize?

- Do you have visibility into the full supply chain beyond your first-tier suppliers?
- What steps are you taking to diversify your inventory?

When identifying the strengths of a manufacturer's supply chain, there are several key practices to look for. First, a reliable CDMO will likely hold inventory of preferred components. These are often materials that adhere to International Organization for Standardization (ISO) standards and are more readily available. It is beneficial to use standard ISO parts due to their global acceptance, high-volume production, and relative accessibility when compared to a custom item with lower demand and a longer lead time.

Another crucial procedure is agreed-upon safety stock levels. In this case, a pharma client and CDMO negotiate in advance on the necessary safety stock levels to reduce risk and keep the supply chain resilient. Clients can establish a rolling forecast — six to 12 months in advance — that can help their manufacturer plan sufficient coverage. Additionally, a CDMO should put future-proofing contracts into place that account for these safety stock levels as well as supply chain risks and coverage to ensure no supply disruptions. There are also a number of tech implementations that can assist with collaboration and supply chain transparency, including enterprise resource planning (ERP) forecasting, advanced planning tools, and electronic sourcing.

Mitigating Supply Chain Risk While Improving Collaboration

Previously, risk mitigation existed in the background of the supply chain, but in the aftermath of COVID-19, it remains at the forefront. Manufacturers must communicate extensively with their clients from the outset to ensure access to the appropriate materials; not having enough material could lead to a line shutdown and lengthy delays. Discussing manufacturing needs with a pharma company's executives in advance can help ensure a CDMO's capacity to secure critical products from multiple

sources and prevent lag time. Though it requires a lot of initial groundwork, identifying multiple suppliers for a product can alleviate risks to the supply chain, including those beyond COVID-19.

For certain products like pharmaceutical glass, the competition is very limited. In a situation like this, regular interaction and relationship maintenance with a supplier is critical. A CDMO must emphasize ongoing communication and a strong understanding of the vendor's escalation process to ensure a long-term partnership. From the vendor perspective, it can be beneficial to understand the criticality of the medicines that a CDMO supports, whether they be lifesaving or life-bettering.

Working with vendors to do collaborative forecasting can improve resiliency planning and cut down lead times. Furthermore, vendor-managed inventory is an increasingly common offering that allows suppliers to hold intermediary components for their clients. This strategy can optimize shelf life and shorten lead times by ensuring that components are stocked. If a CDMO commits to buying

a certain amount of product in advance, this can ensure that inventory is available and lead times are competitive for their clients.

Conclusion

COVID-19 drastically altered the supply chain manufacturing landscape. Now more than ever, risk-mitigation strategies like multi-sourcing and transparent collaboration between vendors, manufacturers, and pharma companies are crucial. In the current climate, just-in-time manufacturing is no longer realistic and CDMOs must continue to prioritize operating efficiently with increased raw material inventory. Though some lead times may begin to fall in the second half of 2023, it is likely that clients will remain risk averse and continue to prefer these high inventory levels. Reestablishing trust in the drug manufacturing supply chain will take time, reliable execution, and an ongoing evaluation of what constitutes good manufacturing practice in this new era. In the meantime, thorough communication and vetting between stakeholders can reinforce resiliency and successful adherence to production timelines.

About Ajinomoto Bio-Pharma Services

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