

Is your clinical diagnostics contract manufacturer prepared to weather supply chain challenges?

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Supply chain security and transparency is a key part of the risk mitigation strategy of companies manufacturing clinical diagnostic assays. Prior to the COVID-19 crisis, complex global supply chains carefully balanced capacity with demand while cost-cutting initiatives pushed towards lower cost raw material providers located in different geographies. COVID-19-driven regional manufacturing shutdowns, surge demands, and logistics disruptions have placed significant pressure on clinical diagnostic supply chains, resulting in raw material shortages and delays.

Supply chain vulnerability becomes a major issue

In step with global supply chain constraints, the need to develop and commercialize new tests to detect SARS-CoV-2 has created an unprecedented demand for increased manufacturing capacity. Both established and emerging clinical diagnostic manufacturers are looking to contract manufacturing organization (CMO) partners to relieve manufacturing constraints and increase capacity. In the current situation of supply chain and manufacturing pressures, clinical diagnostic manufacturers should look closely at the supply chain management of potential contract manufacturing partners. No matter how innovative a new test may be, it can only be manufactured if the raw materials can be obtained.

CMO considerations in turbulent times

CMO partners that had pandemic business continuity plans in place prior to the emergence of the COVID-19 crisis were able to quickly mobilize resources and respond to supply chain pressures. While the current crisis has been unprecedented in both the reach and the impacts on global manufacturing, regional supply chain disruptions have created issues in the industry for years. Moving forward, it would be wise to consider CMO partners with strong supply chain management programs. One strategy is to choose a CMO partner who is also a manufacturer of raw materials or components required to manufacture the reagent, kit, or device. Even during normal business operations, there are many practical reasons for this, including increased supply chain control and lower raw material costs. Larger CMO organizations can also leverage their purchasing power to procure raw materials at lower costs and may be better positioned to secure secondary sourcing of critical raw components. During times of supply chain constraints, CMO partners that also manufacture some or all of the raw materials, particularly those with global manufacturing and distribution footprints, are better positioned to maintain sufficient safety stock by mobilizing a global network of secondary and tertiary sourcing.

The COVID-19 crisis has highlighted that strong supply chain management should be a vital consideration for any potential CMO partner as the risk of regional and global disruptions are unlikely to disappear.

