

ENSURING RESILIENCE: HOW LIFE SCIENCE IS RESHAPING SUPPLY CHAINS IN RESPONSE TO COVID-19

COVID-19 put life sciences supply chains under unprecedented pressure. Almost overnight, the long, global supply chains created in an era of easy cross-border trade were hit by national lockdowns that made it harder to keep getting products to patients. The experience forced companies to consider the effect of globalization on supply chain resilience, driving growing interest in reshoring operations.

The industry was beginning to question whether globalization had reduced the resilience of supply chains even before COVID-19 brought the topic into sharp focus. In late 2019, the FDA shared data showing 72% of active pharmaceutical ingredient (API) manufacturers supplying the US market were based overseas.¹ The US lacked any domestic suppliers of some APIs used in essential medicines, and the FDA said it was working to prevent globalization becoming a national security risk.

COVID-19 confirmed theoretical concerns about supply chain resilience. In March 2020, the Indian government restricted the exportation of tens of APIs and finished products, before going on to ban shipments of drug substances and products as they emerged as potential treatments for COVID-19.^{2,3} Chinese exports of pharmaceutical products halved between January and February 2020.⁴

The life sciences industry contended with the problems at a time of global workforce disruption and surging demand for particular products.⁵ Parts of the supply chain failed to keep up, leading the FDA to warn of shortages of drugs used in the treatment of patients with COVID-19 such as propofol and dexmedetomidine.⁶ The FDA issued a series of drug shortage notices, each attributing the problem to demand increases, in the early weeks of the pandemic.⁷

To understand how that experience is shaping attitudes toward resilience, Informa Pharma Intelligence and Cambrex surveyed 117 leaders, mainly from biopharma companies. Around half of the respondents outsourced at least part of their supply chain to a contract development and manufacturing organization (CDMO).

Why The Crisis Is Driving Change

The survey confirmed COVID-19 put pressure on supply chains. Just 16% of respondents said their supply chains were unaffected by the pandemic. Most supply chains were at least somewhat affected and 19% of respondents saw a significant impact. Among respondents



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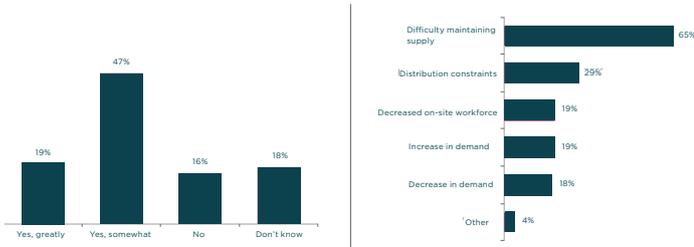
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with affected supply chains, 65% said they faced difficulty maintaining supply and 29% suffered distribution constraints.

Figure 1: Impact of COVID-19 on Supply Chain



Question: Has your supply chain been affected during the COVID-19 pandemic?

Base: All respondents (n=117).

¹Includes "Yes, greatly" & "Yes, somewhat."

Question: How has it been affected? (Select all that apply)

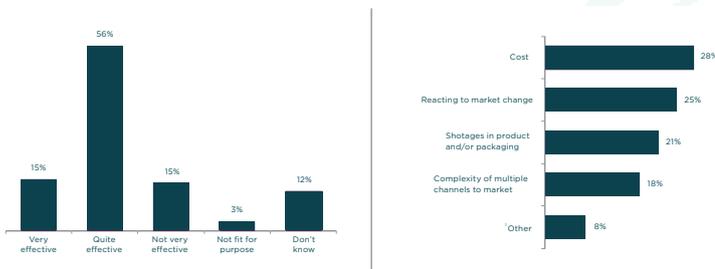
Base: Respondents reporting COVID-19 has impacted their supply chains (n=77).

Other¹ includes Clinical sites shut down during pandemic; court delays; COVID cases.

Specific problems identified by the respondents included order delays, factory shutdowns, increased or decreased demand, and difficulties maintaining consistent inbound raw material supplies. A number of the acute problems faced in the early weeks of the pandemic eased over time, but the survey shows some companies were still trying to catch up after a period of reduced output months later.

In certain cases, the pressures exacerbated existing concerns with supply chain effectiveness. Almost 20% of respondents said their supply chains are ineffective. Just 15% of respondents said their supply chains are very effective, although most are at least somewhat satisfied. Common concerns include reacting to market change and product or packaging shortages.

Figure 2: Supply Chain Effectiveness & Primary Concern



Question: In your opinion, how effective is your current supply chain process?

Base: All respondents (n=117).

Question: What is your main concern regarding your supply chain?

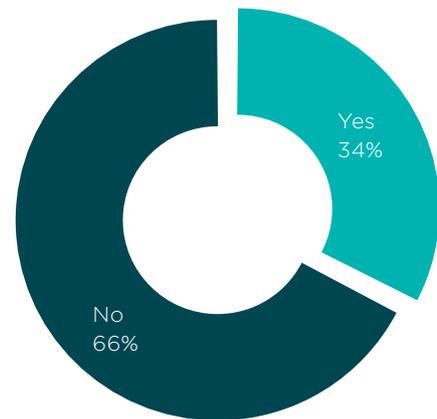
Base: All respondents (n=117).

Other¹ includes Complexity of process; N/A (x4); Slow; To have all for emergency medicine; transparency of suppliers.

The survey suggests COVID-19 has convinced many companies of the need to address such concerns by improving supply chains. One-third of the polled industry leaders said they considered dual sourcing key products as part of risk management efforts during the pandemic. Dual sourcing can equip companies to keep getting products to patients even if one supplier suffers a disruption.

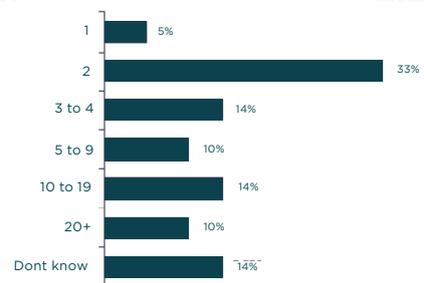
One-third of respondents said they are considering dual sourcing two products, making that the most commonly chosen answer. The finding may reflect the small product portfolios managed by the respondents, 43% of whom work at small or mid-sized biopharma companies. Some respondents at larger companies are considering dual sourcing more widely, with 24% of everyone polled planning to use the strategy for at least 10 products.

Figure 3: Key Products Dual-Sourcing



Question: Has your firm considered dual sourcing of key products as part of risk management efforts during the pandemic?

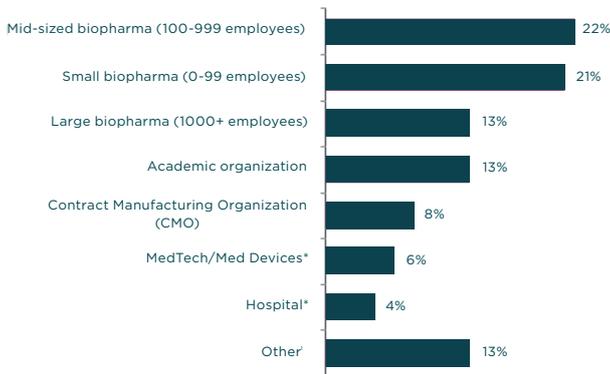
Base: All respondents (n=117).



Question: How many products are you considering dual sourcing?

Base: Respondents considering dual-sourcing (n=40).

Figure 4: Organization Type & Outsourcing Drug Development



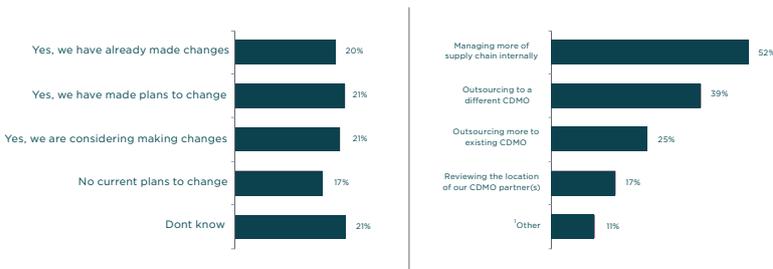
Question: What type of organization do you work for?

Base: All respondents (n=117). *Category was added due to a large number of write-in responses.

Other¹ includes: Advisory; Construction; Consultancy (x5); CRO; Government R&D; Law firm (x2); Non-profit organization; Pension fund; Vendor.

Dual sourcing is one of a number of ways respondents are trying to increase the resilience of their supply chains. Only 27% of respondents said they have no plans to change their supply chains in light of the lessons of the pandemic. Whereas 27% have already made changes in response to the pandemic, and all the other respondents are at least considering changes.

Figure 5: Anticipated Pandemic Changes to the Supply Chain



Question: Do you anticipate your supply chain management approach will change as a result of the COVID-19 pandemic?

Base: All respondents (n=117); multiple answers permitted.

Question: What changes do you anticipate? (Select all that apply.)

Base: Respondents considering changes to the supply chain management approach as a result of COVID-19 (n=71); multiple answers permitted.

Other¹ includes Go Fund Me campaigns to support litigation expenses; Have more suppliers (x2); Increase supply; More products in on shipment; Stockpiling; Supply chain solutions

The nature of the changes point to the desire for more resilient supply chains. Half of respondents said they plan to manage more of the supply chain internally, while significant minorities of these industry leaders

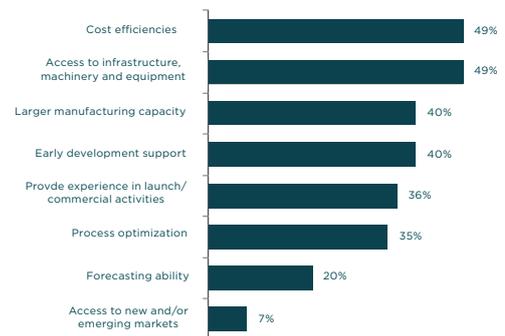
are changing CDMOs or reviewing the locations of their contract manufacturers. Respondents named delays, multiple site supply, dual sourcing, redundancy and a desire for greater flexibility as reasons for the changes.

How Attitudes Toward CDMOs Are Evolving

Interest in bringing work back in house is tempered by recognition of the benefits of partnering with CDMOs. Respondents cited access to infrastructure, machinery and equipment, larger manufacturing capacity and early development support among the top benefits of partnering with a CDMO.

The reassessment of supply chains is driving companies to look more closely at potential partners, as is shown by answers to questions about the attributes they look for in CDMOs. Three-quarters of the respondents said it is important that CDMOs are backward integrated. The response shows a desire among companies that outsource work for their CDMOs to have control over key starting materials.

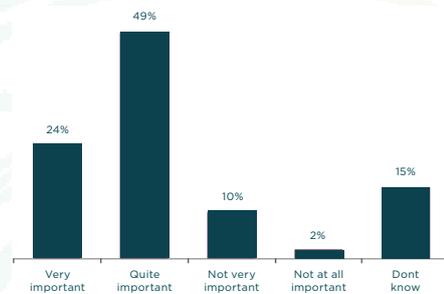
Figure 6: Benefits & Challenges of Partnering with a CDMO



Question: What are the main benefits of partnering with a CDMO? (Select all that apply.)

Base: Respondents outsourcing to a CDMO (n=55); multiple answers permitted.

Figure 7: Considerations in Choosing a CDMO Partner



Question How important is backward integration (i.e. where key starting materials come from) when choosing a CDMO partner?

Base: All respondents (n=117). ²Includes "Very important" & "Quite important."

Respondents also expressed a desire to work with CDMOs that are at the cutting edge of technology. Almost all respondents said they expect their CDMO partners to deploy digital and analytics tools and automation to improve the agility and transparency of the overall supply chain. Two-thirds of the respondents expect CDMOs to extensively or very extensively use digital tools and automation. The findings show details beyond cost are guiding the partnering process and raising the bar for CDMOs.

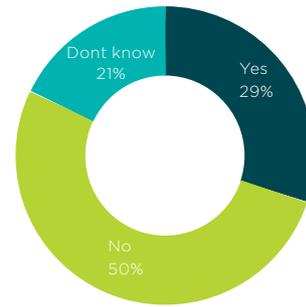
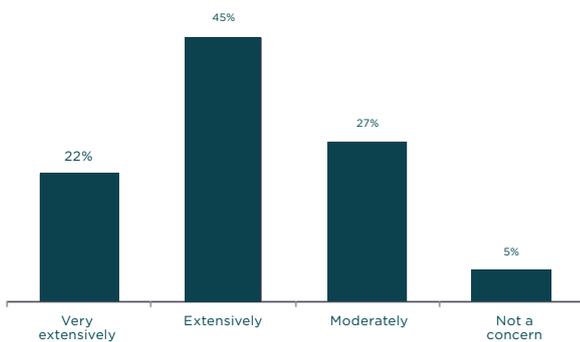


Figure 8: CDMO Location & Supply Chain Digital Tools & Automation Deploy



Question: How extensively does your organization expect CDMOs to deploy digital and analytics tools and automation to improve agility and transparency of the overall supply chain?

Base: Respondents outsourcing to a CDMO (n=55).

Companies are factoring where CDMOs are based into their decisions, too. While the industry has gone through a prolonged period of globalization, 35% of respondents favor domestic CDMOs and a further 21% prefer to work with regional partners. Just 16% prefer international CDMOs.

Figure 9: CDMO Partner Locality

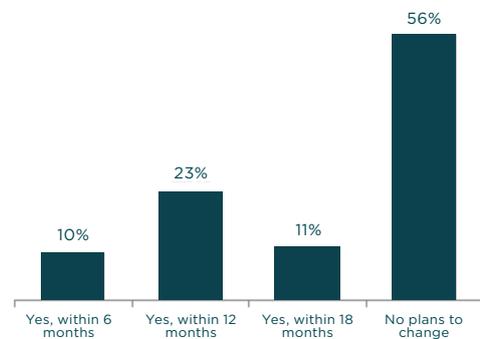


Question: Do you have any preference on the locality of your CDMO partner(s)?

Base: All respondents (n=117).

Question: Has this preference on locality changed as a result of the COVID-19 pandemic?

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Question: Do you have any plans to change the locality of your CDMO partners?

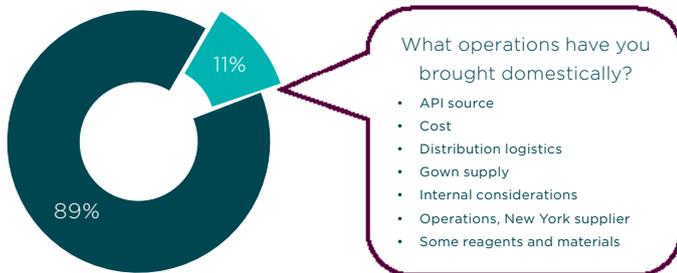
Base: All respondents (n=117).

The preference for local CDMOs is set to reshape supply chains. Almost half of respondents plan to change the locality of their CDMO partner within 18 months. More than 10% of respondents have already reshored API sourcing and other parts of the supply chain. Many more expect to do so in the future, with 58% of respondents saying the pandemic is likely to cause a permanent shift to more localized, lower-risk supply chains.

That focus on localized, lower-risk supply chains is a new development. Asked why they selected their current partners, 24% of respondents said the location of the CDMOs was a factor, making it the most rarely chosen of the seven possible answers. Yet, many companies are now changing the locality of their CDMOs. Most respondents who said the pandemic changed their view on the ideal location of CDMOs now prefer to work with domestic partners.

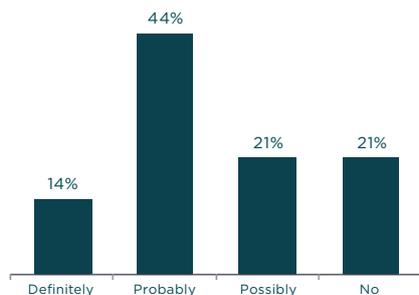
Companies that reshore manufacturing to improve resilience stand to simultaneously lessen some of the biggest challenges of working with CDMO partners. The survey found 38% of respondents regard communication difficulties as one of the main challenges of outsourced manufacturing relationships. A similar number of respondents cited project management. These problems are lessened when working with CDMOs in similar business cultures and time zones.

Figure 10: Reverting to Domestic Operations & Supply Chains



Question: Have any of your operations previously outsourced internationally been brought back domestically?

Base: All respondents (n=117).



Question: Do you expect a generally permanent shift, in the aftermath of the COVID-19 pandemic, from global supply chains to more localized, lower-risk supply chains?

Base: All respondents (n=117).

*Includes "Definitely" & "Probably."

What Next? The Future Of Supply Chains

The findings of the survey echo those of other studies and expert commentary. As the coronavirus spread around the world, experts at the World Economic Forum said the crisis had "revealed the fragility of the modern supply chain" and the United Nations Conference on Trade and Development predicted a move to shorter value chains.^{8,9} Of surveyed companies in the manufacturing and industrial sectors, 64% said they were likely to bring production and sourcing back to North America.¹⁰

Given the essential nature of medicines, the need for resilient, localized supply chains is particularly pronounced in the pharmaceutical industry. Vadim Gurvich and Ajaz Hussain of the National Institute for Pharmaceutical Technology and Education set out the situation in a paper, arguing the globalized supply chain was "under severe strain" even before the COVID-19 pandemic.¹¹

"The globalized paradigm is at a precipice, in part

because of the extreme vulnerabilities in the nation's dependence on foreign-sourced active pharmaceutical ingredients and drug products. To regain reliability, reshoring of the pharmaceutical supply chain to the USA is now a vital national security need," the experts wrote.

Manufacturers that recognize the limitations of long, globalized supply chains and act accordingly stand to do more than just increase their resilience; they will also lessen some of the pain points associated with working with distant CDMOs and position themselves to collaborate with partners that are leading the adoption of the analytics and automation technologies they value so highly.

The upshot is reshoring does not necessarily require productivity or efficiency to be sacrificed to gain resilience. Rather, companies can create new, digitally enabled supply chains that are more efficient than the old local approaches they partly phased out and more resilient than the globalized systems that proliferated in recent decades.

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