RESEARCH REPORT

Pharma Ignite

Using Global Onshoring Trends To Identify Industry Gaps In Life Sciences

NOVEMBER 2023

Powered By: SCRIP CITELINE COMMERCIAL

Brought to you by Cambrex

Using Global Onshoring Trends To Identify Industry Gaps In Life Sciences

As the life sciences industry faces ongoing geopolitical hurdles and recovers from COVID-19 setbacks, globalization is proving to be more difficult to resume. Now, companies are facing a whole new world of intricacy and change that is vastly different from the pre-pandemic conditions they once navigated. Rates of inflation remain unstable and regulation is increasing in complexity, all while technology is advancing at a rate that the industry is struggling to keep up with.

As a result, companies are encountering major challenges to get new products to global markets. For example, there is widespread concern that disturbances to supply chains will increase risk in the pharmaceutical industry, with the likelihood of supply chain disruptions representing a potential loss of 25% of earnings before interest, taxes, and amortization (EBITA) over a given span of 10 years.[1]

Due to these defining challenges, life sciences companies are forced to pivot strategies for future development by focusing more on outsourcing, which is, in turn, creating a higher demand for partnerships with contract development and manufacturing organizations (CDMOs). The pharmaceutical CDMO market is expanding rapidly. From a current size estimated at $223.41 billion, it is expected to grow to $309.5 billion by 2028, with a compound annual growth rate (CAGR) of 6.74%.[2]

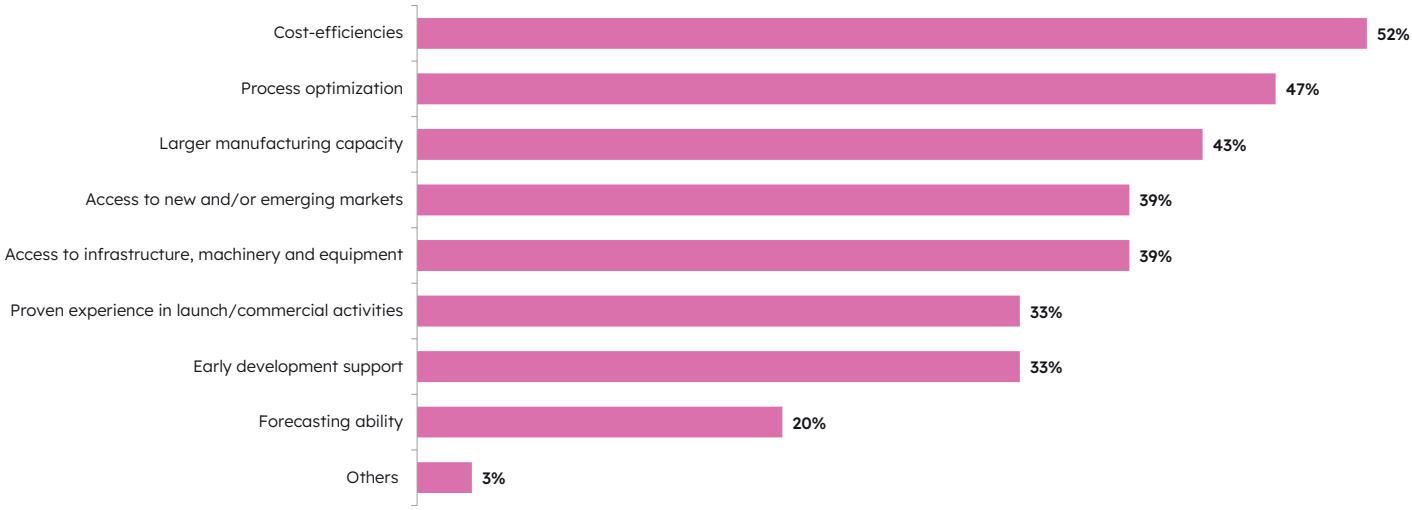
With numerous global CDMOs currently operating and more on the way, industry opinions about outsourcing are evolving. Companies who have partnered with CDMOs are finding that there are many benefits to those relationships, as CDMOs offer the opportunity to prepare for inflation, regulation, the technological curve and whatever other obstacles may arise.

Similar to CDMO partnerships, onshoring is increasing across the globe. There are many potential factors influencing companies to onshore their operations, which is what prompted Citeline and Cambrex to survey 100 industry leaders from emerging, mid-sized, and large pharmaceutical or biotech companies. The following report assesses global onshoring trends based on feedback from real-world industry professionals in this space. Assessment includes comparisons to a previous survey conducted by Citeline and Cambrex in 2020 that collected similar data relating to CDMO partnership preferences.[3]

CDMO Partnerships Continue To Thrive

The survey undoubtedly demonstrated that there are many advantages to partnering with CDMOs. With the recent spike in inflation, for instance, the life sciences industry is looking at higher costs for labor, transportation, and raw materials throughout manufacturing workflows. CDMO partnerships play a large role in cutting those costs, with 52% of

Figure 1. CDMO Partnering Benefits



Question: What are the main benefits of partnering with a CDMO? (Please select all that apply)
Base: All respondent; multiple answers permitted (n=100).

respondents choosing 'Cost-efficiencies' as a main benefit of CDMO partnering (Figure 1). Results showed that 'Larger manufacturing capacity' was another main benefit for CDMO partnerships, further rationalizing the push to reduce manufacturing costs.

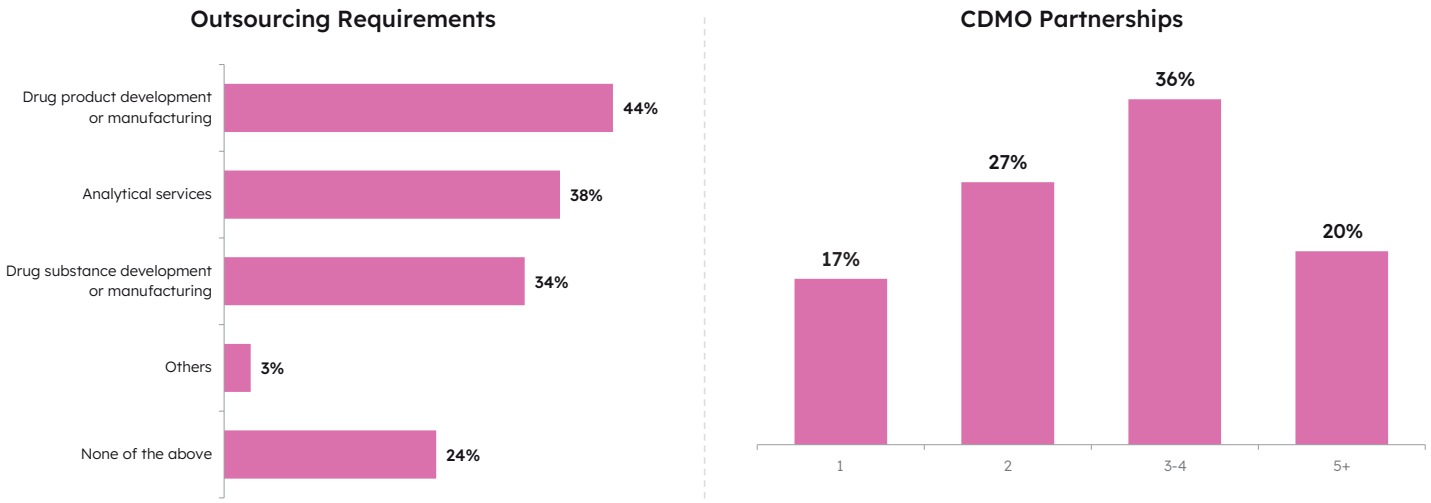
Comparing data to the previous survey, perceptions of 'Process optimization' and 'Access to new and/or emerging markets' rose substantially as main benefits of partnering with CDMOs (Figure 1).[3] Given the fact that these benefits are proving to be just as important to leaders in the industry as manufacturing, there seems to be a perception shift in where the value of CDMO partnerships lies. This could be attributed to "the increasing number of small and mid-sized companies seeking to bring their molecules to market," says Frank Ferrante, Chief Strategy and Corporate Development Officer at Cambrex.

"This new landscape is a product of the surge in biotech investment observed during the pandemic, which was much higher than any funding we've ever seen in this industry," he adds. As reflected in the 2023 CPhI Annual Report, funding peaked between $35 billion and $40 billion in 2021 – around $20 billion more than the normal growth trends for biotech.[4] So, while investment is up, smaller to mid-sized companies see the value of partnering with CDMOs that have expertise in many different molecules across an array of disease states, as they do not have the budget for large R&D operations. Today, for instance, in dealing with molecules that require complex synthesis, life sciences companies are leaning more on CDMOs for strategic support to manage that complexity.

In dissecting which areas companies are outsourcing CDMOs for, the survey found that 'Drug product development or manufacturing' is outsourced the most (Figure 2). This confirms that the wider industry associates lower risk with drug product outsourcing, which is in tune with developing simple formulations that do not require unique workflows. 'Analytical services' and 'Drug substance development or manufacturing' follow closely behind, a trend potentially driven by the availability of evolving digital capabilities offered by CDMOs that can streamline innumerable tasks in these areas.

Advanced computing and process development are just two ways that CDMOs can facilitate process optimization through speed and level of robustness, says Ferrante. CDMOs have access to novel technologies that make investment worthwhile, not only from an efficiency perspective but from a compliance perspective, as well. "If you pair capabilities like continuous flow manufacturing with algorithmic process controls and real time data visualization with the computing and analysis, you allow more thorough evaluation of the design space in less time, often resulting in higher-yielding processes being developed in a more efficient way," he says.

Figure 2. Outsourcing Requirements & Partnerships



Question: Do you currently outsource any of the following? (Please select all that apply)
Base: All respondent; multiple answers permitted (n=100).

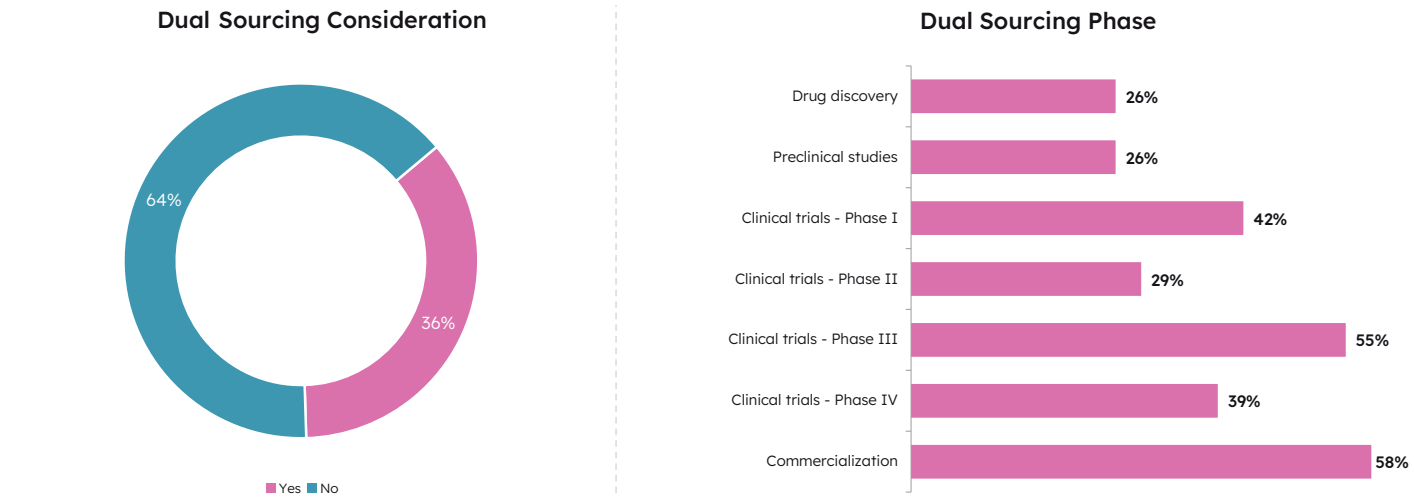
Question: How many CDMOs do you partner with?
Base: All respondents who currently outsource (n=70).

CDMO Outsourcing Trends

The rising number of CDMOs can be seen as a reflection of market competition in the life sciences industry. The top four pharmaceutical companies—Pfizer, Novartis, Roche, and Merck & Co.— own about 20% of the market, making it crucial for smaller companies to differentiate themselves.[5] With a worldwide need for innovation, companies are turning to CDMOs for efficiency, and multiple CDMOs at that. According to the survey, companies partner with three or four CDMOs on average; they could be exploring the opportunity to execute individualized strategies for specific drugs and technologies (Figure 2).

Additionally, dual sourcing remains a common trend in life sciences, with most respondents considering outsourcing with two CDMOs during the commercialization phase of product development (Figure 3). The survey results also exhibited an upward trend in dual sourcing from drug discovery

Figure 3. Dual Sourcing



Question: Have you considered using two CDMOs for the same services (dual sourcing)?
Base: All respondents (n=87). Note: 'Don't know' not included (n=13).

Question: At which phase(s) of the drug development process would you consider dual sourcing? (Please select all that apply)
All respondents who have considered using two CDMOs for dual sourcing, multiple answers permitted (n=31).

to commercialization (Figure 3). Dual sourcing may be more common closer to commercialization due to increased risk, as the priority for companies further down the lifecycle of a drug is to keep approval moving. “Because of the extra risk, many companies that are dual sourcing are often doing so with domestic manufacturers,” adds Ferrante.

Rates of dual sourcing for clinical trials are much less than that of the commercialization stage, but the data shows an interesting spike in dual sourcing during Phase I of clinical trials at 42%. This sharp increase in early development could become more mainstream as molecule complexity grows and more startups need the resources to start administering their drugs in real-world patients.

Despite the fact that dual sourcing consideration was similar in this survey to that of the previous survey, the average number of products considered for dual sourcing increased from two to three or four.[3] That increase ties into the market complexity aspect, explains Ferrante. The need for specialists in certain areas of development grows as molecule complexity grows. If a company is skilled in process chemistry or analytics, it may focus its services primarily on those areas and outsource other parts of the R&D process altogether.

Ferrante also mentions that dual sourcing is a way for companies to mitigate risk in terms of supply chain reliability, “whether it’s real risk or perceived risk,” he emphasizes. “I think having multiple sources lined up is certainly one way to feel more comfortable in your supply chain.” This technique allows life sciences companies to have some level of control over product development success amid regulatory changes or periods of uncertainty, such as the COVID-19 pandemic.

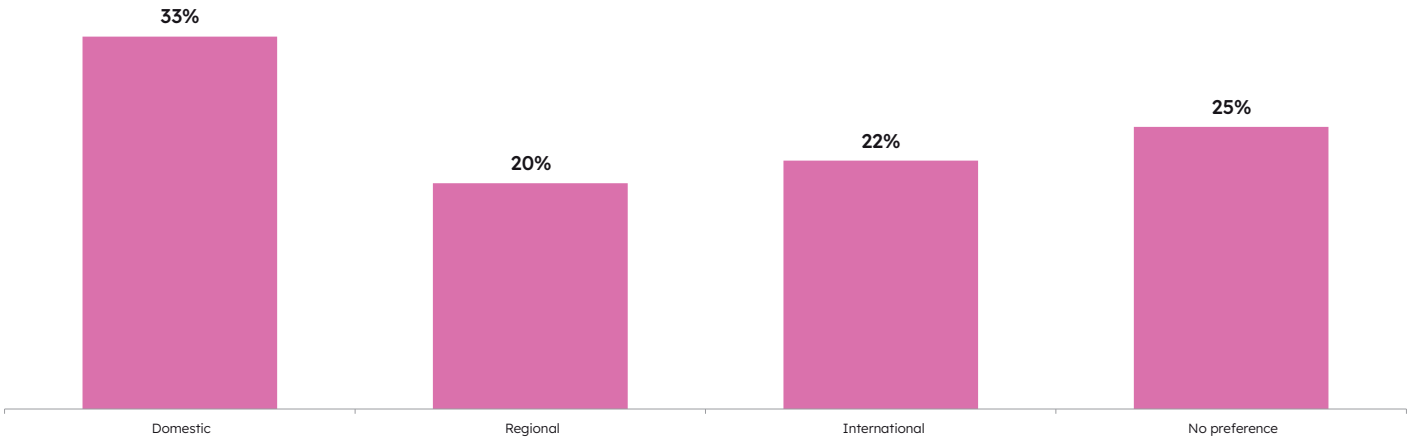
When it comes to single versus dual sourcing, decision-making depends not only on the complexity of the molecule and supply chain reliability, but also on current trends in the landscape. The CDMO sector is becoming more competitive, as these organizations are receiving more funding from venture capital or private equity firms, which drives more capabilities in the marketplace, says Ferrante. There are more opportunities to provide services for molecules and, given the average number of CDMO partnerships from this survey, dual or multi-sourcing seems most popular today.

Impact Of COVID-19 On Locality Preferences

In the previous survey, over 60% of respondents considered, planned, or made changes to their CDMO locality as a result of the COVID-19 pandemic. Thirty-nine percent were ‘Outsourcing to a different CDMO,’ 25% were ‘Outsourcing more to an existing CDMO’ and 17% were ‘Reviewing the location of their CDMO partnerships’.[3] Since then, the supply chain has only grown more complex, and innovations in this space have had time for adoption.

The digital supply chain, for example, is one area where companies are taking advantage of technological advancements such as artificial intelligence (AI) and the Internet of Things (IoT), to oversee product development and manufacturing from any geographic

Figure 4. CDMO Locality Preference



Question: Do you have any preference on the locality of your CDMO partner(s)?
Base: All respondents (n=100).

location in a shared network. Continuous flow chemistry is another area where companies are saving resources and time to develop drugs using methods with greater scalability and flexibility. Now that these innovations are becoming more established in a post-pandemic world, how are opinions changing about the locality of CDMOs?

Survey results suggest that domestic CDMO partnerships are the most popular among life sciences companies today in North America and the UK (Figure 4). It comes as no surprise that the previously mentioned 'big fish' of the global CDMO market—North America holding the largest share at 44.3%, followed by Europe with 33.6% as of 2019—are staying local.[6] However, geographic definition must be considered when interpreting this, as perceptions of country or region may vary among respondents.

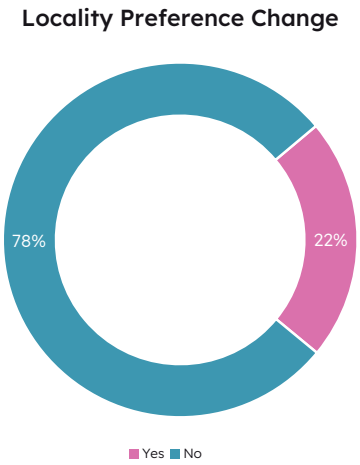
While the impact of ongoing COVID-19 consequences continues to be felt by the industry, only 22% of respondents said their locality preference for CDMOs 'Changed due to, or were affected by, the COVID-19 pandemic' (Figure 5). It is possible that companies have already made a locality change since the previous survey. Based on Ferrante's conversations with other industry leaders, this could also be due to the pandemic accentuating risks that customers have always considered instead of creating new risks. "The companies that have chosen to have complex distributed supply chains are likely adept at handling challenges that come up as well," he adds.

Furthermore, even if life sciences companies want to bring CDMO operations back to domestic territories, that may not be the most cost-efficient option. "The cost structure needs to be attractive enough to support the provision of those products in a profitable way globally," says Ferrante. Regardless of whether a company wants to bring operations back domestically, they have to be able to produce a therapy for whatever market they're in, in a profitable and sustainable way."

For those whose CDMO locality preferences were influenced by the COVID-19 pandemic, there were several reasons noted for the change (Figure 5). The survey showed that the top reasons for the switch included supply chain disruptions, increased efficiencies and labor shortages. Closer operations allow for more oversight over materials, which can be key in mitigating risk in such a volatile industry.

In comparing locality preference data against the previous survey, CDMO locality preference change decreased from 37% to 22%.[3] There are many competing factors contributing to whether this trend will continue in the future, but it boils down to geopolitical pressures, Ferrante notes. While continuous pricing pressures from government bodies necessitate global supply chains, there are other country-specific considerations that need to be factored into CDMO locality decision-making, such as tensions between Taiwan and China or drug shortages in Russia.

Figure 5. COVID-19's Impact On CDMO Locality



Question: Has your CDMO locality preference changed due to or been affected by the COVID-19 pandemic?
Base: All respondents (n=86). Note: 'Don't know' not included (n=14).

Figure 6. Future Project Locations

Question: Which geographic countries/regions will you source for future projects? (Please select all that apply)
Base: All respondent; multiple answers permitted (n=100).

Globalization & Onshoring

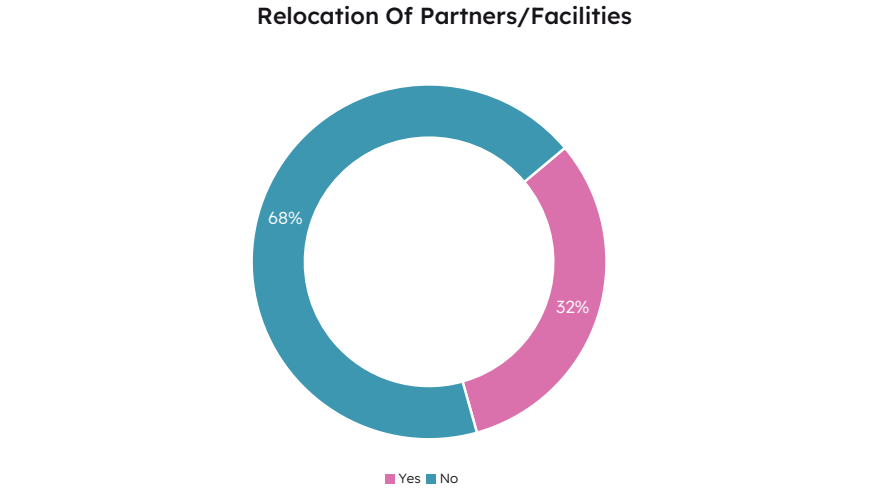
In the context of globalization, regulation in the life sciences industry seems to be an antagonist towards innovation and meeting international healthcare needs. On average, it costs $2.6 billion and requires 10 to 15 years to develop a new medicine.[7] The complexity of multiple channels to market is a major contributor to those numbers, given the unique regulatory hurdles for each country. For instance, import is burdensome for US companies outsourcing active pharmaceutical ingredient (API) development to China, as passing quality validation when coming back into the US is becoming more difficult.

The survey found that country preferences for future project locations with CDMOs were mostly geared towards the US and UK regions (Figure 6). Even though CDMOs in the APAC regions, including China, Japan, and India, are making strides to chip away at legacy perceptions of Western powerhouses, there still remains a bias in favor of the larger and more established competitors in the US and Europe, Ferrante says. The generics source supply, however, is going to be a significant draw to the East in the future, he adds, due to the need for a competitive cost structure.

When assessing CDMO relocation trends, 32% of respondents brought internationally outsourced operations back to domestic territories, and about the same percentage of respondents were planning to change the locality of their CDMO(s) (Figure 7). These results suggest that life sciences companies have already relocated back to domestic facilities or partners, as there are now more operations onshored and fewer plans to onshore in the future. That does not necessarily mean that onshoring trends will continue this way in the future, Ferrante observes, though it does speak to the ebbs and flows of the industry and how strategies can change in an instant.

The main driver for onshoring among life sciences companies is quality assurance, according to the survey, with risk as the main barrier for onshoring. Therefore, the risks are about more than just supply chain disruption. “It’s costly to change locations, and it takes time,” Ferrante reiterates. “The tech transfer process needs to go smoothly. Companies need to reconfigure their distribution route to market. They need to consider cold chain and stability. If you’re a pharma company and going to change all those things, you’re going to be sure that it’s going to work out really well.”

Figure 7. CDMO Relocation



Question: Have you brought any internationally outsourced operations back to domestic partners/facilities?
Base: All respondents (n=85). Note: 'Don't know' not included (n=15).

The other half of the equation is the regulatory burden. Life sciences companies must requalify and achieve sign-off for global regulatory bodies with a new CDMO and a new site, he adds. That is a huge effort for these companies and may reintroduce risk if the product is not yet approved. So, although there are many pros and cons to either onshoring or continuing with global supply chains, considerations evolve with the landscape. Regulation continues to make it harder for globalization to progress.

Outlook

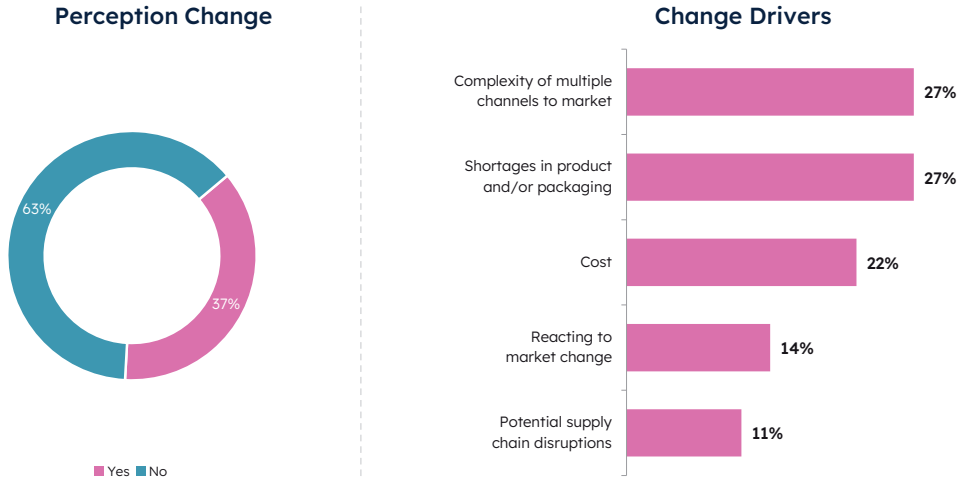
CDMO partnerships continue to grow post-COVID-19 as novel CDMO capabilities facilitate a global approach to pharmaceutical and biotech development. CDMOs can offer a wide range of tools that alleviate burdens of global supply chains, whether it be staying up to date with regulatory guidelines in specific countries, navigating product-specific manufacturing processes or reducing costs related to inflation and labor shortages.

The survey confirmed that perception of collaboration with outside organizations for product development has shifted in the last two to three years, as 37% of respondents' thinking has changed on outsourcing versus insourcing (Figure 8). As more unmet needs arise, the more arduous it becomes to get products to global markets. Along with those unmet needs come challenges in developing complex therapies. There is a growing importance placed on treating every product individually, which goes hand-in-hand with picking the right CDMO.

The opportunity lies in exploring possibilities for CDMO partnerships. The oncology space is projected to grow the fastest in the CDMO market, with a CAGR of 14.2% from 2021 to 2027.[6] It is hard to discern whether other disease areas will follow suit. Regardless, Ferrante feels strongly that CDMOs are placed in the right position in the life sciences industry and that increasing reliance on those partnerships will continue.

"I'd be very surprised if there were anything but continued rates of outsourcing at every step of the product lifecycle over time," he concludes.

Figure 8. Outsourcing Verses Insourcing



Question: Has your company's thinking on outsourcing verses insourcing changed in the last 2-3 years?
Base: All respondents (n=87).

Question: What was the primary driver of the change?
All respondents whose company's thinking on outsourcing verses insourcing has changed (n=37).

References

1. McKinsey. Emerging from disruption: The future of pharma operations strategy (2022) https://www.mckinsey.com/capabilities/operations/our-insights/emerging-from-disruption-the-future-of-pharma-operations-strategy#A%20Perfect%20Storm%20of%20External%20Challenges
2. GlobeNewswire. CDMO market size & share analysis – growth trends & forecasts (2023 – 2028) (2023) https://www.globenewswire.com/news-release/2023/08/16/2726646/0/en/CDMO-Market-Size-Share-Analysis-Growth-Trends-Forecasts-2023-2028.html#:~:text=CDMO%20Market%20Size%20%26%20Share%20Analysis%20-%20Growth,CAGR%20of%206.74%25%20during%20the%20forecast%20period%20%282023-2028%29
3. Scrip. Ensuring Resilience: How Life Sciences Is Reshaping Supply Chains In Response To COVID-19 (2021) https://pages.pharmaintelligence.informa.com/supply-chain-survey-report
4. CPHI. 2023 CPHI Annual Report (2023) https://www.cphi.com/en/digital-products/digital-products/annual-report-2023.html
5. Statista. Top 20 pharmaceutical companies worldwide based on prescription drug market share in 2019 and 2026* (2023) https://www.statista.com/statistics/309425/prescription-drugs-market-shares-by-top-companies-globally
6. Gitnux. The most surprising CDMO industry statistics in 2023. (2023) https://blog.gitnux.com/cdmo-industry-statistics
7. PhRMA. Research & development policy framework. (2021) https://www.phrma.org/policy-issues/Research-and-Development-Policy-Framework

Cambrex is a leading global contract development and manufacturing organization (CDMO) that provides comprehensive analytical and IND enabling services, as well as drug substance development and manufacturing across the entire drug lifecycle.

With over 40 years of experience and a team of 2,000 experts servicing global clients from North America and Europe, Cambrex is a trusted partner in branded and generic markets for API development and manufacturing. Cambrex offers a range of specialized drug substance technologies and capabilities, including continuous flow, controlled substances, solid-state science, material characterization, and highly potent APIs.

Pharma Ignite

Pharma Ignite brings you the most up-to-date and informed intelligence in the industry. Our network of industry-leading analysts and partners is pursuing new intelligence in the core areas of life sciences using Citeline's suite of insights products and services – all of which has the power to fuel your organization and projects.

We also provide cutting-edge lead generation and brand programmes to help you reach and collaborate with audiences across industry events and digital platforms.

Citeline (a Norstella Company) powers a full suite of complementary business intelligence offerings to meet the evolving needs of health science professionals to accelerate the connection of treatments to patients and patients to treatments. These patient-focused solutions and services deliver and analyze data used to drive clinical, commercial, and regulatory related-decisions and create real-world opportunities for growth.

Our global teams of analysts, journalists and consultants keep their fingers on the pulse of the pharmaceutical, biomedical and medtech industries, covering it all with expert insights: key diseases, clinical trials, drug R&D and approvals, market forecasts and more.