Whitepaper

ASSESSING END-TO-END DRUG DEVELOPMENT PARTNERSHIPS

As drug development becomes increasingly expensive and complex, pharma companies are relying on the services of contract development and manufacturing organizations (CDMOs) to aid them in the creation and commercialization of their products. Exemplifying this, 80% of manufacturing by small biotech and pharma companies was outsourced in 2017.[1] This practice allows firms to reserve precious resource for business growth activities, while CDMO partners with extensive experience and expertise can focus on the development and production of their pipelines. Additionally, the emergence of the virtual business model has brought with it the need to form extensive partnerships with CDMOs, covering end-to-end drug development. These pharma businesses need to make their investments into partnerships count, so it is critical to maximize efficiencies.

To cater to this demand, the contract development and manufacturing market is estimated to grow to $117.3bn in 2023 at a CAGR of 6.8%.[2] Accomplished CDMOs are growing their breadth of services, offering pharma companies the potential for a single partnership that spans the whole drug development process. This deviates from the traditional approach of choosing different partners depending on their suitability for each step. With varied strategies for pharma companies to assess, Pharma Intelligence conducted a survey in partnership with Cambrex considering the opportunities and challenges of end-to-end arrangements.

Prioritizing Expertise

For pharma and biotech companies to decide whether working with a single CDMO is the correct route, it is critical to assess the reasoning behind the majority of companies opting to utilize multiple partnerships.

When asked what the motivators were for changing their partner at different stages of the drug development process, the top two reasons were specialist expertise (30%) and access to specific equipment and facilities (29%) (see Figure 1). Emphasizing this, when asked what the main challenges of partnering with a single CDMO were, lack of specialist expertise in both drug substance and drug product development was the second most cited (22%). This infers that if there were a CDMO that could provide all the knowledge and resources needed for a pharma company's product development, there could be scope to limit partnerships to a single provider.

Some established CDMOs can now offer such possibilities, ensuring they have expertise and facilities that make them capable not just of executing the full drug development process, but also of providing consulting and guidance to aid their partners to make effective pipeline decisions.

Why Cambrex?

Cambrex provides drug substance, drug product and analytical services across the entire lifecycle.

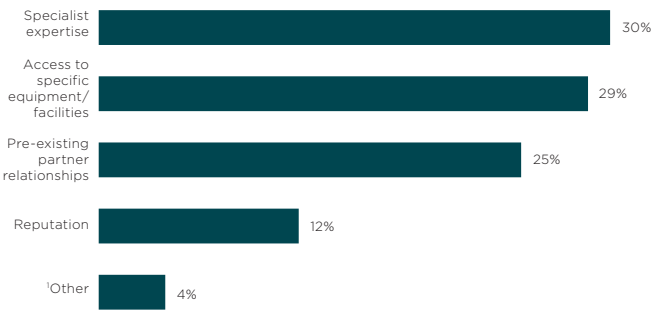
We deliver quality in every aspect of our work, across all of our facilities, systems and teams.

About Cambrex

Cambrex is **the** small molecule company that provides drug substance, drug product and analytical services across the entire drug lifecycle. Enjoy working with our experts to accelerate your small molecule therapeutics into the market.

With 40 years' experience and a growing team of over 2,100 experts servicing our global clients from our sites in North America and Europe, we are tried and trusted in branded and generic markets for API and dosage form development and manufacturing.

Figure 1: Partnership Switching



Question: Why do you change your partner at different stages of the development process? (Select all that apply.)

Base: Respondents currently have more the one CDMO partner; multiple answers permitted (n=76).

[1]Other includes: Available capacity, Capacity & Price and availability.

For this reason, CDMO partnerships are most effective when established early in the drug development process, setting a product on the right track from the very start. Approaching a CDMO with a project later means along with executing the task at hand, partners must also gain an understanding of a product's development history. There is also a need for often complex technology transfers, ensuring all relevant information and material is passed from one CDMO to another.

Pharma companies see the benefits of early instruction: irrespective of their number of CDMO relationships, 62% of survey respondents stated they would generally approach partners in the early development stage. Moreover, the earlier stages were also perceived as those in which CDMOs could offer the greatest assistance to pharma companies, with product development/characterization and clinical manufacturing each being chosen by 33% of respondents, followed by commercial manufacturing with 22%.

Maintaining Flexibility

While breadth of expertise was perceived as one of the key challenges of end-to-end CDMO partnerships, it was eclipsed by concerns about the risks of depending on a single provider, with a third of respondents citing the issue. This has been brought to the fore by the COVID-19 pandemic, during which supply chains and manufacturing operations were undoubtedly challenged by sustained periods of remote working and business closure. As a result, pharma companies are reassessing their supply chain strategies to become more agile and able to adapt to disruption.[3]

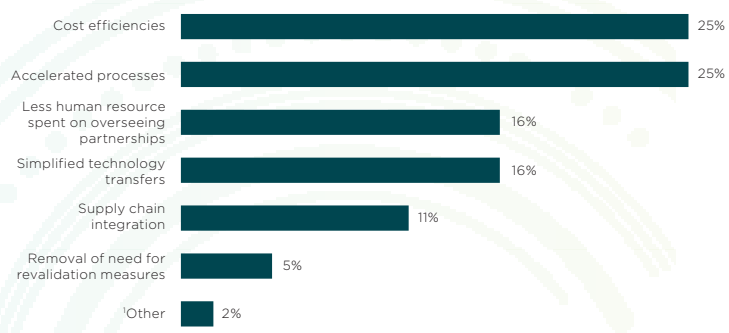
One of the main causes of supply chain disruption during the pandemic was geographic lockdown. For pharma companies with CDMO partners based in regions where business operations were hindered, it caused significant problems and their pipeline progress risked being compromised. An end-to-end partnership with an impacted CDMO could have resulted in a complete halt in product development, so it is unsurprising that pharma companies may be dubious about such arrangements. However, another trend the industry bears witness to as a result of the pandemic is a push from some pharma companies – particularly those based in the US and Europe – to reshore their drug development so as to have greater oversight. The issue has even become political, as seen in US federal backing of Phlow Corporation earlier this year and the Trump administration's "Buy American" executive order.[4,5] As a result, CDMOs that can offer end-to-end solutions in these regions may now represent a perceptibly secure option that warrants commitment from their pharma partners.

As well as pipeline and supply security, effective communication from outsourcing partners is paramount for pharma companies. This was corroborated by over two-thirds of survey respondents (67%), who stated it was very important for CDMOs to communicate well with sponsors. When it comes to end-to-end partnerships, there is a great deal more trust, reliance and pressure placed on the single CDMO to manage the drug development process from start to finish. It is therefore unsurprising that 54% of respondents believed these arrangements heightened the importance of communication, as they will want reassurance that their projects are progressing effectively and on time.

Optimizing Efficiencies

When asked what the main benefits were of end-to-end CDMO partnerships, respondents overwhelmingly perceived this to be efficiency, in varying forms. The most prevalent answers among participants were accelerated processes, chosen by a quarter of respondents, alongside cost efficiencies with a further quarter (see Figure 2). These benefits are intrinsically connected. Accelerated processes in the end-to-end development of a drug ultimately lead to quicker commercialization, which is crucial for pharma companies in meeting investor targets and achieving funding. To that end, while the price point of partnering with a CDMO capable of spanning the end-to-end drug development process may on the surface be more than opting for the most competitively priced options at each stage, if it leads to quicker market access then results will be seen in the long term.

Figure 2: CDMO End-to-End Partnership Benefits



Question: What are the main benefits of partnering with one CDMO for end-to-end drug development? (Select up to three.)

Base: All respondents; three answers permitted (n=308).

[1]Other includes: Do not know, Product history, Established relationship, Rely on expertise & We don't have the capacity.

In addition, accelerated processes have become pivotal during the COVID-19 pandemic. Threats of drug shortages have drawn attention to the importance of productivity in the drug development process, alongside the underlying pressure to ensure rapid vaccine and therapeutic production to combat COVID-19 itself. Moving from one CDMO partner to another at different stages of drug development can be a potential cause of delays. Tech transfers can be a key moment where issues can arise. While these are still needed when a drug moves from one team to another within a single CDMO, many of the potential delay risks can be mitigated when handled within one entity. Firstly, shared systems make the technical process and transferring data more intuitive and seamless than sending to a separate organization that might utilize different technologies. Second, communication between departments and teams can be more fluid within a single CDMO, meaning there is opportunity for a dialogue past the point of the transfer to pass on key knowledge gained earlier in the process. Pharma companies are aware of these benefits, with survey respondents ranking simplified technology transfer as the joint second biggest benefit of end-to-end partnerships (16%) (see Figure 2).

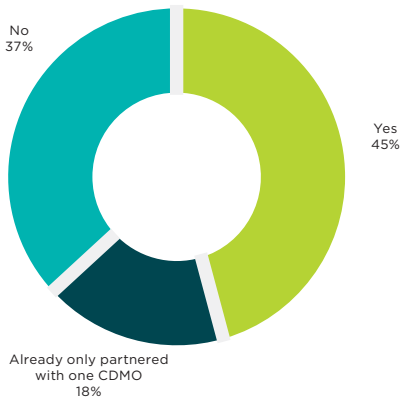
Along with simplified tech transfers, 16% of respondents believed that the fact less human resource would need to be spent on overseeing partnerships was a key benefit of end-to-end partnerships (see Figure 2). This was amplified later in the survey, as 33% of respondents indicated that less human resource would be needed in their organization if they were to adopt an end-to-end arrangement and consolidate partnerships to a single CDMO. This enables pharma companies to save capital in the short term on direct human resource costs, but another approach is to better utilize this human resource spend on business growth activity in the drug development process. Ultimately, this is where the staffing/time costs of pharma companies are best spent on the evolution of successful pipeline prospects, which will also pay financially in the long term.

Prospects For Change

While the benefits of the end-to-end partnership are not necessarily new for the industry, such arrangements have gained increased attention as the outsourcing market has grown. This has enabled more CDMOs to grow their capabilities to facilitate end-to-end partnerships and hone their experience across drug development to offer true benefit to their customers.

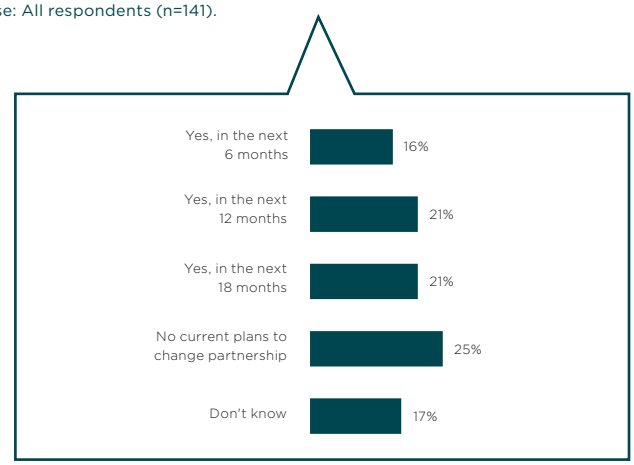
The pharma industry has somewhat of a reputation for being cautious in its approach to change, and therefore it may not be surprising that 65% of respondents currently opt for the more traditional approach of working with different CDMO partners for different stages of drug development. However, sponsors understand the benefits of end-to-end drug development partnerships and there is appetite to implement them. This was reflected in survey responses, with just under half being open to switching to an end-to-end arrangement with a single CDMO (see Figure 3). Moreover, of these some 58% already had plans in place to change to this approach within the next 18 months.

Figure 3: Single CDMO Partnerships



Question: Would you consider switching to one single CDMO partnership for end-to-end drug development?

Base: All respondents (n=141).



Question: Do you have plans to change to an end-to-end partnership with your existing or a new CDMO?

Base: Respondents who would consider switching to one single CDMO (n=63).

To conclude, it is clear from survey results that end-to-end drug development partnerships are set to increase in commonality, and with good reason due to the benefits that can result from them. However, for a pharma company placing such reliance on a single CDMO, when making a decision as to who to do business with it is crucial to give due consideration to the capabilities, expertise and facilities the potential partner can provide. Effective partnerships bring accelerated processes, access to wider knowledge and experience, and ultimately, greater cost efficiencies. Companies that make the right choice can have a pivotal impact on the success prospects of their pipelines, along with the speed at which patients receive critical treatments.

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