The Changing Paradigm in Biopharmaceutical Clinical Development Partnerships

Industry survey reveals key areas of consideration used to evaluate if an integrated service provider is the right fit

Increasingly, drug developers rely on partnerships with service providers to access needed development and manufacturing capacity and to tap into their extensive and often unique areas of expertise and knowledge. Although the use of outsourcing via a CDMO to replace or augment internal capacity and capabilities can be found across companies of all sizes, the practice is especially common among small and emerging companies. Smaller businesses in particular may not have the necessary internal expertise or physical facilities to execute the many activities needed to successfully bring a drug candidate through early development, into clinical trials, and even commercial supply. Conversely, larger and better-resourced companies may opt to outsource a portion of their development and clinical supply needs to an external service provider, whether that is to free up internal capacity for other projects, to quickly gain access to new technologies and approaches, or to address other strategic business needs.

What is an integrated services provider?

An integrated services provider is a third-party partner that provides a broad suite of services throughout drug development and commercialization. If done well, this approach allows knowledge about a project to be passed seamlessly from pharmaceutical development to manufacturing groups. An integrated approach also allows some work that would traditionally follow a linear timeline to occur in parallel workstreams instead.

When evaluating their options for working with outsourcing partners, companies must first determine whether it is in their best interests to use an integrated service provider (see sidebar, "What is an integrated service provider?") for the entirety of their project or to contract with several different specialty providers at various stages of the development project. What factors go into making these important decisions? What specific benefits do companies perceive they can gain from integrated relationships?

Pharmaceutical Technology®

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Pharmaceutical Technology surveyed a portion of its readership from February to March 2022 to better understand drug developers' preferences for CDMO and clinical supply services. This survey was conducted in partnership with Catalent, a leader in enabling pharma, biotech, and consumer health partners to optimize product development, launch, and full life-cycle supply for patients around the world.

About the Survey Participants

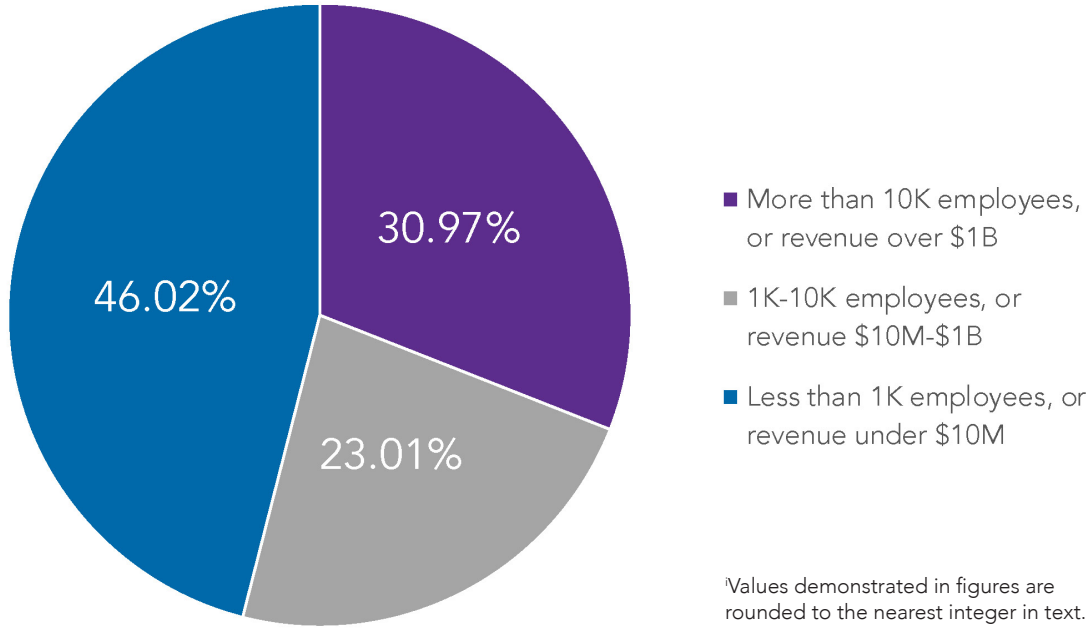
The results presented herein focus on a subset of respondents who work at pharmaceutical and biopharmaceutical companies in order to gain insight into their unique concerns, preferences, and priorities associated with using CDMO services. This discussion only considers responses from decision makers or influencers in the selection of third-party providers for clinical services.

Survey participants represented all sizes of pharmaceutical and biopharmaceutical companies, from smaller companies with less than 1,000 employees or revenue of under $10 million (46%) to those with more than 10,000 employees and revenues exceeding $1 billion (31%) (see **FIGURE 1**). The survey participants also represented a fairly even spread of newly founded companies and well-established companies with decades-long legacies (see **FIGURE 2**). Respondents noted that their companies' current pipelines include oral drugs (55%), biologics (37%) and cell and gene therapies (8%) (see **FIGURE 3**).

Respondents were located worldwide, though the majority were based in the U.S. and Canada (73%). The remaining individuals were located in Asia/Australia (15%), Europe (excluding the U.K.) (7%), and the U.K. (2%).

Further, nearly two-thirds of the respondents have run a clinical trial in the past two years (64%).

Figure 1: Which statement best characterizes your company?



[1]Values demonstrated in figures are rounded to the nearest integer in text.

Figure 2: When was your company founded?

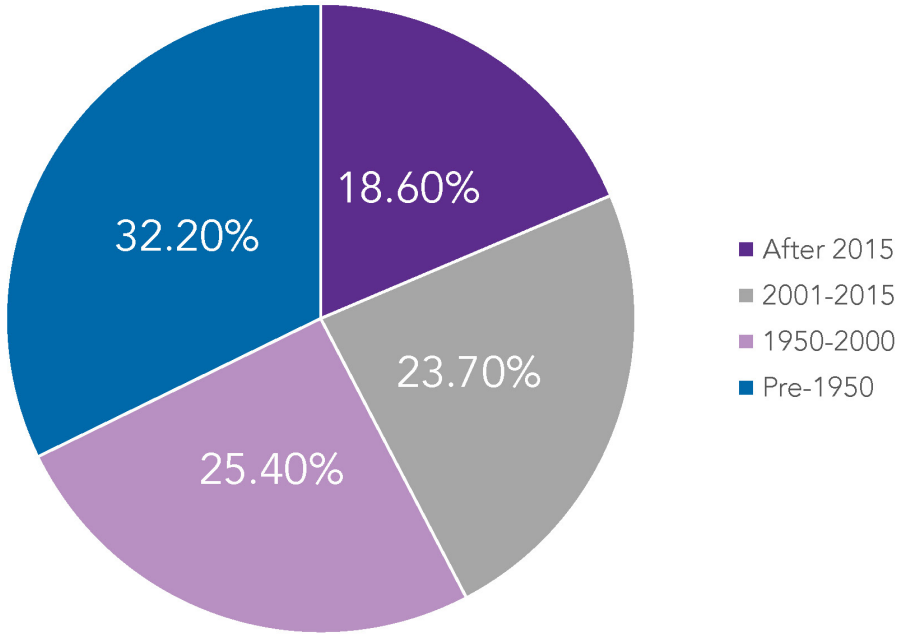
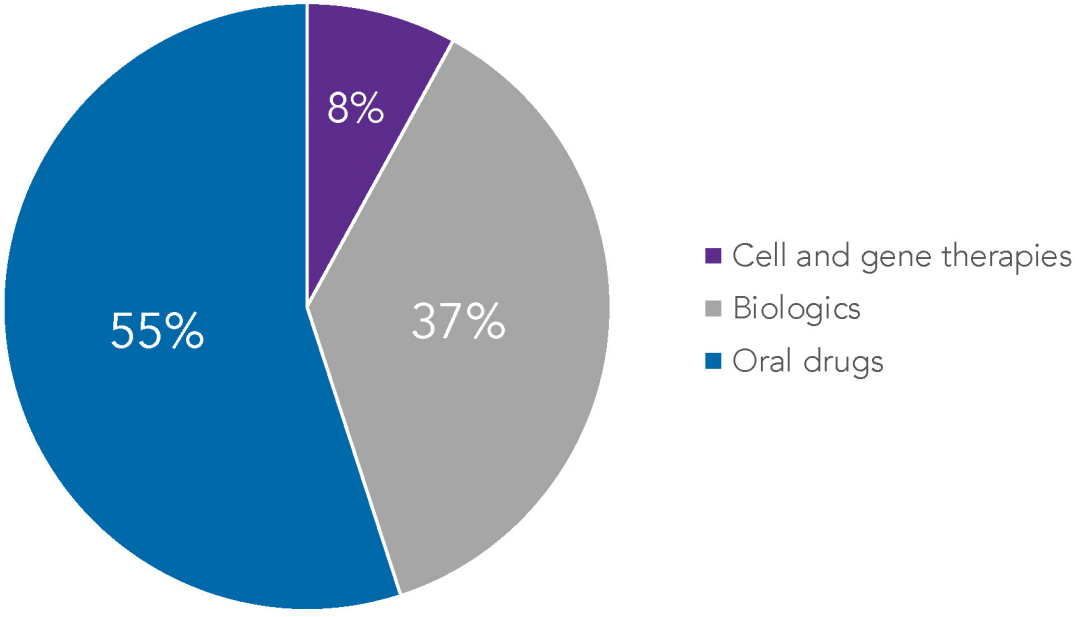


Figure 3: Which of the following modalities most reflects the current makeup of your company's pipeline?



Key Findings

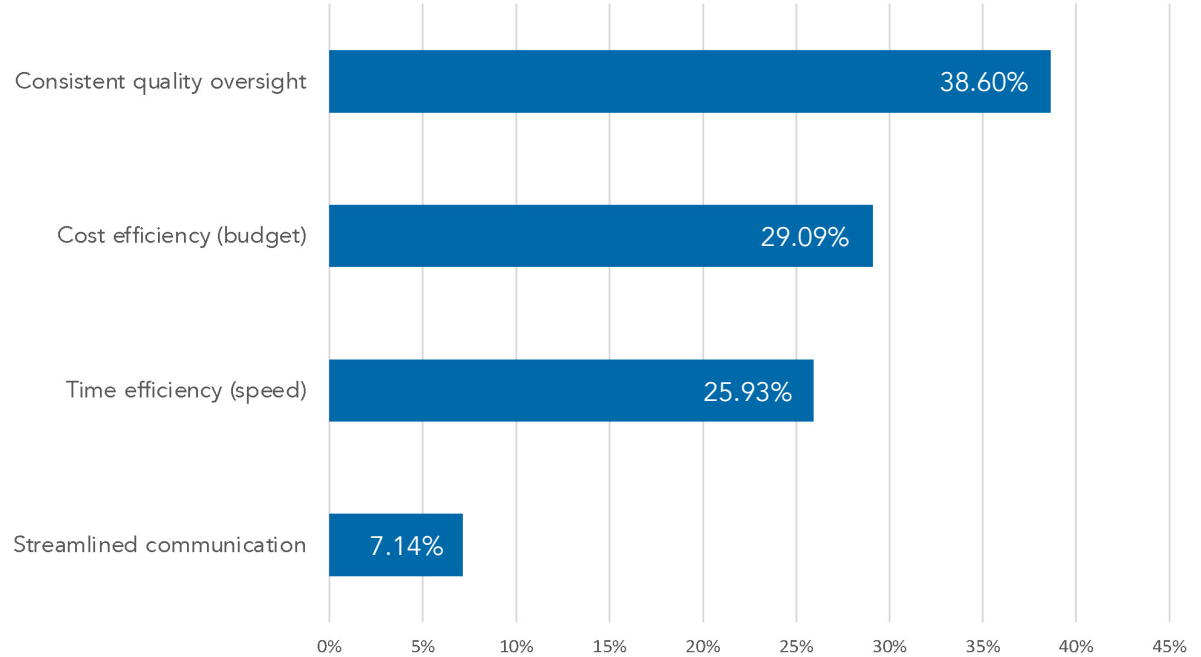
The majority (67%) of the respondents said they were comfortable managing multiple third-party service providers, while 33% prefer to manage a single, integrated provider.

Among those preferring a single partner, company pipelines were nearly evenly split between biologics (50%) and oral drug compounds (45%). Meanwhile, those drawn to the multi-partner approach tended to be slightly more focused on oral drug compounds (53%) than biologics (35%). Cell and gene therapy pipelines made up the remaining percentages in both groups.

Survey participants were asked to rank their expectations for benefits they might see with a project using an integrated services provider. The respondents' answers align with what integration proponents consider to be the core advantages of these services. For instance, 39% of the group identified consistent quality oversight as the top benefit of integrated services (see **FIGURE 4**). Meanwhile, cost efficiency and time efficiency were considered the top benefits by 29% and 26% of the respondents, respectively.

While only 7% of respondents felt streamlined communication was the top benefit of using an integrated services provider, in a separate question, nearly all respondents (93%) said they prefer a single point of contact for projects. To that end, one must also consider how streamlined communication is closely tied to the other benefits ranked in this question as budget overruns and timeline expansions can result from poor planning and miscommunication (see sidebar, "Integrated services: A strategy to consider for improving project efficiencies").

Figure 4: Regarding expectations for an integrated project using the same vendor, rank the following to indicate what is more important to least important.



[1]Values demonstrated in figures are rounded to the nearest integer in text.

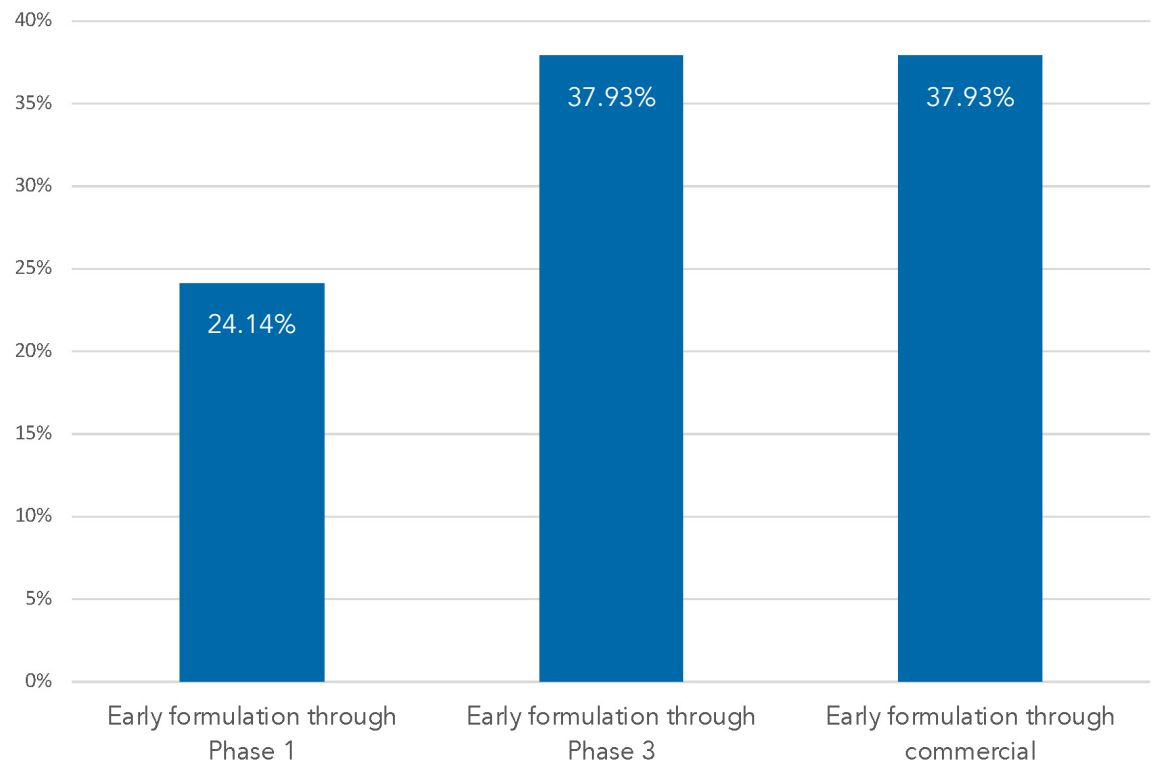
Risk reduction was another important consideration for companies evaluating their CDMO options. Respondents overwhelmingly stated (82%) that an integrated solution could help mitigate or reduce risks within their supply chain by limiting the number of handoffs during the different stages of their project.

As for what stage in the process was deemed the most productive for collaborating with a third-party partner, the majority (76%) of respondents felt it would be most beneficial to contract an integrated services provider right from the start of a project (i.e., during formulation and development efforts) and keep them all the way through to phase 3 clinical studies or beyond (see **FIGURE 5**).

This timeline of early formulation through commercialization includes the critical period for clinical trial material manufacturing, packaging, and distribution. Two-thirds of respondents (67%) felt that having an integrated formulation development and clinical supply services approach is a positive trend.

Proponents of integrated services suggest that having a partner with specific expertise in clinical supply services can be an important differentiator as they might be better able to navigate the local rules/ regulations and have a more experienced team to draw on for transporting clinical trial materials to challenging locations. Merely being able to manufacture and package

Figure 5: What does your ideal integrated solution with the same vendor look like?



Integrated services: A strategy to consider for improving project efficiencies

Survey respondents indicated core advantages to using an integrated services provider include better quality oversight and condensed project timelines—but how exactly are these benefits and efficiencies realized?

Proponents of integrated services often point out at the heart of these benefits are better communication and consistency as a result of not having to transfer projects from provider to provider—each of which likely has unique philosophies, cultures, and processes for project execution. Each hand-off from partner to partner opens a door to possible miscommunication, lost information, delays, and budget overruns.

Meanwhile, integrated development and manufacturing teams can be in regular communication about any special nuances or requirements for the project. Teams experienced in integrated projects should be on the same page and can look for opportunities to schedule tasks that would otherwise follow a linear timeline to occur in parallel. This parallel approach could potentially compress the overall project timeline without having to shorten the amount of time normally allocated for each specific task.

Access to an umbrella of services under a single, integrated provider also means that companies do not need to waste time negotiating or managing multiple contracts.

In summary, as companies strive to increase speed while de-risking development efforts, supporters of integrated services feel that this approach is a valid strategic solution worthy of serious consideration.

About Catalant

Catalent is the global leader in enabling pharma, biotech, and consumer health partners to optimize product development, launch, and full life-cycle supply for patients around the world. With broad and deep scale and expertise in development sciences, delivery technologies, and multi-modality manufacturing, Catalent is a preferred industry partner for personalized medicines, consumer health brand extensions, and blockbuster drugs. Catalent helps accelerate over 1,000 partner programs and launch over 150 new products every year. Its flexible manufacturing platforms at over 50 global sites supply over 70 billion doses of nearly 7,000 products to over 1,000 customers annually. Catalent's expert workforce exceeds 19,000, including more than 2,500 scientists and technicians. Headquartered in Somerset, New Jersey, the company generated $4 billion in revenue in its 2021 fiscal year. For more information, visit www.catalent.com.

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the smaller quantities needed for clinical trials is not enough without the extended knowledge and services necessary to successfully supply clinical trials, especially more complex or global scale studies.

Customization of services was very important to most respondents (81%).

Conclusion

The results from this survey suggest that as companies explore integrated, outsourced services, they expect to benefit from consistent quality oversight, cost efficiency, and time efficiency. Supporting these benefits is consistent and streamlined communication afforded by eliminating the need for project hand-offs from third-party to third-party. Companies feel that the advantages gained by taking an integrated approach from early development work all the way through commercialization can help their new medicines achieve the most efficient, maximum benefit to patients.