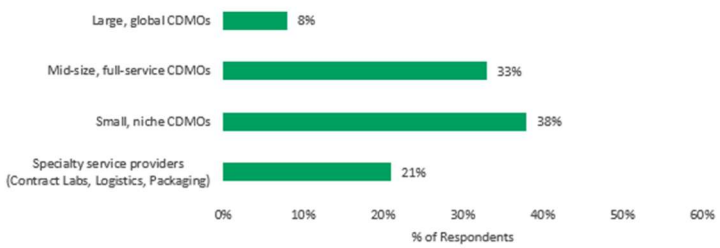
Industry Trends of CDMO Outsourcing CDMO

A recent Industry Standard Research (ISR) study explored CDMO outsourcing models to discover patterns within the selection of CDMO partners that sponsors choose at various stages of development, as well as to determine why sponsors made those choices. Data from our research indicates that preference for provider type shifts from niche CDMOs in early-stage development to global CDMOs by Phase III and for commercial manufacturing (Figs. 1-3).

Partnering with small/niche CDMOs during early-stage development is attractive to sponsors, in part, because those providers are perceived to be more accessible, offering more interaction with expertise early in development to aid in troubleshooting and other problem-solving. For example, the provider can quickly give developers approval to move forward, gather insight indicating some element in the manufacturing process must change, or determine a compound/molecule is unlikely to progress pass the preclinical/Phase I stage. Additionally, small/niche CDMOs generally are presumed to have capacity available at shorter notice and to provide higher-touch service than their larger counterparts.

Fig. 1 — CDMO choice during preclinical stage



By the time Phase III trials or commercial manufacturing commence, respondents prefer global CDMOs because of those providers' perceived aptitude in fulfilling demands for global recruitment, manufacturing scale, and regulatory support, among other factors.

Fig. 2 — CDMO choice during Phase III

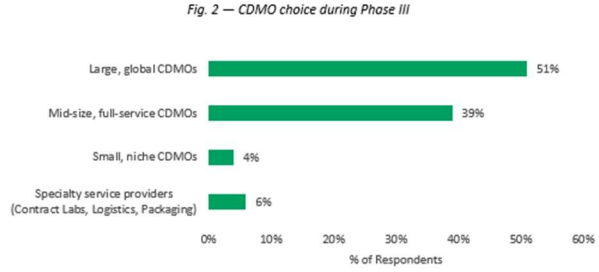
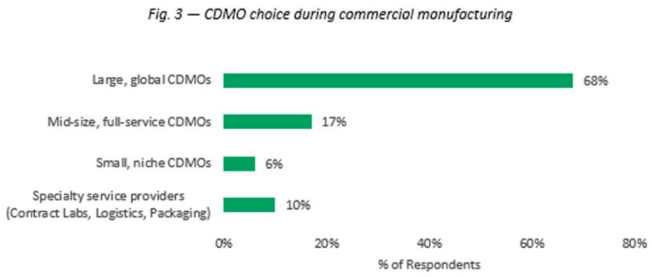
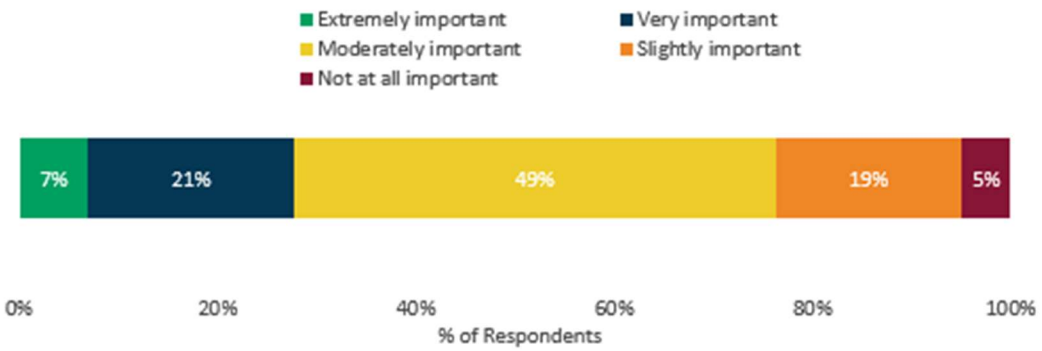


Fig. 3 — CDMO choice during commercial manufacturing



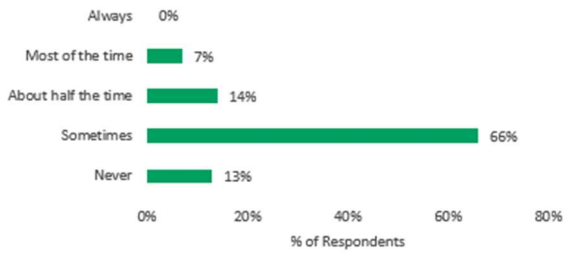
However, switching providers is costly: tech transfer, facility inspections, and working with new customer service/project management teams all have tangible cost and timeline implications. Our study data acknowledges this fact, indicating that organizations value sticking with the same service provider for development and commercial manufacturing when possible (Fig. 4). It also could be that respondents answered this question with their late-phase CDMO in mind, and that it makes sense for their organization to stick with the same provider from Phase II/Phase III to commercialization, but not necessarily from pre-clinical all the way to commercial.

Fig. 4 — "How important is it to your organization to use the same CDMO for development stage and commercial manufacturing?"



While these data appear to conflict — that outsourcers want to switch providers based on the drug development stage, but also want to keep the same provider from development to commercial manufacturing — it is more likely that, while small/niche providers are preferred during early-stage development, there is a recognition that these types of providers are not the best fit to take the project through to later-stage development and commercialization for all types of drugs (in particular, blockbuster drugs with large patient populations). Sponsors sometimes switch providers between Phase I and Phase II/Phase III with the intention of keeping these later-phase partners (mid-sized or large CDMOs at this point) through to commercialization.

Fig. 5 — "How frequently do you switch CDMOs between Phase I and Phase II/Phase III?"



While most respondents indicated they *sometimes* switch providers between Phase I and Phase II/Phase III, 80% of respondents indicated they switch CDMOs after Phase I *less than half of the time* (Fig. 5). This data supports the notion that sponsors typically tailor their outsourcing strategy on a case-by-case basis. For example, a small/niche CDMO might offer both the expertise and the capacity to carry a rare disease drug with a small patient population all the way through to commercialization. But, if the drug is expected to serve a massive patient population (e.g., a statin), the dynamics discussed above may come into play (i.e., utilizing a niche CDMO early, then switching to a larger/global partner as the drug progresses toward commercialization).

Final Thoughts

Tension and risk always exist in choosing a CDMO because sponsors feel equal pulls in opposite directions. On one side is the strategic partnership model: cultivating a mutually beneficial relationship with a single provider, creating cost and timeline efficiencies, and building a rapport that serves both entities in the future.

On the other side is acknowledgement that different CDMOs excel in different areas, that a sponsor's needs are different in early development versus later stages of development, and that locating a single, perfect, start-to-finish partner capable of serving all those needs is a daunting task. Moreover, while some specialized and niche providers have worked toward providing more of a full-service offering to expand their market share, others have worked to become leaders in very specific areas.

In short, no single CDMO strategy or outsourcing model is appropriate for every project. Outsourcers can and should look for the outsourcing model and type of CDMO that best fits their project.

Reference: Industry Trends CDMO Outsourcing (pharmaceuticalonline.com)