Plan Your CDMO Search On A Foundation For Long-Term Success

Outsourcing has become an attractive business model for pharma companies to expedite projects by contracting out all or part of their product development, clinical trials, and/or manufacturing through commercialization. In turn, rising demand for CDMO partners that deliver end-to-end services has pushed global pharmas to expand their service scopes and, in some cases, to upgrade their facilities and add manufacturing capacity.

In this competitive landscape, finding the right CDMO (i.e. a partner that meets a project's criteria, is "right-sized," and/or that has the capacity to produce a given product) for an Active Pharmaceutical Ingredient (API) development or manufacturing project has become more difficult. Accordingly, planning a CDMO search based on a foundation for long-term success often is the difference between a program plagued by difficulties (e.g. cost overruns and delays) and one that thrives.

The Surge of Outsourcing Demand (and Capacity Concerns)

The CDMO outsourcing market is poised to grow to $84.14 billion between 2023 and 2027, accelerating at a CAGR of 12.76% during the forecast period.[i] According to a late 2022 survey by Industry Standard Research (ISR),[ii] one in five respondents who expressed capacity concerns are currently impacted by a bioprocessing capacity shortage. However, the proportion of respondents who anticipate their organizations *will be* impacted within the next 5 years has increased nearly 20 percentage points from 2018, up to 55% in 2022 versus 36% four years prior.

Per the same report, North America is expected to continue holding the greatest market share in 2023 (45.33%), followed by Asia-Pacific (24.07%), Europe (20.24%), Latin America (7.53%) and the Middle East and Africa (2.96%). Thus, organizations from startups and virtual companies through large biopharma firms continue to wrestle with capacity issues, though the nature of those issues tends to vary.

Among larger biopharma sponsors, we see greater focus and attention paid to commercialization of their products. Whether they seek a CDMO partner at the early stages of cell line development, during clinical trials, or once it is time for commercial-scale manufacture, commercialization almost always is the ultimate goal. So, every step along that pathway, from production processes to materials procurement, is considered within the context of commercialization of that product.

Within smaller organizations, the next milestone often is the ultimate goal, with concern for subsequent milestones considered "back-burner" until the project's advancement is assured. Thus, capacity issues often relate to a lack of short-term capacity availability. In this common scenario, a CDMO that can provide insight regarding how current activities impact subsequent steps can be invaluable (in addition to providing capacity).

In any situation, a CDMO's ability to react to a changing program and scale-up needs is critical. Accomplishing that in a single facility further simplifies the process, versus transferring to a facility in another country. Biopharmaceutical companies are looking for ways to simplify their operations and reduce technical and regulatory risks, while also ensuring easy access to capacity at various scales. Given that all CDMOs have growth plans for the future, the distinguishing factor among them lies in their responsiveness to industry demands and their ability to expand capacity while concurrently investing in new technologies or modalities that support industry growth.

On-Demand Readiness — Now and in the Future

It is fundamental that developers find a CDMO partner that offers not only service staples (e.g. end-to-end value and tangible risk-mitigation strategies), but also fulfills more pressing needs, such as secure supply chains and access to scalable capacity. Contract acceptor periodically holds those discussions with all clients, internalizing client plans/needs in terms of overall capacity in the next 1 to 5+ years.

Contract acceptor maintain a regular practice of educating and updating our clients on plans, such as our ongoing efforts. This way, not only do we understand where clients wish to go as a company, but our clients can also see where Contract acceptor's plans align with or diverge from their own. An ongoing dialogue relevant to long-term vision is critical in markets where dynamics can quickly shift, and working with a CDMO that brings global perspective and expertise can provide vital information for decision-making (e.g. while inflation impacts nearly everyone, its impact on pharma organizations may be more severe in some places than in others).

Therefore, CDMO mitigates risks by optimizing the scale of our operations. Raw materials, a significant cost in product manufacturing, are procured at a reduced cost, and these savings are directly passed on to clients. Buying power allows us to navigate inflation and recession by exploring more efficient ways of operating. Additionally, drug substance (DS) development and GMP manufacturing plants enable seamless technical transfer from lab to manufacturing suite, minimizing delays.

Capacity Enables Capability and Flexibility to Shine

Per research conducted by Knowledge Sourcing Intelligence (KSI), the global prescription drug market is projected to grow from $969.3 billion (USD) in 2020 to $1.362 *trillion* by the end of 2027.[iii] Demand is expected to be driven by a rising global elderly population, prevalence of rare disorders, and rising incidences of chronic diseases and cancer.

To meet the healthcare industry's needs as those populations swell, biopharmaceutical companies require options for their products through development, manufacturing, and commercialization — across various technologies. While not a unique concept, few organizations provide a comparable breadth of capacity and technical expertise that enables true interchangeability across multiple products, while also ensuring cost-effectiveness and efficient timelines. Limitations in capacity inevitably restrict flexibility.

Another important aspect of interchangeability is platform products, which can reduce the time to pivot between products and adapt to abrupt changes in the manufacturing schedule because the manufacturer already has the raw materials for that platform. Additionally, capital expenditure (CapEx) on equipment can be spread across all products, a significant advantage as a portfolio grows to include several products. At that point, portfolio optimization—identifying and leveraging shared raw materials and equipment trains, then balancing that portfolio—becomes even more critical. More than just a one-off interchangeable arrangement, the program emphasizes a portfolio management program that can extend not only to multiple products, but also multiple scales and multiple plants.

Conclusions

Capacity constraints typically are accompanied by other challenges, including missed timelines, defect rates, and overall decreased satisfaction with pharma companies' bioprocessing CDMOs. Building in-house capacity generally is cost-prohibitive ($500M+ up-front investment) and takes years to both plan and construct. This

makes partnering with CDMOs—where clients can secure multi-product interchangeable agreements and outsource at an earlier stage of product development—an attractive proposition.

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