A Shifting Landscape

The outsourcing model is here to stay

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Outsourced manufacturing and development companies have responded to the increased demand for their services in full force, evolving into true partners that play a critical role within the life sciences ecosystem.

In general, demand for CDMO services continues to grow. Research and Markets predicts the global pharmaceutical API manufacturing market will expand from US$195 billion in 2022 to over US$250 billion by 2026. This can be attributed in part to life sciences companies resuming their operations, some scientists putting their lab coats back on for the first time in nearly two years.

A more deep-rooted shift, however, is largely responsible for this uptick in demand, one that has been unfolding in the drug discovery space for the past several years: it is no longer the biggest players in pharma who claim ownership to the development pipeline and the commercialization of new drugs. Increasingly, small and mid-size companies, primarily biopharma and biotech, require support to advance their molecules. These companies often receive ample funding to develop their pipelines without having the in-house manufacturing capabilities to do so alone.

Jonathan Hunt, managing director and CEO of Syngene International, an integrated research, development and manufacturing organization noted: "Five years ago, our stereotypical customer was a big pharma company that utilized our services for one aspect of their molecule's lifecycle, whereas today our customer base is filled more with young start-up biotech companies that have small leadership teams and no infrastructure but are well funded."

This shift does not just lead to more work, but also to a more engaged, collaborative environment. According to Hunt: "They are looking for more than just hands to do work; they value the scientific insights, scale and technology we bring to their projects."

The rise of small companies with stripped-down capabilities, some so spartan as to be called "virtual pharma," mean the contract manufacturing model will remain a vital organ for the overall health of the industry.

Standing out in a saturated environment

The heightened attention contract development and manufacturing companies are receiving has forced players in the space to strengthen their competitive edge in order to stay relevant.

One solution has been to work on increasing the speed with which clients can use services to progress their molecules to market. In the life sciences industry speed is paramount; patents remain valid 20 years past the filing date, yet it takes the average company at

least a decade to get a product to market. Any time saved in the process – whether it be three months or one year – is time added to that patent clock, which not only increases the period of economic value for the company but also accelerates treatment for patient populations in need.

For the past few years, Lonza's mammalian biopharmaceutical branch has been working on accelerating its clients' pipelines through its Ibex Design offering. Jennifer Cannon, the SVP global head of mammalian biologics at the company, acknowledged: "We see in the market that many clients are investing in the development of bioconjugates. As such, the market seeks faster, more reliable and simplified supply chains to support the development and commercialization of new bioconjugate molecules."

Ibex Design, which leverages technologies, tech transfer capabilities, and automated bioprocesses, claimed to meet three significant milestones for clients: 5 months from DNA to TOX drug substance; 11 months from DNA to IND/IMPD; and minimum 1.5 kg GMP drug substance for phase 1 clinical trials. The company also invested in a drug product vial filling facility to complement its antibody-drug conjugate facility. "Together, this offers a one-stop-shop experience to our clients, which simplifies the supply chain, de-risks technical exchange of materials and data, and facilitates program management," explained Cannon.

In addition to speed, clients also want ease. Rather than working with several service providers along a product's lifecycle, for example, it is much easier to work with just a few. To streamline the drug development process, Quotient Sciences' CEO Mark Egerton sees value in CDMOs managing both drug substance and drug product in parallel. "Previously, customers would use service providers upstream from us and make decisions on which compounds to progress without much consideration of what would happen downstream," explained Egerton. "The customer would sometimes manufacture the drug substance only to find out later they had made an error in the compound selection process. Having already made significant investment, they are reluctant to take a step back and thus start to make compromises for their downstream development plan."

Instead, Egerton believes his company's involvement in the development process from the moment in which a drug molecule is selected from the discovery program reduces such complications down the line and allows for a more streamlined workflow.

Specialized technology drives the day

While more streamlined, one-stop-shop business models entice clients with heightened speed and facility throughout the outsourcing process, the true differentiator in a bustling service provider environment is investment into specialized technology that can suit clients' ever-complexifying demands.

As Jan Kengelbach, CEO of Aenova Group sees it, competition on older lifecycle products is exacerbated by the relevance of Asian competitors. Since assuming the role of CEO, he has taken the company down a different route – focusing instead on tapping into more strategic and technologically advanced manufacturing of drug products. "It is imperative to have a technological edge," Kengelbach commented.

Aenova was already a leader in the European market for solid dosage forms, but he decided to investigate unique technologies the company could provide to further differentiate itself in the space. "If a customer might have a more complicated request, like a multi-unit pellet system, we can provide the appropriate level of scientific expertise and cutting-edge process technology such that the client immediately trusts they have found a reliable counterpart," Kengelbach explained. "Recently, we won a project on highly innovative intra-oral implants, something that is not obvious to do in solid dose manufacturing. We got this contract because of our upfront investments in the right scientific and technological expertise."

Kengelbach believes this tech-forward focus has changed the way Aenova is perceived in the market and plans to continue along this path. "While it is always easier to deny a certain service if you do not yet have the technical expertise in a particular area, in the long-term it is advantageous to explore the possibility of investing in that area with the customer," he added. "The minute you have your first proof of concept, more requests will come quickly and you are off to building a new growth platform."

As the CDMO space is becoming more competitive, finding the right balance between cutting-edge technology and scalable, cost-effective manufacturing practices will be imperative for success.