

The need to consolidate the CDMO industry

Pharma companies leveraging integrated offerings by Contract Development and Manufacturing Organisations (CDMOs) continue to struggle to fully rationalise their supply chain, since they rely on a high number of suppliers and providers



BY VIVEK SHARMA

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Pharmaceutical research and development (R&D) is a long, complex and resource-intensive process. While the cost per New Molecular Entity (NME) approval has increased by 50 percent between 2014 and 2017, the median peak sales value per FDA approval has remained fairly constant at \$1.0 billion during the same period.

[1]

For pharmaceutical companies, innovation and speed are more critical than ever and there is a need to drive more programmes through the clinic, to alleviate the impact of clinical attrition. Large pharmaceutical companies are striving to de-risk R&D efforts and improve the speed-to-market of their life-changing drugs, while at the same time, reducing their development and manufacturing costs.

An increasing number of specialty and biotech firms rely on service providers as they lack in-house development, manufacturing capabilities and expertise to drive their molecules through clinical development. Due to increasing complexity of drug molecules, pharmaceutical companies prefer to access these competencies externally, instead of building these capabilities in-house. Another key factor that drives growth in outsourcing is a strategy adopted by companies to focus on core areas and outsource the non-core activities.

With over 600 active Contract Development and Manufacturing Organisations (CDMOs) serving both global and local markets, the segment remains highly fragmented. The CDMO space in the pharmaceutical industry is evolving, owing to recent big-ticket mergers and acquisitions. One of the key growth drivers for companies in the CDMO space is their ability to offer integrated services, with reliable and impeccable quality across the drug life cycle. CDMOs offering specialised services in niche areas like antibody-drug conjugation (ADC) and high potency manufacturing are also in high demand, owing to the significant investment required to have these capabilities in-house. Outsourcing is now a strategic function in most pharmaceutical firms as they leverage CDMOs to deal with the increasing complexities of drug candidates, gaining access to specialised expertise, easing the pressure of capital investments and managing soaring drug development costs.

In the past few years, many companies in the outsourcing space have participated in mega deals with a focus on expanding their offerings and building capacity through smaller transactions. When CDMOs consider adding a new capability, the buy option weighs favourably as compared to the build option. Buying a facility will increase the customer base and the funnel of projects, while providing significant cross-selling opportunities.

Cambrex Corporation, based out of the US, added formulation development and finished dosage manufacturing capabilities with the acquisition of Halo Pharma, Inc. Additionally, with its recently completed acquisition of Avista, it expanded its portfolio from generic APIs & Finished Dosage Forms to the complete drug lifecycle.

Lonza, a small-molecule and biologic API CDMO, made its entry into the drug product services segment with the acquisition of Capsugel, from the global investment firm KKR. Piramal Pharma Solutions acquired Coldstream Labs and Ash Stevens to add sterile injectables and high potency API manufacturing services to its portfolio. These acquisitions, coupled with ADC capability, provide Piramal Pharma Solutions the opportunity to be an integrated service provider in oncology.

Private equity (PE) has played a significant role in transactions within the pharmaceutical outsourcing industry. In June 2018, Alcami was acquired by the Chicago based PE firm Madison Dearborn Partners; in September 2018, Nautic Partners, a PE firm acquired Mikart, a CDMO company based in Atlanta, Georgia. Albany Molecular Research (AMRI), a global contract research and manufacturing organisation, was acquired by affiliates of The Carlyle Group and GTCR in 2017. Between 2012 and 2016, private firms accounted for 56 percent of all CDMO deals. [2].

Multiple factors drive consolidation in the contract manufacturing space. Specialty CDMOs focus solely on one segment of services. For example, specialty CDMOs within the Finished Dosage Formulations (FDF) segment are only involved in providing services such as Finished Dosage development, manufacturing and formulation technologies, and also invest in the same areas. This enables specialty CDMOs to gain global reputation in their domain of expertise.

Many firms aspire to become a one-stop-shop, covering services that might be required by a pharmaceutical client through the drug life cycle, including discovery services, drug substance and drug product offerings, while managing required project timelines and globally dispersed teams. The integrated model allows cross-selling, stronger client relationships, client lock-ins and a better marketing story. CDMOs also acquire sites to expand the manufacturing or development footprint

across geographies to access new customers. It is, however, essential that CDMOs strike a fine balance between science and service to be the partner of choice for their customers.

However, pharma companies leveraging the merits of CDMO's integrated offerings continue to struggle to fully rationalise their supply chain, since they rely on a high number of suppliers and providers. As a result, there is an ever-growing demand for integrated, one-stop-shop service providers. By establishing a strategic relationship with a service provider, companies can focus on their core competencies, access specialised expertise, control costs and significantly accelerate the commercialisation of their molecules. Hence, there is a greater propensity to outsource to integrated service providers who offer a spectrum of services.

*References:

[1]. Clarivate Analytics (2018 – Year in Review) [2]. EY: The pharmaceutical CDMO industry is consolidating, Sept.'17

The author is CEO of Piramal Pharma Solutions.