Pharma Trends in 2019: The rise of outsourcing

Vivek Sharma, CEO, Piramal Pharma Solutions (PPS), predicts that outsourcing will be a central cog in the future pharma supply chain as it evolves from a transactional need to a strategic function

As pharma companies lever external capabilities to drive growth, outsourcing has now become a key component of the drug development and drug manufacturing supply chains. As customers demand scale, reach, and breadth in capabilities, Contract Development and Manufacturing Organisations (CDMOs) have begun to consolidate, to obtain both, proximity to clients and the end markets, through a network of global sites. This extended footprint has also allowed CDMOs to become full-service providers that offer end-to-end capabilities.

By establishing strategic partnerships with CDMOs, both large and small companies can now focus on their core competencies, lever external capacity and specialised expertise with no capital investment, control costs, while rapidly accelerating programmes towards commercialisation. These partnerships help mitigate the risk and costs associated with drug development, by extending the runway for the capital invested. With new drug approvals on the rise - the FDA approved 50 NMEs by November 2018, second only to 53 NME approvals in 1996 - signalling a robust clinical development pipeline, these external collaborations provide the bandwidth needed to drive these approvals to successful launch.

On the other side, by developing these preferred relationships, CDMOs are now migrating from a 'vendor-customer' model to a 'partnership' model, one that can be both sustainable and rewarding. CDMOs now are providing platform solutions that can assist customers in taking programmes from Concept (discovery) to Commercial launch. As the future needs of pharma companies evolve into personalised medicine, niche therapies, fast track programmes, and novel delivery systems, CDMOs are now investing in these future needs on the strength of these strategic partnerships. Other areas of collaboration include CDMOs taking over the manufacturing of late life cycle commercial products, by levering their superior scale and cost structure, allowing pharma companies to increase profitability while allocating their internal capacity to newer, higher-value drugs.

The comparison between small molecules and biologics is also an on-going discussion in the industry. A lot is happening in the biopharma market with the advent of cell and gene therapies. As compared to small molecules, biologics offer high margins and long term value to the companies. Manufacturing of biologics is a complex process and a multi-discipline activity. Therefore, most big pharma companies have invested in biologic manufacturing facilities to manufacture their biologic drugs in-house. This helps them retain full control over the supply chain and

quality of the product while ensuring security of supply. CDMOs are, in some cases, unable to fulfil requirements that demand flexibility and small volumes for biologic molecules. Therefore, one evolving trend is for pharma companies to virtualise their small molecule portfolio while retaining large molecule manufacturing in house. Small molecules continue to dominate the FDA approvals as almost 70 per cent of NMEs being approved over the last five years are small molecules. We expect that the small molecule outsourcing trend will continue to strengthen in the coming years as companies continue to streamline their manufacturing footprint.

In line with the focus on biologics, Antibody Drug Conjugates (ADCs) are now in the news again with the recent wave of third generation ADCs that are site specific and are homogenously conjugated. This has led to an increase in the clinical trial of ADCs with almost 600+ clinical trials on going worldwide. With close to 17 drugs, that are either approved, or are in late stages of clinical development, the ADCs therapeutics market is anticipated to grow at a CAGR to 19.4 per cent between 2017 and 2030 with an estimated value of $8 billion in next five years. The global market for antibody drug conjugates is expected to be driven by the advancement in medical technology, rising incidence of cancer, and an increasing demand for biologic therapies. Unlike conventional chemotherapies that also damage normal tissue, ADCs target only cancer cells and hence the majority of the antibody drug conjugates under development are for oncological indications propelled by the availability of monoclonal antibodies targeting different types of cancer. Some market players are also looking outside the oncology domain to develop antibody drug conjugates, though such drugs are limited in number and are in the preclinical stage of development.

An ADC manufacturing/fill finish facility is a substantial investment, which is why most ADCs are manufactured at CMOs. Most smaller companies, and even some larger companies, do not have enough of a pipeline to justify the level of facility investment needed for ADCs and/or cannot keep the facility fully utilised. In addition, the supply chain for manufacturing ADCs is complex, including linker/toxin manufacture, antibody manufacture, conjugation/QC/stability testing, and fill finish. As a result, most pharma companies have opted to outsource the manufacturing of their ADCs with approximately 70 per cent of all ADC manufacturing activities conducted by CMOs.

In summary, we expect outsourcing to be a central cog in the future pharma supply chain. It has become a 'must have' from a 'nice to have' as pharma firms seek to extend their capital runway, while focusing on their core competencies. Consequently, Outsourcing has evolved from a transactional need to a strategic function. Working with a limited number of supplier-partners helps firms optimise costs and management time, while ensuring that these partners focus on investing capital to meet their future needs. We at Piramal continue to invest in the future requirements of our customers, and now offer a customised suite of integrated solutions that can drive programs from Concept to Commercialisation. Our range of offerings, breadth of capabilities, geographical reach, and integrated network of sites has propelled us to become the 'Partner of Choice' for several pharma and biotech companies. We expect these trends to continue as the industry focuses on developing breakthrough medicines, rapidly and cost effectively, for the one person we are all focussed on the patient.