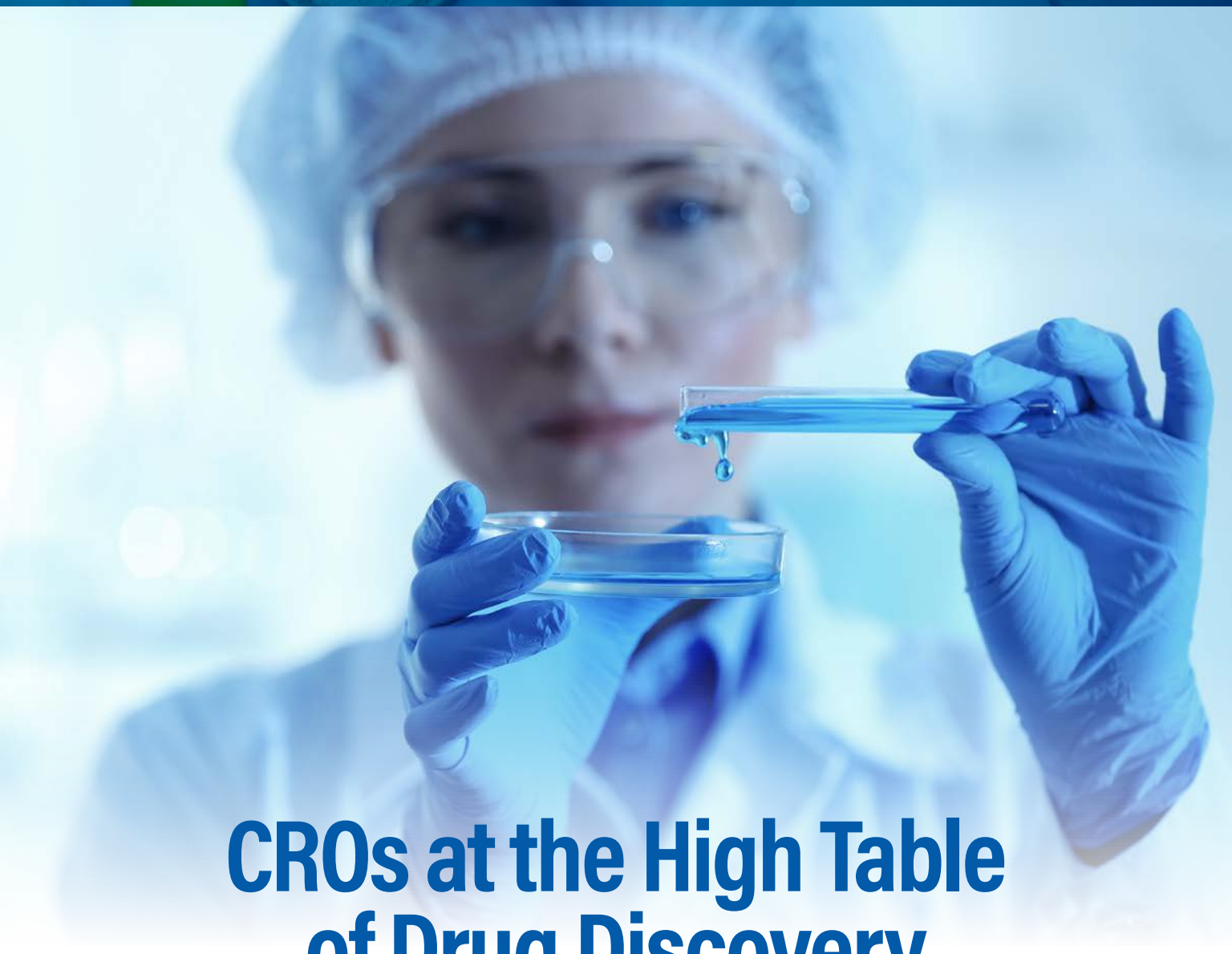
Drug Discovery Outsourcing



CROs at the High Table of Drug Discovery

Offshoring reaches an inflection point as CROs turn risk-sharing partners in discovery research.

This is the first of a nine-part series of articles addressing pharmaceutical outsourcing industry trends.

SOMAN HARACHAND - CONTRIBUTING WRITER, CONTRACT PHARMA

From their roots as once-upon-a-time mere service providers, contract research organizations (CROs) are rapidly emerging as trusted partners in the high-barrier, high-stakes business of drug discovery research even as outsourcing in drug discovery expands at an unprecedented level.

If historically, outsourcing was limited to rather small pieces of the process, the pharma and biotech sectors today prefer to externalize the continuum of the long-hauled process of discovery research from the idea stage to Phase 1 trials in a more integrated way.

Big Pharma, which initially started out offshoring to reduce costs, is now on the hunt for CROs who can give more intellectual inputs rather than the traditional piecemeal services. These pharma behemoths prefer to sit together with the collaborating CROs,

> "From a CRO/CDMO standpoint, working with biotechs has the most value as they often foster deeper partnerships, unlike Big Pharma whose outsourcing may often be limited to a few components."

have a broader discussion of ideas, and seek their expert guidance. They want to get CROs involved in decision making with accountability. So, obviously, the discovery CROs are moving from service providing to a partnership setting, point out industry experts.

Top pharma firms, which always held core research activities close to their hearts wary of risking intellectual property and fostered in-house drug discovery with huge investments, are now ploughing back the money and putting in to externalize the whole activity.

Concerns about the risks of sharing IP with a third-party CRO have drastically reduced. Of course, the concerns are not yet zero. The companies still do want all the assurance that their IP is safeguarded in every possible manner. But what is significant is that the Big Pharma and biotech companies have now come to a confidence level that the IP-related issues are, largely, "manageable."

While big players join hands with CROs as partners in discovery, those firms constrained by resources find the assistance and guidance of experienced CROs indispensable.

With their seemingly uncanny abilities to quickly fulfill any demand from a whole spectrum of activities, CROs are turning out to be the driving force behind the discovery of drugs.

No task related to drug discovery—from the very simple to the most complex—is, virtually, there today that can't be externalized. By enabling client firms to increase capital efficiency through shifting fixed costs to variable costs, CROs address gaps in internal expertise and capabilities as well as capacity shortfalls.

Models of CRO association too change with the requirements of the outsourcing companies. Conventional modes of service-oriented associations with CROs are fast giving way to closer, risk-sharing partnerships.

Today, the association with CROs is becoming more achievement driven, rather than purely service-oriented. This model helps accelerate the discovery process as everything depends upon how soon a CRO achieves the desired milestones in a partnership project.

Studies show that the use of CROs by companies as trusted collaborators and as a source of new projects and ideas enhances the potential for innovative new drugs.

The surge in the global demand for outsourcing services for drug discovery has spurred the growth of the global drug discovery outsourcing market which is expected to reach $6.3 billion by 2030 at a CAGR of 7.4% from $3.5 billion a year ago, according to a report by Research & Markets.

The outsourcing activities will be focused more on the key therapeutic areas of oncology, cardiovascular, and anti-infectives. While small molecules led the market holding nearly three-fifths of the global drug discovery outsourcing market, the lead identification and candidate optimization segment dominated the market in 2021.

HIGHER EMPHASIS ON BIOLOGICS

In line with pharma, biotechs too are looking for a deeper collaboration with more intellectual contributions from the CRO side. For firms in the emerging biotech sector working in a non-lab way, the expertise of CROs becomes a must to remain competitive. Many small- to medium-sized biotechs are eager to work with partners having consolidated, end-to-end capabilities so that they could work on the project all the way through from initiation to clinical testing. These biotechs do have the skillsets. However, they find it hard to operate without the technical expertise of CROs.

Industry reports say that biotechs are approaching contract development and manufacturing organizations (CDMOs) with a more fleshed-out roadmap and the intention of advancing further from the offset. Apparently, outsourcing plays much bigger a role in their business strategy. Almost always, securing the development capabilities they don't have is the top priority for the biotechs.

From a CRO/CDMO standpoint, working with biotechs has the most value as they often foster deeper partnerships, unlike Big Pharma whose outsourcing may often be limited to a few components.

Moreover, outsourcing is more common in the large molecule space where the majority of development and manufacturing falls under the mammalian category, and outsourcing is common in this market segment.

DRUG MAKERS IN SEARCH OF CROS

Even as more and more companies, large and small, consider the capabilities of discovery service providers to achieve greater efficiencies and address critical challenges, CROs and CDMOs are rapidly bolstering their know-how and capacities in the newer, highly specific technologies such as cell and gene therapies, immunotherapies, PROTACs, ADCs, cytotoxic/highly potent active pharmaceutical ingredients (HPAPIs), and mRNA-based therapies and vaccines.

In addition, companies look to broaden their offerings by adding new services that meet changing demands from the

pharmaceutical industry, expanding into new territories, or adding capacity for larger projects and investing in quality standards.

Digitization is also progressing rapidly as the use of the latest technologies by CROs/CDMOs is emerging as a key factor in selection criteria by pharma and biotech companies.

Meanwhile, CROs aver that currently what they see on the outsourcing front is a role reversal, sort of. Earlier, it used to be CROs looking for prospective clients. But now the customers themselves come calling the service providers seeking their expertise and guidance.

Besides research services, drug developers also look for solutions in the areas of data management and compliance, particularly in decentralized clinical trials (DCTs).

Not only the big-time, end-to-end service providers, but small CROs with specialized capabilities are also in great demand from those companies looking for expertise in niche therapeutic areas. There are, for example, several CDMOs specializing in the cell and gene marketplace. Niche partners are also sought after by drug developers for early-stage development as well as for capacities for specialized products.

Although the smaller players cannot provide a fully strategic outsourcing solution to their customers, these entrepreneurial CROs have the benefit of less bureaucracy and greater speed. They possess a very strong depth of expertise too. This makes the association with a small CRO a very valuable proposition, particularly for small, medium, and virtual pharma and biotech companies, show studies.

SPEED IS THE DETERMINANT

Among the various geographies, Asia-Pacific is projected to be the fastest-growing regional market while North America held the major share in 2021, generating nearly two-fifths of the global drug discovery outsourcing market, according to a report by Allied Market Research.

In the Asia-Pacific region, China and India are emerging as the main locations for outsourcing. Several CROs in these regions who moved pretty early into this space have now been considered approaching maturity in certain processes of discovery research which they specialize in. Along with the significant reduction in operational costs—the key driver in outsourcing—these CROs offer to cut short the development timelines of the notoriously time-consuming process of discovery research. This ultimately helps bring down the otherwise enormous costs of drug discovery. It is the "process maturity" of CROs that often comes to their aid to achieve this goal by helping speed up certain crucial stages of discovery and development.

Further, the number of end-to-end service solutions providers in the market is rising by the day. The integrated service providing "one-stop shops" are rapidly emerging and drawing major attraction for multinational drug companies expanding their discovery research outsourcing scope in these countries.

Choosing a single vendor who handles the process from start to finish can simplify the process a great deal. It enables the sponsor to map out the entire product journey and if there is a delay in one phase, timelines can be easily adjusted. This is in contrast with a multi-vendor approach, wherein the sponsor must communicate with multiple vendors who may be located in different geographic locations for any unexpected change. This centralized communication channel is a significant advantage of the integrated services model for those who consider speed more important.

Speed in early-phase development is often crucial for the new drug as it can avoid the potentially significant added costs and delays at a later stage.

MANAGING GEOPOLITICAL RISKS

The pandemic-induced supply chain disruptions in China as well as the geopolitical unrest that ensued from a prolonged Russia-Ukraine conflict are making many companies re-evaluate their outsourcing strategies, say CROs.

Certainly, the unusually fast development of the Covid-19 vaccine turned the spotlight on the importance of outsourcing in the discovery process. However, the pandemic has left a deeper impact on the outsourcing industry.

While the pandemic aggravated the backlog in clinical activity, it is the large molecule space that took the worst hit with many projects affected by shortages of glass vials, syringes, and stoppers due to the Covid-19 vaccine push. The small molecules market too experienced unprecedented growth in 2020, exacerbating capacity issues. However, due to the sheer number of CDMOs that offer small molecule services, the issue was somehow offset, notes the CPhI 2022 report.

Also, labs in Ukraine used to do a lot of early-stage screening for drug candidates. When the war broke out all the activities came to a halt completely, leaving many outsourcers in the lurch.

After realizing the pitfalls of the model of continued reliance on one particular region, especially with an uncertain political climate, many firms are either shifting their outsourcing base or mulling to spread their footprints to other geographies, according to them. Interestingly, contract service firms based out of India are, perhaps, the ones benefitting from the trade-off as their demand grows. **CP**

SOMAN HARACHAND is a pharmaceutical journalist based in Mumbai and a regular contributor to Contract Pharma. He can be reached at harachand@gmail.com.