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ASIA EDITION

The next frontier for CMOs

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The global pharmaceutical companies will continue to look at China and India for their outsourcing activities for both research and development and manufacturing. This is because of demographic profiles of these two nations. With vast populations, these are also likely to become the growth markets for them in the not so distant future. Engaging with these CMOs therefore helps to not only test the market but also accelerate the subsequent scaleup.



Long-term success of a pharmaceutical company is very closely linked with its ability to consistently research, patent, develop and market new drugs that can tackle as yet incurable diseases, or at the very least make them a little more a ordable to the population. However, with the threat of an impending patent cliff in the last few years, real trouble has arguably been brewing and business warrants a re-imagination. Other than these expiring patents, companies also need to worry competition and squeezed margins because of generics ooding the markets, as well as tighter regulations because of renewed government focus on quality as also an evolving public awareness.

Therefore, organizations are being forced to not only look at top line revenues but bottom line costs as well. In such situations, it is but natural to turn to the experience of other industries that have gone through such tectonic shifts in their business landscape – in particular, contracting out of non-core business activities, with the objective of controlling costs. This is not a new concept, neither in the pharma industry or elsewhere. But it has definitely found renewed focus and interest in recent times, as the global economy limps from one crisis to another. With this trend attempting to now fundamentally restructure the industry, it is imperative that various nuances at play are better analysed – to aide major players as well as start-up evangelists alike – in taking a considered view on whether or not they should become active participants.

Drivers for Contract Manufacturing

In the pharmaceutical industry parlance, a contract manufacturing organization (CMO) is a company that provides various business relevant services on a contractual basis. These may include activities as varied as pre-formulation, formulation development, stability studies, method development, pre-clinical and phase1 clinical trial materials, late-stage clinical trial materials, format stability, scale-up, registration batches and commercial production, etc.

From a demand perspective, contracting out non- core and relatively commoditized activities de nitely helps pharmaceutical companies better manage costs, at the very least. It also frees up or redirects valuable human and capital resources that can instead be focussed on strategic business activities like drug research and discovery or sales and marketing.

Cost and process e ciency is the bread and butter for a quintessential CMO. The business model of CMOs hinges on being able to aggregate demand across multiple companies and become more effective by leveraging economies of scale, thus providing improved solutions and service levels. Additionally, they may also be able to drive costs down by servicing demand from geographies with cheaper labour or capital costs required for scaling infrastructure and building capabilities.

It will however be myopic to view this trend to be purely focussed on delivering cost efficiencies, especially in the pharmaceutical industry that heavily relies on scientific and technical expertise at each step of the process. The next blockbuster drug can falter at the altar of manufacturing, if not done right. Rami cations of such errors can also be extremely severe, with both money and lives at stake. In many cases therefore, the decision to engage a CMO has to be strategic, and in more ways than one.

In the way that business has been traditionally conducted, innovation dramatically loses its appeal post the R&D stage. In a rush to launch, pharmaceutical companies have attempted to scale up laboratory methods to industrial scale, rather than re-imagining the path to commercialization. Very few firms have cared to include top manufacturing people on their executive boards either. As long as manufacturing is relegated to simply being a compliance matter or an inevitable check in the box for getting the product out, change will be slow. While this is partly understandable, saddling manufacturing with ine cient techniques and unsuitable equipment will however almost never be a justifiable business decision in a cost-conscious environment.

Although early research and development is arguably still the harder and time consuming part of taking a drug to market, manufacturing comes with its own challenges. For instance, just producing the active ingredient of a chemical dug can take a number of iterations before being perfected and will still involve multiple reactions, while subsequent formulation and packaging may have additional considerations. Further, there are regulatory requirements to be met. In the US for instance, FDA registration of the manufacturing process is a key and sometimes be lengthy step before medicines can be marketed - involving elaborate procedural checks to ensure that safety, dosage and quality controls are in place and can be e ectively monitored post commercialization. To add another layer of complexity, such regulatory oversight and requirement will also vary by geography. While cost e ciency is a critical hallmark of a good CMO, one with the appropriate experience and expertise can also play a key role of strategically partnering with the pharmaceutical company in reducing the time to market or providing a relatively easier access to geographies that are tightly regulated from a quality control perspective.

CMOs that constantly review and innovate on various operational dimensions related to formulation, process, manufacturing and delivery are therefore not only able to better leverage economies of scale but are also able to constantly adapt their operational and manufacturing processes. Further, this will also prove to have a positively compounding impact as it draws more clientele- leading to better economies of scale, shorter learning curve in meeting new business demands or changing regulatory requirements, more pro ts and retained earnings to reinvent in growth infrastructure, and a more diversi ed and deeper expertise and process maturity.

Emerging Trends for the Industry Segment

Given that recent times have been amongst the most challenging ones in the history of pharmaceutical industry, outsourcing caught on with big and smaller players alike. More speci cally, the trend seems to have been towards contracting out the late-stage, scale-up and commercial manufacturing activities.

This can also be evidenced by the fact that last few years have seen over a 100 manufacturing facilities owned by pharmaceutical companies shut shop in U.S. alone. On the other hand, the global pharma contract manufacturing market is on a growth trajectory. According to the Pharma & Biotech 2017 report on outsourced manufacturing, total outsourced manufacturing market was as big as $71.5bn in 2015 and growing at 6.6%. This is expected to further pickup, given an expected increase in outsourcing activity in the near future.

World Bank’s more recent estimates indicate that healthcare expenditure is close to 10% of GDP, with global pharmaceutical market touching close to $1.1 trillion and expecting to grow at about 5.5% per annum, reaching to $1.5 trillion by 2021. Fundamental drivers to this seem to be the changing demographics and lifestyle associated healthcare costs. Although this may help the industry finally turn a corner from the impact of patent cliff and the threat from biosimilars, pro tability to be

accrued by leveraging this growth story will just as much have to be driven by the trend of outsourcing for achieving cost-e ciency and strategic business re-focus for e ectively driving the top-line. While there is indeed a renewed focus on research and development, a pragmatic approach towards cost discipline is just as much the new reality.

With this view largely, many large pharmaceutical companies have divested significant manufacturing and logistics facilities and re-aligned business priorities. On the other hand, CMOs have also made good of this opportunity, especially by deploying and delivering through a cheaper capital and infrastructure base as well as lower operating and human resource costs of manufacturing hubs like China and India.

There is likely to be a partial reverse trend as well, given that some pharmaceutical industry players will be willing to explore this as a growth engine and a new revenue stream. They are therefore likely to warm up to the idea of exploring potential product and service diversi cation, especially in growth markets and through investment and participation in this industry segment via acquisitions or even through spun-off incubators, etc.

Mergers and acquisitions are more likely to be driven because of the consolidation agenda however. That said, the landscape of CMO industry continues to remain fragmented at this time. According to reports, even the major players in the sector only command a 2-4% market share each presently. This is however expected to change as the industry matures and imminent winners emerge, who will then attempt to consolidate and capture an even greater market share through inorganic growth. That said however, the players in this sector are varied, with a large proportion also being family owned and therefore more resistant to being acquired. According to reports, the total deal value in this industry segment was around $12 billion in 2015, and showing a promising upward trend. While the reasons for the activity has been varied, key drivers for M&A have centred on getting foothold in the global market or building a critical mass, gaining access to advanced technologies, and expanding the suite of services. Realization of business bene ts has however been mixed, and this may put the industry in a bit of a caution, as it grows.

Another fallout of increased competition is that some CMOs are attempting to differentiate and position themselves as an integrated service provider, acting more as a partner to the pharmaceutical company that can be solely relied upon. Despite perceived bene ts such as simpli ed supply relationships and better traceability and accountability,this is still in a nascent stage and the business model of CMOs are still evolving.

The Asian Landscape

In the last decades, Asian CMOs have become a signi cant competitor in the industry. Industry also continues to grow most rapidly here, with China becoming a particularly favoured destination and an increasingly important player. Although it presently accounts for a small percentage of the global CMO revenues, this is also rapidly changing. Improved cost efficiencies – partly because of a lower wage bill, significant investments in infrastructure and capacity development, better adherence to global manufacturing standards, increasing regulatory oversight, and a skilled workforce are a few reasons that are driving this trend.

Concerns do still exist regarding enforcement of intellectual property rights held by western pharmaceutical companies, but confidence is also on an uptrend. Creation of the State Food and Drug Administration (SFDA) has been a significant catalyst for a number of these companies to start looking at China for having business ties.

Similarly, India is also growing very fast and the CMO industry is likely to become another macro- economic growth engine in line with the other outsourcing trends leading to it. Chinese and Indian companies have ooded the market with generic products in recent times. However, FDA warnings around quality controls are sometimes wanting, and need to be addressed, as controls become more stringent.

Another important reason for pharmaceutical companies to look at China and India is their demographic profile. With vast populations, these are also likely to become the growth markets for them in the not so distant future. Engaging with these CMOs therefore helps to not only test the market but also accelerate the subsequent scaleup.

As all this takes shape, it has also caught the attention of the governments here, which are likely to actively support the growth through appropriate policy intervention and incentives, as this can lead to employment generation opportunities along with economic growth.

The Asian growth story for CMOs is indeed quite promising.

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	Catalent
	Daito
	Nipro
	Pfizer
China	Zhejiang Hisun Pharmaceuticals
	Zhejiang Huahai Pharmaceuticals
	Shandong Xinhua Pharmaceuticals
India	Aurobindo Pharma
	Divis Laboratories
	Dr. Reddy’s Laboratories

Priyanka Bajpai