Advantage CDMO

In an exclusive interview with *India Now Business and Economy*, Vivek Sharma, CEO-Pharma Solutions of Piramal Enterprises, elaborates on India's growing potential in the global CRAMS market.

What makes contract manufacturing attractive?

In the recent past, the pharmaceutical industry has been crippled by decreasing R&D productivity, reduced rate of approvals, absence of blockbuster medicines, and policy-driven changes in healthcare spending, driving companies to focus on cost and identify core areas to focus on. This has also led to outsourcing of various activities along the value chain to Contract Manufacturing Organisations (CMO) and Contract Research Organisations (CRO).

Outsourcing is expected to have a positive impact on the flexibility and efficiency of pharmaceutical players—costs are reduced by turning fixed into variable costs and removing assets off the balance sheet. While commodity services have been the focus in the past, today value-added services such as design, delivery, process development, and optimisation techniques are increasingly demanded by the industry.

Could you provide an overview of the Contract Development and Manufacturing sector?

India is one of the world's best known low-cost manufacturing centres, having the highest number of US Food and Drug Administration (USFDA) approved manufacturing plants outside the US. The Indian CMO/CRO industry has been rapidly moving up the value chain with key players investing in better technology and higher capacities. The CRAMS market in India continues to grow and is estimated to reach US$ 18 billion by 2018. We expect this to result in India becoming a key hub for the manufacture of value-added products in the life sciences industry.

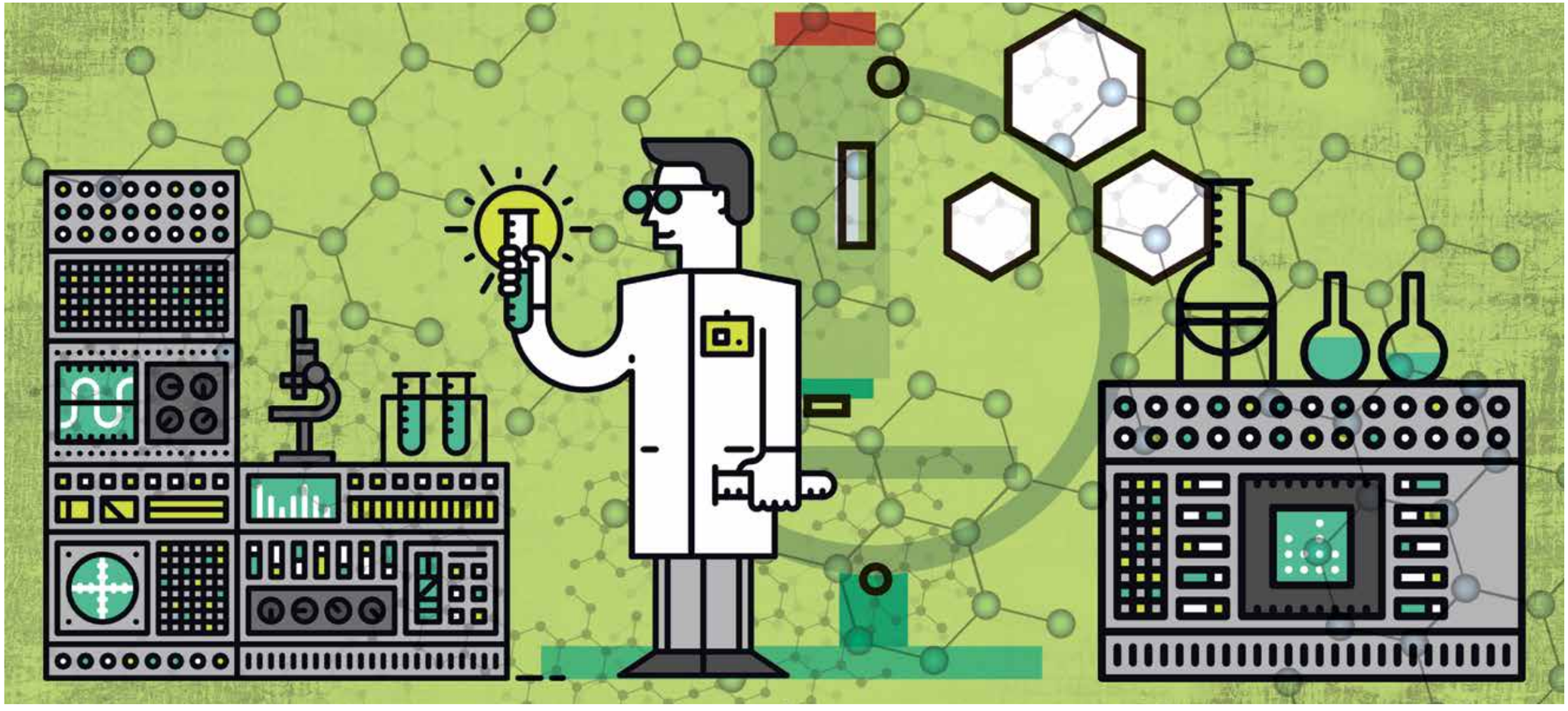
What makes India a preferred outsourcing hub for manufacturing services?

India offers access to a workforce characterised by historically strong process chemistry skills, a vibrant entrepreneurial ecosystem, robust infrastructure, good communication skills, and access to leaders with several years of global experience. Growth is also facilitated by a business-friendly domestic manufacturing policy that includes 100% FDI. Patented drugs worth approximately US$ 85 billion in potential annual sales in US are expected to go off-patent during 2014-2020, which will place high emphasis on price competitiveness. This will also provide an impetus to the highly cost-efficient contract manufacturing setup in India.

How does India ensure a trade-off between cost-competitiveness and quality?

At Piramal, there is no trade-off between ensuring quality and being cost-effective; we consider them mutually exclusive. Without quality, cost competitiveness would not matter. We at Piramal have focused on 'Quality as a Culture', as opposed to 'Quality as a Compliance Tool'. While our buyer, who pays for the goods, is the pharmaceutical client, we believe that our end obligation is to our patients who trust our products to make their lives safer and better. We continue to invest in quality procedures, protocols, and people efforts that were recently recognised by the industry when Piramal's Quality Head was named one of the 50 Most Influential Quality Professionals by World Quality Congress.

Cost-competitiveness at Piramal comes from: its highly trained scientific personnel who focus on developing atom efficient routes with minimal waste; experienced leadership



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that encourages research to identify the best solution; investment in innovation using tools such as biocatalysis and flow systems; and access to world-class infrastructure that helps run/scale reactions efficiently. The bottom line is that we view quality and cost-competiveness as equally important, and hence have invested in being a global leader in both functions.

What are the emerging opportunity areas in contract manufacturing?

Oncology has emerged as a key focus therapeutic area for the industry. We expect high potential for growth in contract manufacturing capabilities that are aligned to this segment such as sterile injectable manufacturing, Antibody Drug Conjugates (ADCs), and High Potent APIs (HP API). Within the oncology segment, there is an increased focus on developing biologics and targeted therapies which has led to an increase in the need for injectable drugs. The sterile injectable contract manufacturing market is presently valued at US$ 6 billion and is growing at a CAGR of 11% compared to the overall global CMO market which is growing at a CAGR of 7%. Specifically, good opportunities for growth are expected in the drug delivery systems and pre-filled syringes space.

Some of the factors driving growth are:

- Specialised technologies and dedicated capacities required for biopharmaceutical products lead to increased outsourcing
- Preference to outsource products that require handling of high-potency materials and containment suites
- Rapid growth of pre-filled syringes' market leading to spike in the demand of CMOs
- De-risking of supply chain by brand manufacturers by adding a second source to their product manufacturing
- High growth in emerging markets resulting in local players looking at local CMOs to enter the geography

Also, the industry is now taking initiatives to reduce its carbon footprint and introduce greener manufacturing solutions for a more sustainable development. At Piramal, we offer 'green chemistry' services to our clients by lending our route scouting and biocatalysis expertise that helps in designing smarter routes to chemical synthesis—routes that are created with lesser number of steps, lesser organic solvents, and have higher yield.

You recently acquired Coldstream Laboratories in an all cash transaction. What kind of growth do you envision in the next five years?

Coldstream is an asset that will drive our growth in the injectable space. Within this space, Coldstream allows us to cater to manufacturing requirements for both small molecule oncology drugs and biologics. The acquisition further consolidates our leadership position in the ADC space by providing fill and finish services. We can now provide services from development through commercialisation in injectables. The facility, located in North America, provides geographical proximity and easy access to several of our key clients. We firmly believe that Coldstream will be a key component in our long-term plans. Large parts of Coldstream's business comprise projects that are in the development stage. Once commercialised, we expect the growth to be faster than the market growth rate for injectables.

What is the role of technology adoption in boosting growth in the sector?

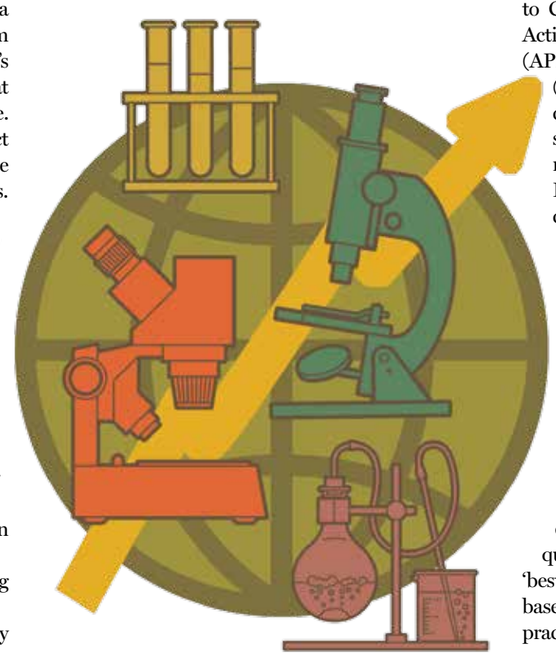
Some key trends observed in the pharmaceutical manufacturing industry over the last couple of decades are as follows:

1) Manufacturing chemistries have become more complex for small molecule APIs
2) Increased share of biologics in the pipelines
3) Increased focus on developing oncology-targeted therapies
4) Development of environmentally and sustainable manufacturing practices.

The contract manufacturing industry has evolved in response to these broader changes in the pharmaceutical industry. Increased investment in infrastructure and scientific talent has helped contract manufacturers move into value-added services such as biologics, ADC manufacturing, high-potent APIs, etc., to cater to the evolving needs. Further, contract manufacturers such as Piramal now also offer route scouting, flow systems, and biocatalysis as technologies to help implement cost-effective and greener solutions.

The ability to provide specialised capabilities and innovation via technologies has certainly provided a boost to the contract manufacturing sector.

What are the major markets of CDMOs? Which markets are you currently focused on?



We have two facilities, one each in Europe and North America which are the largest markets for CDMOs (Contract Development and Manufacturing Organisation). Our senior management team and our business development teams are working out of these locations. Proximity to our customers and their end markets will help us drive business in these target markets.

Your firm offers end-to-end services—could you take us through the infrastructure, talent and research and quality assurance capabilities put in place?

We have created a global network of development and manufacturing facilities located in North America, Europe, and Asia that offer a multitude of services covering the entire drug life cycle, from Drug Discovery & Development to Commercial Manufacturing of Active Pharmaceutical Ingredients (APIs) and Finished Dosage Forms (FDFs). Our development centres and manufacturing sites have accreditations from regulatory bodies in the US, Europe, and Japan. We are committed to R&D with a pool of 450 scientists; including 100 PhDs across the globe. This helps us tap into the best talent irrespective of location.

We have invested in an experienced quality team and have empowered the quality function with independent reporting to the Executive Director. We continually strive to evolve quality management systems to 'best in class' from a robust quality base including adoption of best practices from our valued clients.