

## Why Indian Pharma Must Evolve As 'Value Creator'?

01 July 2022 | Views | By Dr Mahesh Bhalgat, Chief Operating Officer, Syngene International

**As the third-largest drug producer in the world, India is already a major global pharmaceutical player. However, when it comes to the value of production, India ranks fourteenth. A deeper dive into the details reveals an important fact: India is the largest producer and supplier of generic medicines globally, delivering a 20 per cent share. India's pharmaceutical sector has the highest number of USFDA-approved manufacturing plants outside the USA, 3,000 pharmaceutical companies, a network of 10,500 manufacturing facilities and a rich talent pool. So, why does it lag so significantly in deriving value from its assets? Is there an opportunity for the Indian pharmaceutical industry to evolve in a way that moves India up on the value scale by increasing innovation – and what will it take? Let's find out.**



Contract Research Organisations (CROs) constitute one such opportunity. Focusing on the early years of drug discovery and development, CROs offer a smart avenue for pharmaceutical companies to conduct their research activities by outsourcing to a competent entity that specialises in pharmaceutical research. The dynamics are similar to the journey of the IT services industry in India that has evolved with time, and today, they partner around sophisticated end-to-end solutions that add value to the sector in many ways. The pharmaceutical companies today appreciate the value that Indian CROs can add by critiquing, challenging and adding to their scientific ideas and hypotheses. They expect their outsourcing partner to bring in their own experience and expertise to the table. It's about the intellectual added value that segues perfectly.

The Indian CRO/contract development and manufacturing organisations (CDMOs) industry has also started moving towards integration of services. Earlier companies started out with standalone, siloed services. Consequently, piece-meal activities in chemistry, biology were outsourced, but most of the value creation work remained within the pharma companies. Over time, CROs and CDMOs have started integrating services in the value chain. This helps in plotting a course through innovation,

solving problems and moving a molecule through discovery into development and manufacturing, ultimately, for the benefit of patients. This has been an essential factor that is driving more collaborations between the pharma/biotech companies and CRO/CDMOs.

Innovation in this space is increasingly driven by small and medium-sized biotechs, with few molecules, a very limited pipeline and limited resources with no desire to set up their own large scale R&D facilities. CROs in the emerging world have been successful in advancing molecules along the discovery and development value chain by providing qualified scientific talent, laboratory capacity and quality assurance combined with a cost advantage.

However, for the strategic partnering brought by strong CRO's cost is no longer seen as a deciding factor; Globally cost over the years have seen an upward trend. The rise in attrition as an example has increased manpower costs in the east and the west. Cities such as Bangalore offer the adjacency for the pharma-biotech industry to the IT industry, which help drive innovation and offer technological solutions for problem solving and bringing in efficiencies. Today pharma and biotech companies are willing to offer a higher rate for CROs/CDMOs that deliver world-class quality, innovative solutions and delivery commitment to continuously grow the research pipeline and supply the market.

A big differentiator for the Indian market is its abundant availability of scientific educated talent pool. A work force graduating from close to 1000 universities and around 40,000 colleges in India is reflective of India's young population. It is estimated that 70 per cent of the workforce in India is under 40, and this key factor needs to be leveraged further to drive growth of the pharma-biotech sector.

### **India emerging in the forefront**

The COVID-19 pandemic changed attitudes towards pharmaceutical research. It has demonstrated the value of exploring novel therapeutic approaches, conducting complex clinical trials and nurturing specialised skills and expertise to navigate through the drug discovery and development process. India has played a crucial role in the pandemic as the largest vaccine manufacturer in the world. However, the sources of innovation have been the traditional players in the US and Europe.

While battling COVID-19 and struggling to get the vaccines approved, the key was speed. The role of Indian providers in facilitating speedy trials is now widely acknowledged: AstraZeneca's vaccine development programme included a clinical research organisation from India to expedite efforts and generate reliable data for regulatory approvals. Similarly, ICON provided clinical trial services to the Pfizer and BioNTech COVID-19 vaccination programme.

The biopharma industry has also played a role in developing and deploying vaccines closer to home. India tackled the pandemic with a record-breaking vaccination campaign and the effort continues as companies like Akston Biosciences are conducting human trials of second generation COVID-19 vaccines in India.

With the COVID-19 as a template, CROs and CMOs have put India front and center of the global stage for their agility, capability and quality in supplying effective vaccines in large quantities. It will be important not to stop here. The Indian pharmaceutical sector must continue to focus on moving upstream following the path of companies like Syngene International that deliver discovery research, development and manufacturing of small and large molecules to create the next generation of medicines and materials while building value for investors.

### **The path ahead**

Building R&D capabilities is a path well travelled in other parts of the world and the requirements are clear: educational institutions committed to nurturing world class researchers, a well-established IP framework, and funding to attract research and investment incentives.

According to the Brookings report, India has a mere 216.2 researchers per 1 million population as against 1200 in China, 4300 in the US, and 7100 in South Korea. The Indian Government has shown intent to reverse the brain drain with the New Education Policy, 2020. This is certainly an important step towards creating a better academic ecosystem but there is more to do to incentivize academia to build educational environments and curricula that produce talent that are industry ready to hit the ground running.

Then there is funding. To date, the percentage of GDP invested in R&D in India has been very low at 0.7 per cent, which is among the lowest. Countries, like Israel (4.6 per cent), South Korea (4.5 per cent), Germany (3 per cent), or Brazil (1.3 per cent) have consistently invested more. The biologics-fueled pharmaceutical ecosystem requires significant additional

investment in facilities to drive a step change in capacity and capability while the talent pipeline builds. Although private investment is growing, it may not be enough for the top 10 pharmaceutical majors of India (7.8 per cent) to equal half the amount of the top 10 global pharmaceutical companies (16.5 per cent) spends on R&D, as a percentage of their revenue.

Nearly 80 per cent of all new drugs are biologics, so, CROs - particularly those working with large molecules as well as small molecules - can play a critical role in building greater value for the Indian pharmaceutical industry. Collaborating with the government to build an attractive ecosystem, a supportive education system, a legal and regulatory environment aligned with global practices; and sustained research funding, will be imperative. The pandemic has provided an inflection point. It is time to realign priorities and build momentum to foster pharmaceutical innovation and move the industry from a volume provider to a position of value creator for India.

**Dr Mahesh Bhalgat, Chief Operating Officer, Syngene International**