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Will Indian CRAMS lose to competition?

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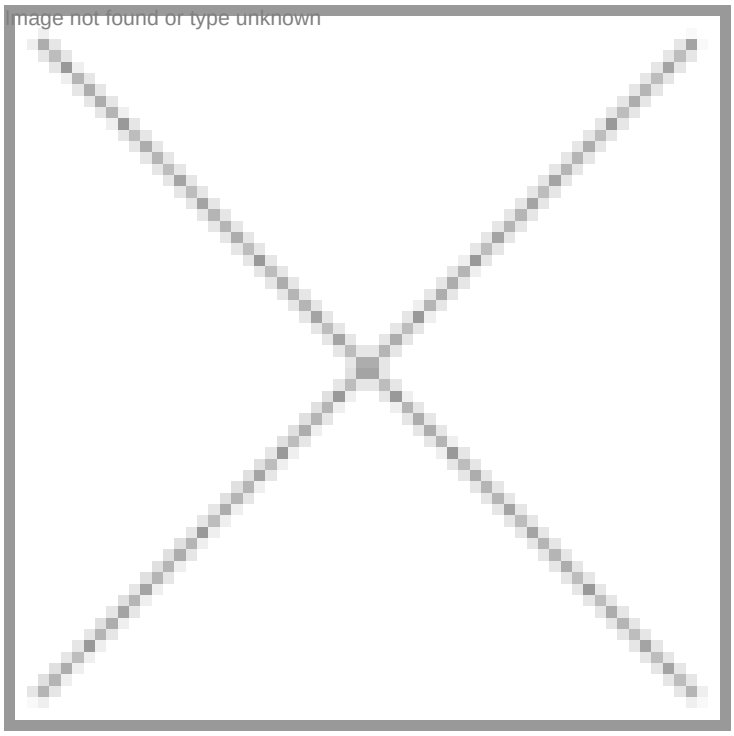

Despite the numerous hassles in its path, the Indian contract research and manufacturing services (CRAMS) market has retained its growth. However, with increased competition from other countries, industry veterans are keeping fingers crossed for the future

Bioanalysis The surge in demand for contract research and manufacturing from international clients, who have invested in the emerging markets through outsourcing, has resulted in the gradual increase in the number of Indian contract research and manufacturing services (CRAMS) companies. As per the Confederation of Indian Industry (CII), the estimated market share of the CRAMS market is around 19,950 crore ($3.8 billion) out of the 350,075 crore ($67 billion) global market.

India contributes significantly to serve the entire spectrum of the value chain, covering basic research, pre-clinical, clinical services to active pharmaceutical ingredient (API), formulations and generics manufacturing services. Estimates say that about 20 percent of spending in R&D is outsourced to cut cost. The Indian contract research market estimated to e 7,837 crore ($1.5 billion) is dominated by clinical research organisations followed by preclinical and discovery research. Contract manufacturing worth about 12,017 crore ($2.3 billion) dominates the Indian CRAMS business capturing 60 percent of the market in India.

With the business slated to grow further to reach fro 36,575 crore) 41,800 crore ($7-8 billion) by 2015, Indian CMOs are strategizing to strengthen their current offerings to their clients by capturing new technologies to meet the requirements of prospective clients. Most of the companies engaged in manufacturing services are spreading to cover the entire gamut of services to gain recognition in the industry as CRAMS organization.

Mr Anil Kubchandani, vice president and growth unit head-exclusive synthesis, Jubilant Life Sciences, says, â€œThe top 20

companies account for 50 percent of the revenue and rest is shared by smaller players. With the developed countries having stagnant market for CRAMS companies, outsourcing has added to growth of markets such as China, Russia and India."

India is a hub for the largest number of US FDA-approved plants outside the US and also having developed competency for the regulatory requirement of UK and European markets. Globally, the services provided under manufacturing comprise custom synthesis, scaling up and large scale production, active pharmaceutical ingredients (API), intermediate manufacturing and formulations involving varied dosage forms.

Citing the paradigm shift in the CRAMS industry, Mr Manoj Mehrotra, head, global CPS business, Dr Reddy's Laboratories, says, â€œBig pharma companies are shutting down R&D centers and venturing into emerging markets. Outsourcing is catching up in a big way as in-house R&D is no longer feasible in the wake of increased costs."

In the recent past many companies have outsourced to reduce their cost burden from manufacturing and concentrate more on increasing their sales and new product development in the emerging markets. Kemwell Biopharma has entered a strategic collaboration with Boehringer Ingelheim, Germany, for scaling up of analytical facilities in cell banking and characterization.

Mr Durgaprasad Annavajjula, senior VP, R&D, Kemwell Biopharma, says, â€œIt takes 2,090 crores, ($400 millin) to 10,450 crore ($2 billion) in order to start a facility in three-to-five years. However, it doesn't take much to buy CMOs. So there are tremendous opportunities for the CRAMS industry. Besides that, new areas such as biotherapeutics are going to be the new booming segment."

Hurdles before services sector

Talking about the issues faced by the industry, Dr Rashmi Barbhaiya, CEO and MD, Advinus Therapeutics, said, â€œThe issues that we face currently need to be dealt with seriously as our future looks bleak when compared with competitive countries.â€? While using strong words, he added, â€œThe Indian industry needs a level playing field, so that it is not at a competitive disadvantage.â€?

The challenges faced by the industry include issues such as intellectual property, competition with international competitors like China, safety concerns, long regulatory timelines, rise in the manufacturing cost, lack of effective project management capability, non-tariff barriers from developed countries and inadequate facilities to conduct studies.

Mr Madhusudan Rao, COO, global generics, Orchid Chemicals and Pharmaceuticals, says, â€œThere are shortfalls intalent, limitation in technology, problems in satisfying a client with huge expectation, confidentiality issues and the quality is still not good enough and up to the mark.â€? The regulatory hassles are taking its toll on the industry. The industry experts belive that numerous approval agencies have led to the chaos and is a major deterent for hassle-free functioning.

Mr Apurva Shah, chairman, Association of Contract research Organizations (ACRO), feels that both the government and the industry has to be more proactive in resolving the issues. â€œThe government must stick to the regulatory timelines. The Drug Controller General of India (DCGI) must have a proper mechanism in place to deal with the regulatory hiccups,â€? he says. Mr Shah, who is also the group managing director of Veeda Clinical Research, adds, â€œBenchmarking is required and that incudes catagorization of CROs in which ACRO has to be involved. There must be a legislation for making the good laboratory practice (GLP) mandatory for preclinicals.â€?

Ms Vineeta Sharma, advisor and head, national good laboratory practice (GLP) compliance monitoring authority, Department of Science and Technology, says, â€œThe GLP-graded India has received a great but cautious response as the third party audit is still lacking." The shortage of skilled human resources and increase in the rate of attrition is another important area where the CRAMS industry has been finding itself helpless.

Dr Rama Mukherjee, managing director, ARA Healthcare, believes that institutions lack the right training program. â€œThe educational courses too require regulation at the right level as this is dampening Indian capabilities," says Dr Mukherjee. Commenting on this, Mr Apurva Shah says, â€œThe practicality of courses is missing and is a neccesssity. We have scientific workers but not scientists. Veeda is putting in place a program for students in audit and training."

Keeping the growth trajectory moving

The government and the industry agree that the streamlining of work between various regulatory agencies would be a great boost for the smooth functioning of the CRAMS companies. Going further, the Department of Pharmaceuticals, Government of India, is in the process of setting up a website jointly with ACRO to list all the CROs and CRAMS companies in the country. The deadline for the same has been kept as January 13, 2012.

Maintaining that the regulators cannot be blamed for all the ills faced by the CRAMS industry, Mr Devendra Chaudhary, secretary, Department of Pharmaceuticals, Government of India, says, â€œThe industry has to be more responsible and it

would be great if it could function with a self regulatory model to minimize the loopholes."

Dr Vibhav Garg of CII has proposed a consoritium of CRAMS companies that may have the power to do self-compliance and self-certification. Dr Garg says that the industry may try to help the goverment in minimizing its role by following self-compliance and then proceed to the DCGI for approval. Although he agrees to its uniqueness, Mr Madhukar Rao says, â€œThe regulatory authorities generally prefer their independence. It can be part of a regular discussion but cannot be implemented right away."

Comparing CRAMS with the IT industry, Mr Manoj Mehrotra said, â€œWe have to ensure that we tap the opportunities by improving the supply chain and ride the wave. We have not achieved so far what our counterparts in IT have done."

Dr Arjun Surya, president and CSO, Curadev Pharma, says, â€œIt would be arrogant on our part if we think that everyone will come to India. We have to always keep the competitive countries in mind and it is certainly going to be make or break for us."

The experts point to the fact that China has less than 50 US FDA-approved plants, while India has 100 such plants. Despite the fact that the Chinese API market has registered a drop due to quality issues, the number of innovation facilities are more as compared to India. It is the right time for the authorities to find a solution to the genuine issues, which will boost the morale of the industry and prevent any loss of work due to competition.

Rahul Koul in New Delhi