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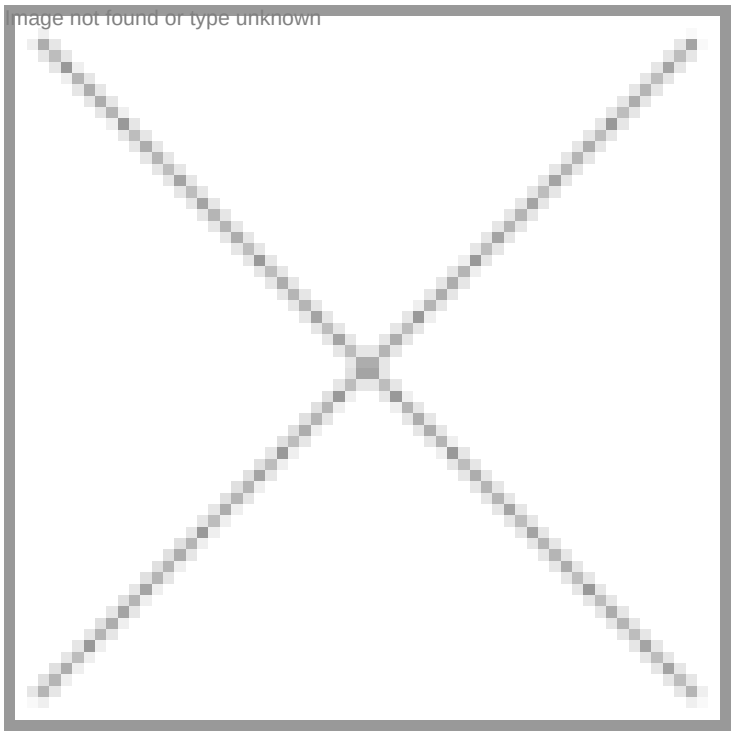

Clinical trial supply market thrives in India

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Nilesh

India began to utilize the opportunities in clinical trials few years ago. Some companies grabbed the opportunity, some looked at it and some simply created obstacles. Now the sector offers lot of hopes.

Today, after conducting more than 700 clinical trials in India, the market seems to have matured and more and more companies and service providers are getting attracted to this promising market. Other than clinical research organizations (CROs), we now have support companies like clinical trial supply (CTS) companies, life science logistics companies, clinical trial material depot providers, specialized packaging companies, software solution providers, and clinical trial data management companies and a host of other companies that have emerged in the last few years are capitalizing on the clinical trial market growth in the country.

These ancillary industries of particular interest and relatively naive territory provide huge 'clinical trial supply market' opportunity.

With more and more clinical trials being outsourced to India, it is only logical for sponsors and CROs to start sourcing the clinical trial supplies from within India. Prohibitive cost of imported clinical material, lead time for procuring import license and ambiguous regulations for imports have created a need for a reliable and efficient local clinical trial supplies partner with global reach more imperative than ever before.

As per an estimation study by the global consulting firm, Mckinsey & Co, European and the US pharmaceutical companies will spend $1.5 billion (about Rs 7,038 crore) per year on clinical trials in India by the year 2010. Though there are no scientific estimates available for determining the share of clinical trial supplies as a percentage of this total cost, even we conservatively estimate only 10 percent as the cost of clinical trial supplies, we are looking at a market of around $150 million (about Rs 703 crore). And this market would definitely grow at a rate faster than the rate at which CRO industry is growing locally (30-35 percent), as it would not only cater the domestic trials but also cater to the export market of the clinical trial supplies.

In India, the CTS industry is still at a very nascent stage with only a very few companies like Rubicon Research, Bilcare and Thermo Fisher have forayed into this segment offering varying services and expertise. Rubicon offers a one-stop-shop for all clinical trial supplies, right from manufacturing and packaging including labeling, blinding and randomization to CTM depot services, while companies like Bilcare offer only clinical packaging services. For Rubicon Research, CTS has been a natural vertical integration of its formulation development services, and for Bilcare, it is a diversification from its core packaging business.

The opportunity for CTS companies lies in offering clinical trials supplies services to clients including clinical manufacturing, packaging, labeling, blinding and randomization and depot services.

Services offered by CTS companies should be differentiated value-added services that can provide the flexible infrastructure needed to accommodate the complex and variable requirements for CTS. These differentiators in terms of capabilities have been illustrated below:

Opportunity and potholes

In spite of the high expectations on India to do well in the area of pharmaceutical R&D, there are many concerns that hinder the growth. The hindering factors include the lack of adequate skills, unrealized market potential and inadequate infrastructure in many areas of CTS, imprecise documentation systems arising out of ambiguities in the interpretation and implementation of global clinical trial protocols and requirements for world-wide multi-centered CTM depot. While India still could offer CTS at economical costs, there are concerns about the quality aspects. India has for long been viewed as the low cost destination for clinical trials. The country has also gained a dubious reputation of low quality, thus marring image in the process. This would mean that Indian supplies would be viewed with suspicion, and though, we would be rightly expected to deliver high quality global supplies, clients from the regulated markets or otherwise would still be looking at substantial cost advantage. This cost advantage would be difficult to provide considering the heavy investments that are needed for putting up a US FDA approvable manufacturing and packaging plant for CTS supplies, and the long gestation periods for return on investment, considering the sporadic and non-cyclical nature of manufacturing and supplies, unlike a typical supply chain set up.

Therefore, India needs to strike the right balance between quality and economics in cost. Joint efforts are needed from the industry and regulatory bodies to ensure that India's relatively late entry into the CTS arena is without any regulatory bottlenecks, quality and cost prejudices.