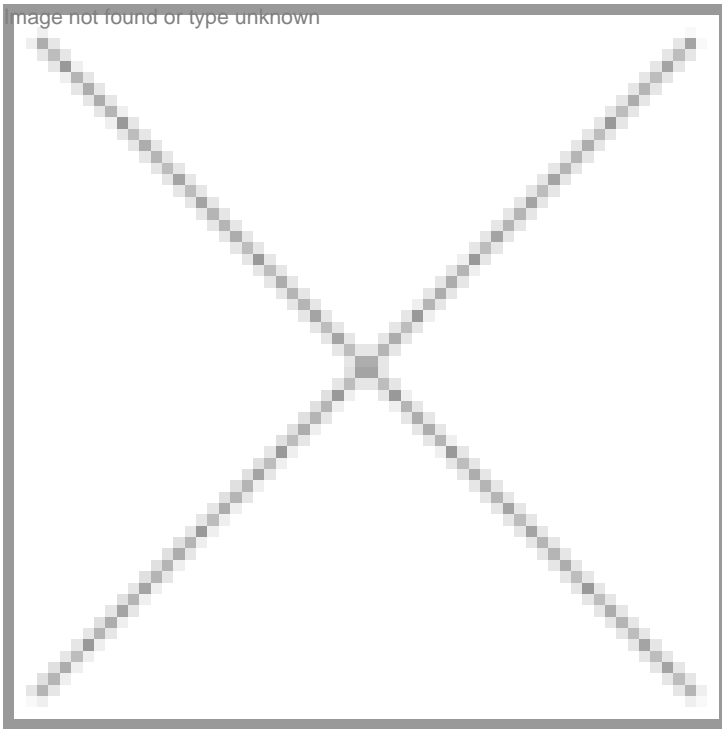


Expert Opinion - Nidhi Saxena

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BIOSERVICES

Nidhi Saxena, President

Adopting new business models

With BioServices accounting for about 19% of the \$4 billion Indian, biotech industry, it continues to be an important and growing segment.

While the overall biotech sector is growing at a CAGR of 23.8 percent in India and is about to cross the \$4 billion mark (\$3.4 billion revenues in FY 2010-11), the BioServices industry accounts for 18.82 percent of the industry and stands at roughly \$640 million and growing at a rapid pace of 23 percent CAGR. What's more, 95 percent of the BioServices revenues contribute to export revenues. Hence, it is an important and fast growing segment for the country.

India is well placed for BioServices given its technically skilled manpower including highly competent medical, clinical and engineering professionals, good base of over 100 GMP manufacturing facilities in the country that are approved by the US FDA, low cost manufacturing and research and a strong IT base to support the clinical data management and analytical work.

Within BioServices, the key segments are pharma contract manufacturing, contract R&D and clinical research. Analysts foresee growth at around 25-30 percent every year in these segments. So ideally, India is slated to become the hub for pharmaceutical companies and the industry has the potential to cross the \$10

billion mark in the next five years.

That notwithstanding, we are still very far away from achieving our goals and there are several bottlenecks. For one, the regulatory framework in India is still unpredictable, arbitrary and time consuming. The approval process is highly fragmented with multiple agencies being involved in approvals. Further, these agencies have low scientific expertise and have very little ability to deal with innovative technologies including gene therapy and biologics. More importantly, there is no clear cut agenda on what type of research to support and the approval norms are a lot more complex than those in the developed countries.

The segment still does not attract the same kind of investment as does the IT services which is a hot favorite with private equity and venture capital groups. Also, while schemes such as DBT's SBIRI support biotechnology, there is no organized funding for BioServices companies.

From the perspective of the BioServices firms, they need to adopt newer and innovative business models; for example, these firms need to look at changing from being pure play services companies to becoming innovation led companies adopting creative, risk sharing engagement models such as licensing and co-development. Here again, funding support for such bets shall be the key.

India needs to show a high degree of strategic value add-over and benefit above these locations in order to attract businesses from key markets such as the US, Europe and Japan.

In summary, while the BioServices industry undoubtedly has immense potential, it still needs a huge government funding and entrepreneurial thrust to see it really get to the \$10 billion mark.

- **Nidhi Saxena**, president and CEO, Karmic Lifesciences