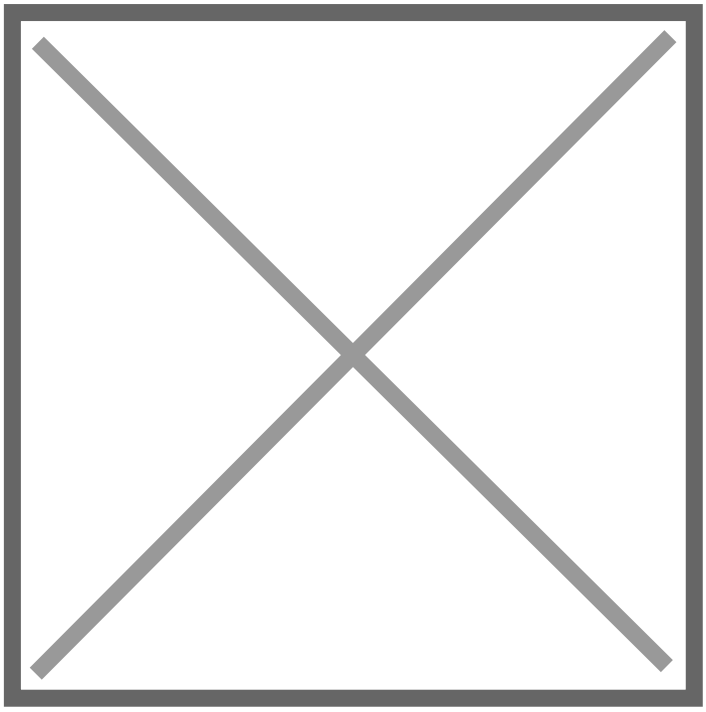
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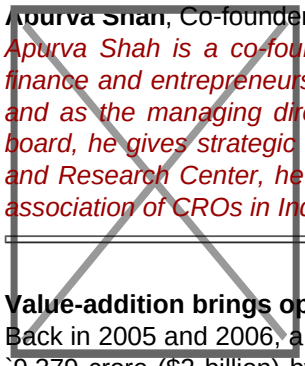
Value-addition brings opportunity

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Apurva Shah, Co-founder and Group MD, Veeda Clinical Research, Gujarat

Apurva Shah is a co-founder and group managing director of Veeda Clinical Research. He has an MBA in international finance and entrepreneurship from Babson College in Boston, US. Shah has strong entrepreneurial and organizational skills and as the managing director, is responsible for establishing and running Veeda's India operations. As a member of the board, he gives strategic and financial direction to all group companies. As a trustee of The Ujjain Charitable Trust Hospital and Research Center, he helped setup a medical college and two 500-bed hospitals in central India. He is the chairman of association of CROs in India, since January 2010 for a term of two years.



Value-addition brings opportunity

Back in 2005 and 2006, a lot of prediction was made that the then `937.40 crore ($200 million) CRO market would scale up to `9,379 crore ($2 billion) by 2010. Needless to say that the target will not be met. The main reason has been the onset of a serious market crisis in the recent global economy, followed by a lack of immediate changes in the regulatory environment, local infrastructure not able to develop fast enough, and lack of expertise in various services.

Further, the growth rate for global CROs has also been almost flat for 2008 and 2009. In order to understand some of the reasons for not meeting the predictions, and to be able to make a new revised forecast for 2015, one needs to know what is happening in the global pharmaceutical industry and its impact on the future of CROs, globally and in India.

Increased global outsourcing

Cost, efficiency and speed of recruitment pushed sponsors to explore new areas for R&D.

In the past few years, most of the new markets (other than the US and Western Europe), have delivered good quality data, and hence, it is expected that those CROs will enjoy a more robust growth, as compared to the global growth.

In the past few years, the large pharmaceutical companies have lost a lot of talent due to downsizing, and therefore, they will need to outsource more, in future.

Only the CROs known to the sponsors and with a clear track-record of performance in the past, will gain a lot of business. Thus, the large ones will become larger.

Considering India as a fast growing market for their products, it becomes an added incentive for the sponsors to move more R&D here. Of course, the regulatory and the intellectual property factors will affect the pace of scale up of outsourcing to India.

Need to diversify risk of drug development

Due to the high cost of getting a drug into the market, there is a need to enter strategic partnerships for sharing the cost and risk of drug development. Considering this concept is not yet well developed, Indian CROs have a chance to establish

themselves in this segment.

As the liquidity improves in the market, the venture capitalists and other financial investors, would prefer to have their development done in India, to get a better ‘bang for their buck’, and improving the chances of success, by putting more molecules through development, in the same budget. They are expected to have a much more open view of the issue, as compared to large pharmaceutical companies who have their own staff.

Growth of generics
With a number of patented drugs going off-patent in the coming years, and the pressure to reduce the cost of healthcare, there is a need for pharmaceutical companies to join the bandwagon and start developing generics, in lieu of the drugs going off-patent to maintain revenues and market shares.

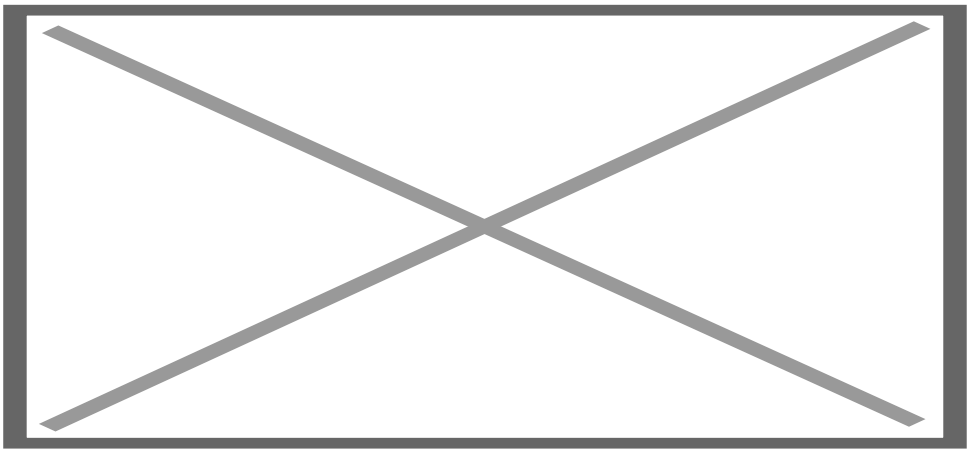
India is very strong in generic development, and therefore, India will have the opportunity to consolidate its leadership position in this segment, provided we stick to the quality and continue to add more value to the process.

Decline in US domination of clinical trials
With a number of fragmented players coming up across the globe, and the development of Europe and Asia as favored destinations for clinical trials, the domination of the industry by the US, has reduced from 70 percent to 50 percent, in the recent years.

Countries in Eastern Europe and South Asia offer a cost advantage to sponsors and the quality, as per the Food and Drug Administration (FDA) standards.
There is an opportunity for India to provide better infrastructure and resources to conduct ethical trials, and generate quality data.

Full service CROs/Specialized CROs preferred
Sponsors are preferring to partner with CROs that can offer a complete range of services globally, to reduce cost and improve speed and efficiency.
Sponsors will always favor CROs with specialty, in any particular therapeutic area or technique or population access, in order to reduce risk of failure and value addition, due to expertise and experience.

Indian CROs that possess a global footprint and specialization, will gain the most due to this move.



Factors that impact the growth of Indian CROs

Past Practices have led to the Current Situation

- Increased R&D costs and declining productivity
- Rise in regulatory requirements
- Fall in pricing and rise of generics
- Reduction in healthcare budget and uncertainty in reforms

The Future Outlook

- Increased global outsourcing
- Need to diversify risk of drug development

- Growth of generics
- Erosion of dominatin of clinical trials by the US
- Full service CRO/specialized CRO preferred