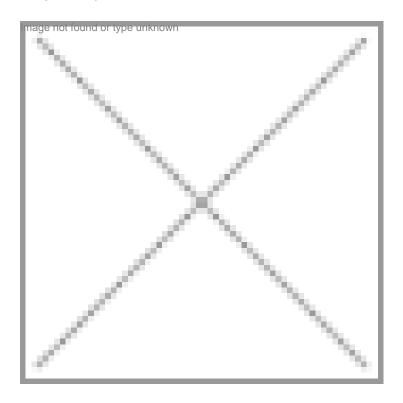


ELS to expand its footprint

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Excely Lifter Sciences, a US-based clinical trial management organization offering comprehensive clinical trial and site management services with 25 operational locations across India, claims to have trained 1,500 clinical ersonnel in India.

In an exclusive interview with *BioSpectrum*, Dr Vijai Kumar, President and CMO of Excel Life Sciences, shares his views on various aspects of clinical research related to government volunteers in India.

Could you tell us about the growth and expansion plans of Excel Life Sciences?

We have been maintaining a philosophy of good site management to ensure data integrity and data quality. As an organization, ELS in India has grown from being a three person company to 100 member organization in just three years. We have trained over 1,500 clinical trial research personnel in India. We have participated in 20 NDA submissions as a team. Financially, we have grown considerably with 413 percent growth in 2007-08 and 113 percent in 2008-09 and our expected growth for 2009-10 is 215 percent.

We are cautious about expansion. We would establish our credentials that good site management is vital for good quality data. We have established a successful partnership with Zürich-based PFC Pharma Focus Consultants for Europe and Israeli markets. This partnership helps us provide end-to-end solutions for our US and European clients.

What are your views on the government support to clinical research industry in India?

Government has the right intentions but implementation has not been uniform. We need to have clear set of guidelines and there is always a room for improvement.

Also, I feel the need to provide overseas exposure to the regulators. They should get hands on experience of the functioning of international model of FDA regulatory system. There is also need to train them in undertaking site inspection. I am glad

they have made a good beginning in this important functional area and the process has been initiated.

What according to you are the things most needed for the promotion of clinical research industry?

I believe FICCI, CII and other industry associations, and all stake holders in drug development and clinical research -national regulatory agency, IRBs, pharmaceutical industry, CROs, medical professionals and patients should have ongoing interaction to identify issues confronting different stake holders and address them openly and in a time bound manner.

Society at large has a number of misconceptions of clinical research. All the stake holders need to create an atmosphere for the media to collaborate to educate the community about benefits of participating in clinical research.

It will be useful to provide opportunities for patients to share their experience of participating in clinical research to the community. This could be through print, electronic media and personal meetings. Social organizations like Rotary and Lions also have an important role to play in disseminating positive information about medical research in general and clinical research in particular.

Where do you see ELS after next five years and what is your prediction for growth of the industry?

In the next five years, ELS will expand its footprint into promising new geographic areas where ELS can make a difference and spread the awareness of global clinical research across India. The clinical research industry in India is also poised to make remarkable progress, with growth and competition, consolidation and maturation has to take place. We are likely to see mergers and acquisitions in this space in the not too distant future.

So long as we do all we can to build the trust and confidence of the community in clinical research, we will continue to provide opportunities to global biopharmaceutical and medical device industry to bring their products expeditiously to the market, and we can assure them of the data quality and data integrity generated in India.

Rahul Koul in New Delhi