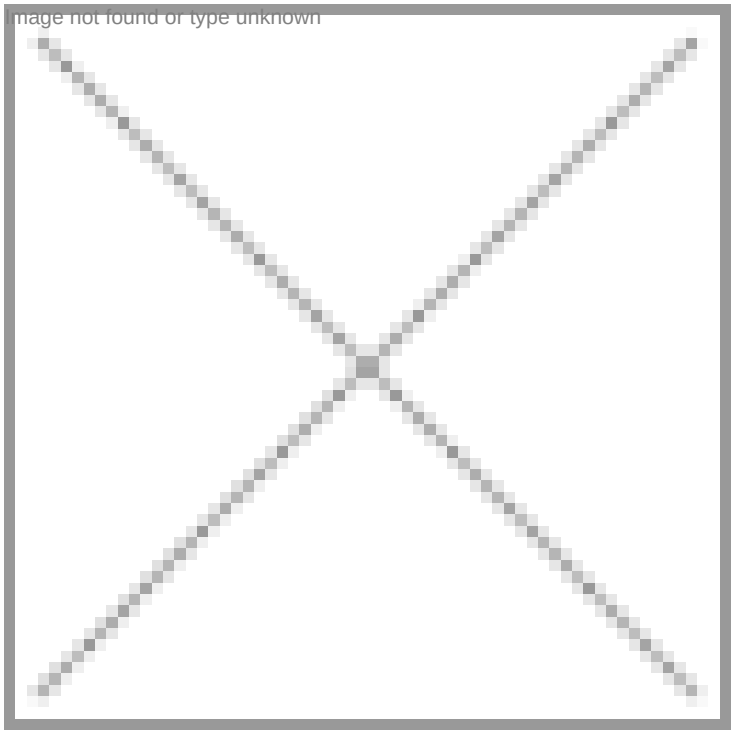
BioSpectrum the business of Bio & Health Sciences

# "India has enough manpower for CROs" -Bharat Doshi, Country Manager, Kendle India

08 April 2005 | News

Image not found or type unknown



**Why are most of the CROs are based in Bangalore, Hyderabad, Mumbai and Ahmedabad?**
The CRO industry initially seeded itself in Mumbai and Ahmedabad and then expanded to Bangalore. Mumbai has been the trade capital and the hub for pharma companies since years, where as Bangalore became known as IT hub and hence the concentration of CROs in these regions. To add to this, the biotech industry also started in the southern region and gained momentum there. Moreover, the region boasts of a robust health care facility, which is essential for this sector.

However, this essential element for a CRO industry i.e. clinical material is available throughout our country because of widely spread healthcare facilities, serving a huge patient population. Thus, the CROs will spread to other regions as well.

One major factor for growth of this industry in India is a very good patientâ€“doctor relationship. This relationship in India is traditionally built upon virtues like trust, honesty, rights of confidentiality and rights as an individual. Communities of Indian doctors traditionally believe in values and ethics, which are now considered as pillars of ICH-GCP. This combined with advances in medical education and training will be the driving factor and the essential fuel for the Indian CROs to develop further.

**Many Indian sponsors are looking at outsourcing clinical trial (Phase I) to MNCs outside India. What could be the reason for this trend?**
Many of the Indian sponsors do have their in-house clinical research and trial set-up to which they entrust the work. This is

understandable when the volumes are small. In many cases, Indian companies, which are planning to take approval from the foreign regulatory agencies like the USFDA, prefer getting their phase I trials and especially the bioequivalence and the bioavailability studies, done in that country.

With Indian sponsors getting involved more and more in R&D, the volume of clinical research activities are going to increase and it will become mutually beneficial for Indian sponsors as well as CROs to harness efficiency by outsourcing to Indian CROs.

**What are the advantages that an Indian CRO can offer in the global scenario?**

Presently only the low cost of patient management is perceived as an advantage. But over a period of time, when India establishes its credibility in this sector and the Indian CROs have built the "Indian brand" in international clinical research, then the speed at which patients are enrolled, trials are completed, will become the primary attraction in global scenario.

**Are there sufficient trained people to carry out clinical trials/research in India?**

I do not believe that there is a huge lack of trained people as was seen in the IT sector during its boom time. India has enough manpower with the basic qualifications like a degree in pharmacy, medical or para-medical education or in life sciences. What is additionally needed is training or hands-on experience in this sector for about six months to a year to familiarize with the ICH-GCP norms.

Practice-based training is very important and only theoretical knowledge is not enough. One can comply with the most stringent standards of GCP if he/she believes in these principles. One can believe in these principles if one experiences them in practice. If institutes offering courses provide practice-based education and exposure, then they can be an excellent training ground for students.

**What are the factors that an MNC looks at before outsourcing to CROs?**

The CRO industry is a new, sensitive and a serious field. Indian companies having the experience of working on international studies have an advantage in the global scenario. The foreign companies prefer to outsource their studies to CROs, which have worked on international projects, where the studies were conducted in adherence to international rules and guidelines and where the data had been submitted to international authorities. Thus concentration of experience is of utmost importance in making this decision.

Rolly Dureha