

## Innovation, a key factor

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image not found or type unknown, managing director, Auriga Research, New Delhi

*Saurabh Arora, is the managing director of Auriga Research. A post-graduate in pharmaceutical technology from the National Institute of Pharmaceutical Education and Research (NIPER), Arora has been spearheading the rapidly growing team of over 150 professionals in the contract research and testing services business, for the past five years. He has setup a clinical research center and a second analytical lab, and rapidly grown the services business, by increasing the scope of services offered, and a strong commitment to quality and customer satisfaction. He is actively involved in the development of new services, and the adoption of new technologies in the organization.*

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Indian CROs provide small and medium enterprises (SMEs), worldwide, access to a rich pool of scientific knowledge and capabilities, with minimum investment. This has made it possible for SMEs to take their innovations further down the development pipelines, before the need arises for venture funding, or even selling the technology to bigger companies. The value-addition greatly enhances the profitability and helps to further expand such ventures.

Usually when organizations think of outsourcing their research activities to an Indian CRO the decision is invariably motivated by the obvious advantages of lower costs and faster recruitment rate for clinical trials. Today, Indian CROs have a larger value proposition to offer, which goes beyond these obvious advantages, companies can come to India with just a concept, and walk away with products ready for the market.

Indian CROs have been successfully attracting and executing clinical trials from the world over, because of many tertiary care and specialty hospitals with high patient numbers and skilled medical specialists. We have access to a vast disease distribution, and patients that are often 'therapy naïve'. Our workforce is well-educated, largely English-speaking and IT-

savvy, making it easy to communicate with, and to utilise the latest IT tools. The strengthened regulatory and intellectual property environment, has made India the ideal destination for outsourcing critical research projects.

Over the years, many Indian companies have successfully launched products in various global markets, and Indian CROs have delivered numerous and diverse projects for international clients.

Indian CROs have developed state-of-the-art infrastructure for serving various phases of drug discovery and development. Facilities complying to, and often surpassing the global regulatory requirements and client expectations, are available for custom synthesis, chemical characterization, high throughput screening, preclinical toxicity studies, drug metabolism and pharmacokinetics, formulation development, analytical development, contract manufacturing and clinical data management.

SMEs use these facilities, and depend on CROs to deliver quality data, without incurring the huge capital investment needed to establish and maintain such infrastructure. Projects are delivered within tight budgets, not by cutting corners, but by sharing costs between numerous projects they handle each year.

We have worked with clients on projects spanning almost the entire length and breadth of the drug development cycle – for synthesis of the active pharmaceutical ingredient, its characterization, analytical development, stability studies, clinical trial formulation development, in vitro characterization, pharmacokinetic studies, multi-centric clinical trials and regulatory approvals.

For one of our clients, Alung Technologies, a US-based developer of extracorporeal respiratory assist devices, partnering with an Indian CRO was an important strategic decision. “As a company, it was very important for us to get early experience with our Hemolung device, before proceeding to a larger clinical study. Being a US-based company, it was very important for us to find the right partner to work with. Our CRO, Qualtran Auriga Research, was key to the success of the study. We have now expanded the trial of our device in Germany, and are looking forward to obtaining the CE mark in 2011,” says Scott Morley, vice president of marketing for Alung.

SMEs now rely on their partner CROs, to quickly identify and deliver solutions to problems. We often develop and offer custom services to support our clients. Rick Tullis, chief science officer at Aethlon Medical, says, “Auriga Research helped us in completing our clinical safety studies in India, with a new technology for treating infectious diseases, using a blood filtration device. These studies required highly accurate and sensitive measurement, using quantitative PCR, and some unusual tests for potential contaminants that most clinical labs would have difficulty in implementing.”

There is a major shift in the research-based work outsourced to India; SMEs involved in developing innovative technologies are also harnessing these potential advantages in India.

Though adopting the model of setting up their own research and development centers may not always be economically viable; they are actively partnering with Indian CROs to quickly take their innovative products to the market.

To conclude, I would like to borrow the terminology of ‘cloud computing’ from the information technology industry, and say that we are in the era of ‘cloud research’ where shared resources and knowledge are provided, on demand, to organizations of all sizes, to drive their innovations, and create greater value through research and innovation.