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'India should have a stringent inspection program'

09 January 2012 | News

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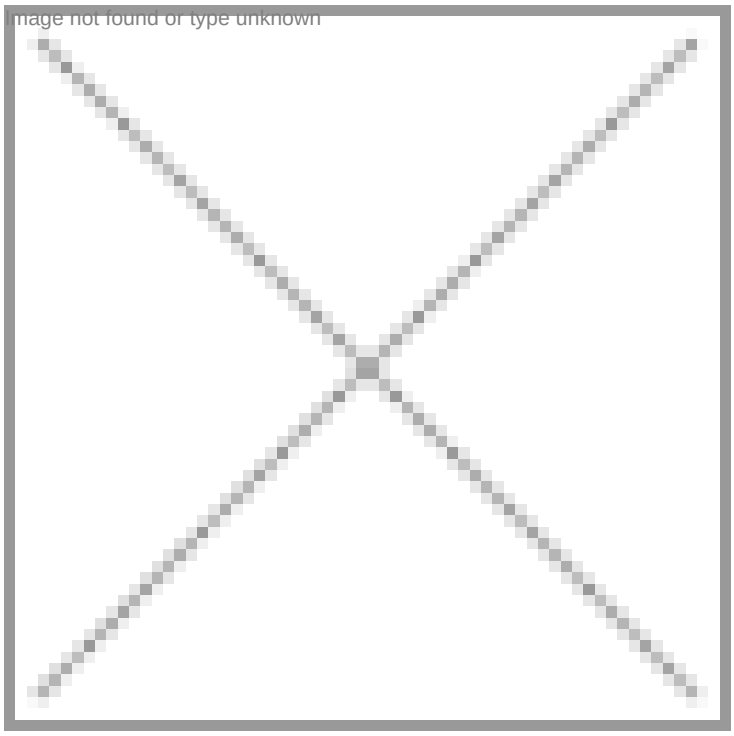

Interview

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Dr Shoibal Mukherjee,
chief medical officer Quintiles India

Quintiles India, the only global contract research organization (CRO) in India whose study sites have been inspected and approved by the US Food and Drug Administration multiple times, has appointed Dr Shoibal Mukherjee as its chief medical officer. Dr Mukherjee represents the company's position on various government, ethical and public policy issues. He works closely with the Quintiles' clinical business team.

Dr Mukherjee, a physician with an MD and DM in pharmacology with over 20 years of experience, joined Quintiles from GVK Biosciences where he was a member of the executive committee and served as senior vice president and head of clinical development strategic business unit. Prior to this, he held similar senior positions at Ranbaxy and Pfizer. He was the founder president of the Indian Society for Clinical Research and has been closely involved with the evolution of pharmaceutical regulations in the country.

In an interview with BioSpectrum, Dr Shoibal Mukherjee shares his thoughts on the impact of global economic crisis onIndian CROs and issues before the company in India.

Q Do you think the global slowdown has affected the CRO industry in India positively?

Dr Mukherjee: I think the positive and negative influences of the global slowdown have canceled each other out, and

the future of clinical research in India now depends more on internal rather than external factors.

Q What advantage does India offer as compared to other APAC countries?

Dr Mukherjee: India has the advantages of scale and of a large and well-qualified pool of talented investigators. We also have a more diverse disease profile as compared to both, developed and less-developed countries. In a world where an increasing proportion of global research and development effort are moving to developing country environments, the importance of India as a location for clinical research cannot be ignored.

Q What are the regulatory hurdles faced by Quintiles today?

Dr Mukherjee: Much like the clinical research industry in India, the regulatory environment of the country is still evolving. Ambiguity in regulations and the absence of a formal mechanism to obtain reasoned scientific advice from regulators make planning and coordination required for global drug development a challenging task. However, this is a process of evolution. There is a lot of healthy discussion on regulatory issues in India, that we believe is good for the industry. We are very open to working with regulatory bodies to bring in regulations and processes that will enhance the standards and performance of the clinical research industry in India, while ensuring that interests of patients are kept in the forefront in the next phase of development of the country as a global hub in life sciences.

Q What steps can the government take to ensure that CROs abide by the regulations and eventually discourage dubious organizations?

Dr Mukherjee: The country should have a stringent inspection program conducted by qualified inspectors with rigorous training and experience in the clinical research domain. In the absence of adequate resources available to the regulator, a system of third-party audits should be considered, as is done in the financial world.

Q What sets Quintiles apart from its competitors?

Dr Mukherjee: The quality of its people, experience base, ability to think global and act locally, and its insistence on doing the right thing.

Q Which diseases are the focus of clinical research at Quintiles?

Dr Mukherjee: As a CRO, we are open to accepting assignments in any therapeutic area that may be of interest to our sponsors. There is a natural tendency of sponsors to assign to India projects in therapeutic areas for which there is high patient availability in the country, so that the project meets recruitment timelines. This also ensures that there is commercial incentive to launch the product in India if and when it comes to market. Increasingly, we are finding ourselves involved with projects from local sponsors and not-for-profit organizations working in areas of domestic public health concern, such as the development of vaccines for prevention of childhood infections.

Quintiles is involved with approximately 50-60 projects in India that are in the recruitment stage or active follow-up phases. We perceive significant future demand too, particularly from local sponsors.

Q Tell us about the role played by local sponsors and your past collaborations.

Dr Mukherjee: India has the world's highest disease burden (ranging from 40 to 60 percent) as estimated by the World Health Organization. Childhood pneumonia and childhood diarrhoea are the biggest killers, taking young lives and contributing the most to disease burden. India also carries a disproportionate amount of the world's burden of leishmaniasis (kala azar), Japanese encephalitis, leprosy and burns. The government as well as non-governmental organizations and other international sponsors are making efforts to help develop better therapies and preventive vaccines for these diseases. The need to encourage and support these endeavors cannot be overstated.

Q Is there a shortage of experienced staff in clinical research? If so, what solutions do you suggest?

Dr Mukherjee: Clinical research is a relatively new domain in India and even the most experienced professionals in the country have around 15-16 years of intensive clinical research experience. However, the industry has evolved considerably over the last few years. In Quintiles, most managers have experiences of eight-to-10 years or more. While the clinical research industry, being relatively small, will find ways to meet its human resource requirements, the talent shortage in the country cuts across industry lines and is expected to deepen in future. The government must spend more on quality primary and secondary educational facilities and open up higher education to private investment, doing away with entry barriers and regulatory bureaucracy while ensuring output quality by conducting national exit examinations in all major disciplines.

Q Are there any particular centers in India that you plan to focus on for conducting trials? Also, tell us about the phase I facility at Hyderabad.

Dr Mukherjee: Our phase I facility in Hyderabad has been developed in partnership with Apollo Hospitals Group. It is an 86-

bed facility that complements Quintiles' existing phase I facilities around the globe and has been modeled to deliver the same capabilities. As new molecules emerge from discovery pipelines following a resurgence of pharmaceutical innovation in the country, we hope to be able to contribute to their development by helping customers in this part of the world navigate early development challenges and embark on global development programs.

Q What are your views on the emerging market of biosimilars and how will it impact the operations of Quintiles?

Dr Mukherjee: Though currently very small, the size of the biosimilars market is expected to cross $10 billion in five years from now and reach $20 billion by 2020. We had a headstart in the biosimilars segment because of the absence of clear regulations for biosimilars in the country and now we have more companies in India planning to enter the biosimilars market than anywhere else in Asia. Quintiles is keen to help these companies navigate the complex global biosimilars regulatory pathway. It is emerging as a partner of choice for the development of biosimilars for companies elsewhere in Asia and we hope that will be the case in India too.

Q How do you see your role evolving at Quintiles and how will it enhance business in India?

Dr Mukherjee: I hope to be able to help the organization align itself to the needs of the healthcare and pharmaceutical segments in India and move in step with evolving regulations. By doing so, Quintiles can begin to be seen as an essential part of the growth of drug development science in India, helping bring healthcare solutions to patients and to a country that bears the world's largest burden of disease.

Manasi Vaidya in Bangalore