Dr Shoibal Mukherjee

Dr Shoibal Mukherjee is Senior Vice President and heads the Clinical Development function at GVK Bio, Hyderabad, India. Dr Mukherjee has been associated with the development of clinical research as a specialty within the pharmaceutical industry in India. He is closely involved with the evolution of pharmaceutical regulations in the country, representing the pharmaceutical industry through the Medical Committee of the Organization of Pharmaceutical Producers of India (OPPI) and as a member of the Schedule Y Review Committee whose recommendations led to the revision of clinical trial, pharmacovigilance, and new product submission requirements in early 2005. He was the founding President of the Indian Society for Clinical Research.

Contract research in India

Cost, developmental and regulatory issues

Contract research came to India in the 1990s. A number of key developments came together around the turn of the century to make it all possible. First, there was the Indian Patents (Amendment) Act of 2005 that forced Indian pharmaceutical companies to invest in innovation. This created the initial staffing pool and generated a local market for research personnel. Then there were the implications of the process of harmonization of research regulations led by the International Conference on Harmonization (ICH) since 1990 that spelt out common regulatory requirements for countries covering 85 percent of the world's pharmaceutical markets, making it mandatory for regulatory authorities in these countries to accept research results from anywhere in the world provided it complied with the requirements. And finally there was the communications revolution that swept the world making real-time collaboration across geographies a reality.

All this led to significant growth in research activity in the country, and contract research as an off-shoot. Contract research took on a life of its own after year 2000. Companies were set up to provide services in the drug discovery space, with chemistry and biology labs, and collaborative research models. Large and small drug development service companies sprung up all over the place with clinical pharmacology beds, bioanalytical services, compound scale-up and clinical supplies units, clinical trial management teams, and data management, biostatistics and medical writing offerings.

The growth seemed rapid and remarkable, yet its impact on worldwide pharmaceutical research remained marginal. The world contract research market is estimated to be worth $26 billion in 2010 while estimates of India's share do not exceed two percent at this time. Clearly, the potential for India is much greater.

Competition from China

India competes closely with China, and while in the initial years of globalization of pharmaceutical research it seemed that India had the advantage – booming generic formulations industry, English-speaking workforce, western-style medicine, and all that – in recent years China has pulled ahead with better infrastructure, more supportive regulations and incentives, and a much faster growing pharmaceutical market that demands and gets investments from overseas. The big pharmaceutical companies have, over the last 10 years, invested much more heavily in R&D in China than in India. And in the last year we have seen some large CROs following suit.

India seems to be losing to China on cost and pricing. With a reputation for low prices, international sponsors seem to expect services to cost less in India than in China. On the other hand, costs are continuously going up, with inflation now into the double digits while the Rupee (Indian currency) seems to be strengthening in contrast to the artificially weak exchange rate for the Yuan. And payroll costs are growing at double digits too, with salary increase being higher here than anywhere else in Asia. Tax and other incentives for contract research in India fall far short of compensating to these disadvantages, leave alone matching what other countries in the region have on offer to attract contract research spending by global sponsors.

Regulatory issues

When one thinks of the state of drug development regulation in India, it seems almost as if the government is deliberate in throwing the match away. Animal rights bureaucracy has made it almost impossible for the country to grow in the area of animal testing despite some easing in recent years. Yet the length and types of animal studies that need to be completed to get permission for human trials are much more demanding in India than anywhere else in the world.

Consequently, if you discovered a promising new medicine you would be forced to go abroad to do the first-in-human studies. And it would be a good thing too, since there is no expertise in bench-to-bedside translational medicine in the country as a result of a long-existing ban on phase I studies. When it comes to phase II and III studies, many innovative biotechs and small entrepreneurs in Europe and the US are interested in contracting to Indian CROs, since India has an advantage in patient numbers and the costs are low. But our regulators will not permit it unless at least half the patients are to be recruited abroad. This beats the very purpose of coming to India.

Yet one can't blame the regulators for this – the government support provided to the office of the Drugs Controller General is so poor that the regulator is heavily dependent on regulatory assessments done by foreign regulatory bodies and is diffident in approving anything that hasn't been reviewed abroad.

Fortunately, Indian entrepreneurship manages to survive. Government regulation has a much smaller impact on areas such as discovery research, informatics, and clinical trial allied services such as data management, biostatistics, pharmacovigilance and medical writing. Constraints in these areas mainly relate to the cost, quality and availability of a qualified workforce.

The future

Institutions in the country that can provide quality education at the cutting edge of scientific research can be counted on the finger tips – but the news that education will be opened up to international investment provides a glimmer of hope. The key to a long-term future in these areas depends on the availability of a large pool of scientific manpower trained in the various disciplines that contribute to the science of drug discovery and development.

The future of contract pharmaceutical research in India, then, is related to the future of much else in the country. General development such as infrastructure, education, and the economy will play a role, as much as more specific issues like the development of regulation and incentives for medicinal research. We may have to rejoice in patchy successes in some areas of the domain and reconcile to mediocrity in others.

Getting to a leading position in drug discovery and development will require much more than that – a focused national approach and clear policy directives from the administration. Unfortunately, there are no signals of that at the present time. ■