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Asia - The Emerging Pharma R&D Hub

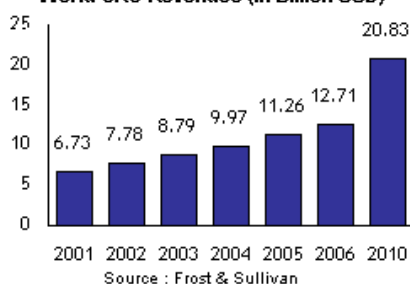
Rajeshwer Chigullapalli and **Feroz Zaheer**

Asia is emerging as a powerhouse of pharmaceutical R&D facilitated by the availability of a vast patient population, quality data, lower costs and skilled manpower .

The large number of patent expirations, decreasing R&D productivity and high costs of drug development are forcing big pharmaceutical companies to outsource their R&D operations to other locations. Asia is proving to be the most preferred destination to carry out their drug development activities. Availability of a vast patient population, low costs, R&D workforce and a favorable regulatory environment are the main driving forces to transform Asia into the hub of R&D activities.

A number of Contract Research Organizations (CROs) have set up shop in Asia to provide trial monitoring, project management, data management, safety reporting, drug distribution and central laboratory services. Many top-notch western multinational companies have already moved their R&D operations to Asian countries including Glaxo Smith Kline, Pfizer and Novartis. Reenita Das, Vice President, Healthcare, Asia Pacific, Frost & Sullivan at the "Asia Pacific Clinical Research Outsourcing Development Summit: Understanding The Paradigm Shift" hosted by Frost & Sullivan recently, said, "Low cost of conducting trials in Asia, large samples and specialization in clinical research can generate economies of scale."

World CRO Revenues (in Billion USD)



Opportunities in India and China

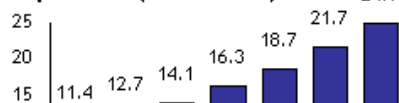
The Chinese pharmaceutical market is one of the fastest growing in the world. It is estimated to be the fifth largest by 2010 and third largest by 2020. The country offers many advantages like economical costs and huge patient population. As compared to the West, the cost of carrying out clinical trials in China is 15% lesser for Phase I and 20 percent cheaper for Phase II/III. China also has the advantage of a cheap and educated R&D workforce . According to estimates, 100,000 undergraduate / graduate students are enrolled for Chemistry, 120,000 for Medical Sciences and 60,000 for Biological Sciences. The Chinese Government is concentrating on drug development as a "Pillar Industry". Mark Engel, President and CEO, Excel PharmaStudies - a leading CRO in China commented at the Summit, "Grants and loans are readily available under multiple programs, world-class government pre-clinical facilities are established in Beijing and Shanghai."

AstraZeneca has announced its plans to spend \$100 million in expanding its research operations in China. The main focus of the new effort will be a program to better understand Chinese patients' genetic profile as it develops new therapies for China. David Brennan, CEO, AstraZeneca said, "With China's rapid economic growth and increasing demand for better healthcare, China has become one of the most important emerging markets for AstraZeneca and will be important to our future success. We fully support China's national focus on innovation by substantially increasing our R&D investment, both in financial terms and scientific collaboration terms."

India is also one of the most preferred Asian countries for R&D activities. Easy availability of patient pool, diverse disease profiles in the patient population, an estimated cost savings of 50 percent in Phase I studies and 60 percent in Phase II & III studies and well-equipped institutions with skilled professionals are the major driving forces behind this trend . The country has also become TRIPS compliant since the year 2005, which also makes its pharmaceutical industry more attractive. The drug laws are also being amended to allow same phase clinical trials as in the country of origin. In addition, India has regulations that provide fiscal incentives for R&D activities. Consider this - India has the largest number of FDA approved plants after the US.

J. Rajagopal, Director, Global Life Sciences & Health Care Practice, TCS opined, "Improving medical infrastructure - large international standard hospital facilities, emerging and increasing role played by medical colleges in conduction of clinical trials are making India a preferred

Global Pharmaceutical R&D Expenditure (in Billion USD)



destination for R&D activities." Globally, around 30-35% of total drug discovery and development costs are for clinical research. According to experts, such costs are reduced to half when clinical research activities are outsourced from low cost economies such as India. The clinical research market in India is estimated to be \$100 million and is expected to grow to \$ 300 million by 2010.

India is the fourth largest reservoir of scientific manpower in the world and with 150,000 chemistry graduates per year, the country is filling a gaping hole being left in the EU and US, where graduates are abandoning science field for more lucrative careers in business. The country also boasts of a robust IT industry offering IT solutions to help pharma companies decrease time-to-market. The CRO segment in India is also growing at a steady pace. According to TCS Research, the CRO segment in India has grown from \$ 5 million in 1995 to \$ 120 million in 2005.

Other Asian Markets

Other Asian countries like Malaysia, South Korea and Taiwan are also attracting a number of international pharma companies to outsource their R&D activities. These countries provide a regulatory environment conducive to clinical trials and are gradually moving towards e-submissions too. The Clinical Research Center (CRC) in Kuala Lumpur is the clinical research arm of the Ministry of Health, Malaysia (MoH). The CRC promotes, supports and conducts clinical research and this shows efforts by the government to promote their R&D activities. With a population of over 50 million, South Korea offers large patient pool with diverse disease profiles, a large workforce in life sciences and a good number of trained doctors.

The government of Taiwan is planning to spend \$4.48 billion on bio-medical research. It is also creating industrial parks including Hsinchu Bio-medical Park. The country is witnessing a growing CRO industry with the presence of leading local players like Genovate Biotec, Protech Pharmservice, Virginia CRO and Apex International Clinical Research Co. Ltd and Foreign CROs like Quintiles, ICON, Omnicare CR etc.

Asia Beckons

In spite of the Asian R&D doing exceptionally well, there are concerns galore like lack of adequate skills and infrastructure in many areas of R&D, imprecise documentation systems, ambiguities in the interpretation and implementation of global regulatory and intellectual property protection standards and issues on maintenance of confidentiality. While the region is known for its economical costs, there are concerns about the quality aspects. As Reenita Das opines, "Asia Pacific has for long been the low cost destination for clinical trials. But we have also gained a reputation of low quality and image in the process. Currently, we are suffering from a PR crisis."

Therefore, Asia needs to strike the right balance between quality and economics in cost. Concerted efforts are needed from the pharmaceutical industry, academic institutions and regulatory bodies. All parties should work with the common objective of faster drug development to provide better medicines to the needy. The region should aim at generating more talent with the right scientific skills in order to meet the ever-increasing demand for professionals.

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