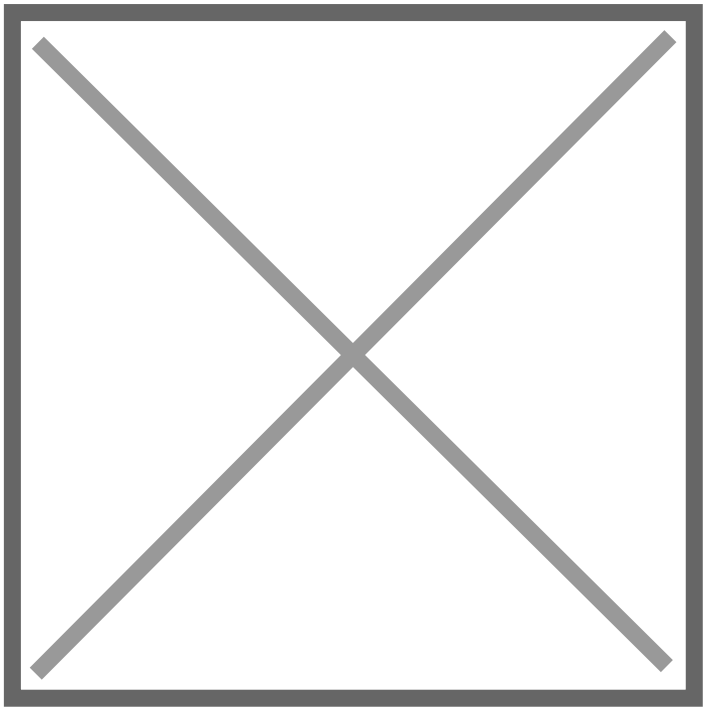
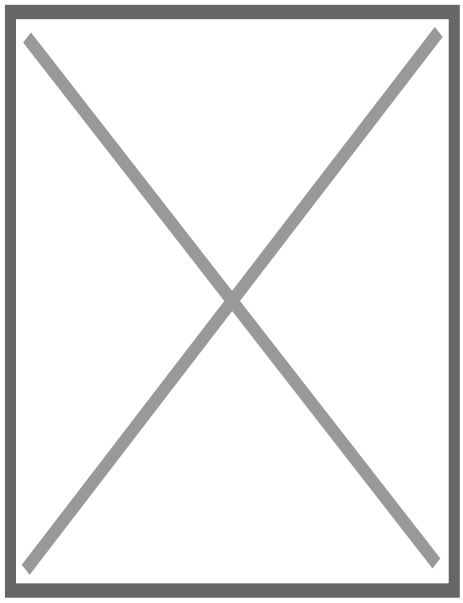


India can become significant global player by 2010

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India can be counted as a leader in cutting edge research in genetic engineering, immunological techniques, cell culture methods, stem cells and hybridoma technology.

Utkarsh Palnitkar, Director, Life Sciences Ernst & Young India

The global biotechnology industry is pegged at $54 billion and is growing currently at 17 percent annually. This is a clear indicator of the huge potential which the industry promises. In contrast, India's biotechnology industry is worth only $1.1 billion which constitutes around 2 percent of the global revenues. However, the encouraging factor is that the Indian biotechnology market is growing at a scorching pace of 36.5 percent per annum which is one of the highest in the world today. India would be considered a significant player on the global arena should it capture at least 10 percent of the market by 2010. India, which ranks among the top 10 biotech hubs of the world, would join the elite club of top 5 biotech hubs, should it achieve the $5 billion mark by 2010.

Emerging segments

The global bio-pharma industry is witnessing maximum growth in segments such as targeted therapy (antibodies, vaccines), theranostics (molecular/gene based diagnostics that determine therapies) and clinical development services (Phase I-IV human trials). India is already in a pivotal position to secure a significant share in important segments such as vaccines, diagnostics and clinical trials. For instance, it is considered that India already has the largest vaccine production capacity in the world. By 2010, India could open new frontiers by developing the globally fast growing segments facilitated by the capabilities developed indigenously.

India would be in an enviable position globally if it were to meet expectations of becoming the clinical trials hub of the world. Even if 15 percent of all clinical trials were to be outsourced in the next 3 years and predictions made by BCC Research come true, $4 billion worth of clinical trials will be conducted in developing countries. (Source: Economic Times, Nov 2004) and a large part of this opportunity can be secured by the Indian biotech industry. It is estimated that India can secure around $250-300 million of the global clinical trials market by 2010. (Source: Center Watch, Aug 2003).

Innovative products

India can become a global leader by 2010 by leveraging on its established pharmaceutical industry and developing innovative biopharma products. This is further encouraged by India's commitment to the product patent regime which is now aligned with the global IPR system. This eventually can be possible should India enable biotech innovation in areas such as diagnostics, recombinant biotherapeutics, stem cell biology, bioinformatics, proteomics and genomics. Considering the growth rate to be constant at around 30 percent, the biopharma segment has the potential to reach an estimated value of $3 billion by 2010. (Source: Ernst & Young)

Time to market

In the biotechnology business, time is of more essence than the cost in which case should India be able to minimize the go-to-market time for products it will have attained a sustainable competitive advantage globally.

Regulatory issues

Till 2005 India only recognized process patents. However, in 2005 India committed to the product patents regime aligning its IPR system to global standards. Although this is a major step in a direction to achieve recognition of its IPR system globally, large MNCs continue to be apprehensive about the IP protection in India. Hence the industry is primarily led by entrepreneurial leadership (Biocon), fragmented research and government support. If India needs to attract foreign investment and in the larger scope become a center of cutting edge technology and product development, a strong product patent regime and its implementation is imperative.

Seed funding

Due to a lack of valuation benchmarks available in the biotech industry, the venture capitalists are deterred from investing in seed capital. In fact it is lack of awareness amongst financial institutions and VCs and not so much the risk involved that keeps the seed funding for biotech companies at bay.

Synergy between stakeholders

Most of the quality research which takes place in India in the biotech sector is conducted in government institutions such as CSIR, ICAR and ICMR. Some of the most successful products (vaccines) launched in India have been the result of successful collaboration between private players and the government. In addition there exists a clear gap between the industry and academia. The educational curriculum currently lacks in terms of industry-oriented research while the resource skill differ from those required by the industry.

Attractiveness of Indian market

The large global biotech MNCs such as Genentech, Amgen do not find the Indian market feasible in terms of value. The prime reason for this is that the innovative drug costs are too expensive for local consumption since the patient in India mostly pays from his own pocket and does not receive support from reimbursements by the government.

Strategy to surmount challenges

India would evolve the growing partnership between the pharmaceutical and biotechnology industries to create complimentary capabilities in terms of research, products, marketing and manufacturing. The government support in terms of financial and

resource incentives can facilitate implementation of this strategy. Such optimal alliances will allow the pharmaceutical companies to enhance their drying pipelines and the biotech companies to secure financial muscle to sustain efforts towards developing innovative products. Further, this will also enable companies to reduce time to markets via the established foothold of our pharmaceutical companies across the globe. This is likely to become Indian biotech industry's successful business model going ahead.

The second most important strategy is to nurture the industry in terms of attracting investments, promoting research and supporting entrepreneurship in the emerging areas. The large MNCs can be attracted by strengthening India's patents regime and ensuring enforcement of the same to send a clear signal to the world of India's commitment to honoring global standards of IP.

India has already formulated its first National Biotechnology Development Strategy which outlines the importance of industry oriented research. The skilled human resources must be developed in accordance with the requirements of the industry and hence the educational curriculum needs to be amended accordingly. Further, entrepreneurs should be supported by establishing funds, incubators and biotech parks so that innovative ideas are not lost due to a lack of resources.

Cutting edge research in globally emerging segments (such as contract bio-manufacturing services, clinical development services etc) and developing in-house capability to manufacture innovative biopharma products for these segments, will provide India with a sustainable competitive advantage for a long time to come. India can be counted as a leader in cutting edge research in areas such as genetic engineering, immunological techniques, cell culture methods, stem cells and hybridoma technology. Each of these areas will open up new frontiers in terms of developing more effective products more efficiently and hence has the potential to make India the center of excellence for research and product development.

Great potential

In context of the size and growth of the current Indian biotechnology market vis-Ã?Â -vis the Asian and global markets, it is clear that India promises great potential to become one of the most significant players on the global arena by 2010. However, the various challenges need to be surmounted to achieve the vision 2010 and this can be made possible by implementing the broad strategies at the earliest. With a steadily growing prominence in the global biotechnology market, India will be all set to transform into a global leader by 2010 should it continue to unravel opportunities in the right segments and develop long term capabilities to harness the same.

FDA blueprint for modernizing medical product development

FDA has released Critical Path Opportunities List, an initial list of priority research projects that could advance innovation in medical products. The announcement of this List signals the next major step in FDA's Critical Path Initiative, aimed at modernizing medical product development to bring new medical discoveries to patients at a lower cost.

The Opportunities List outlines an initial 76 projects to bridge the gap between the quick pace of new biomedical discoveries and the slower pace at which those discoveries are currently developed into therapies. The release of the list marks a starting point in identifying priorities to be accomplished under the Critical Path Initiative. Government, industry and academic experts estimate that, if accomplished, the new tests and tools developed under the Critical Path Initiative will modernize the drug development process by 2010 and help to get new medical discoveries to patients faster and at a lower cost.

The Critical Path Opportunities List, the first specific blueprint for this nationwide modernization initiative, was developed based on feedback to the agency's 2004 Critical Path Report. The report diagnosed a slowdown in the development of innovative medical therapies, and proposed an FDA-sponsored long-term initiative to address the problem. The research projects in the Opportunities List, designed to deliver smarter tools to evaluate candidate medical products, were identified through numerous sources.The Critical Path Opportunities Report is organized into six broad topic areas: development of biomarkers, clinical trial designs, bioinformatics, manufacturing, public health needs and pediatrics.

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