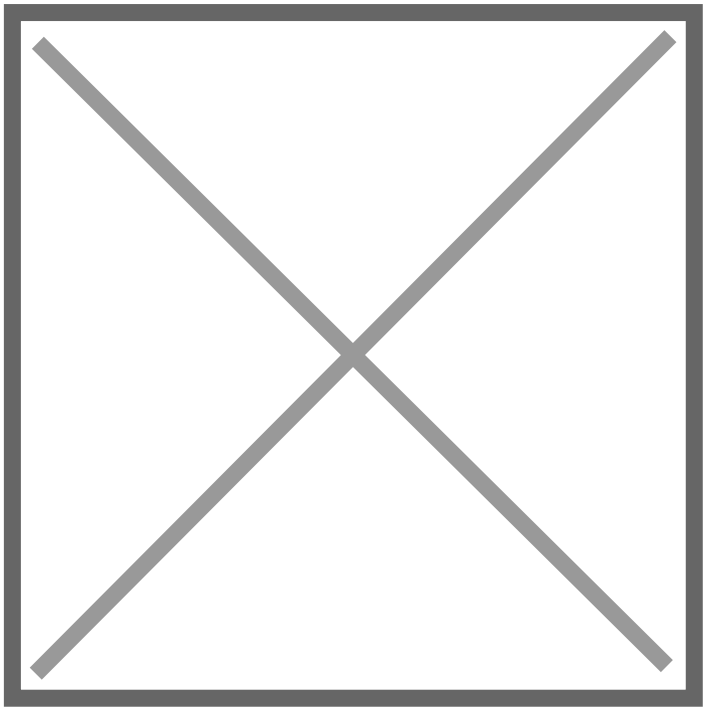


Challenges and opportunities in 2020

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India already belongs to an elite club of five nations identified as emerging biotech leaders in Asia Pacific



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Biovision 2020 for Indian Biotechnology is about predicting the ability of India's human capital to deliver intellectual and industrial value on a global scale. Some pointers are already available on the shape of things to come over the next 10-15 years:

- The biotech sector is growing at a faster pace (46 percent increase in revenue last year) in the Asia-Pacific region than anywhere else in the world, including the U.S and Europe
- Nearly half of the over 600-odd publicly trade companies are today found outside of the US, the "cradle" of the industry
- India already figures in the elite club of 5 nations in the Asia-Pacific region identified by Ernst & Young as emerging biotech leaders
- Revenues of the Indian biotech industry recorded a 37.5 percent increase last year Ã¢â?¬â?? impressive by any standard
- Mounting cost of drug discovery and development, extended timelines for bringing new drugs to market, fierce competition, pricing pressure, and funding challenges have combined to prompt pharma companies in the West to look to countries beyond their own borders on multiple fronts. A development that places India at a particular advantage.

- Opportunities for discovery research that India offers is encouraging overseas pharma and biotech companies to set up basic operations that could evolve into integrated arms of their own R&D efforts in the fullest sense. Astra Zeneca and GE, for instance, already have significant research centres in India

- Several international bio-partnerships already dot the Indian biotech landscape with more on the anvil

Promising segments
Let's now take a quick look at segments that hold the maximum promise, as well as the challenges that lie ahead:

Biogenerics and Biomanufacturing: Biological drugs today account for 10-15 percent of the world pharma industry as a whole, growing at twice the pace in some cases as, for instance, Oncology. The key drivers, from the Indian perspective, are the following:

- A number of biogenerics are slated to go off patent in the coming years, opening opportunities for Indian firms. Frost & Sullivan reckons that the US and Europe alone offer potential to generate sales of $16.4 billion by 2011. Besides, the Indian market itself is quite large, thanks to changing economic demographics

- Our competitive edge comes from strong bio-manufacturing skills coupled with low-cost base, generating high capital efficiency.

- It's now possible to establish that indigenously made biosimilar drugs are comparable and o the original products through pharmacokinetic, pharmacodynamic, and clinical studies. A plus factor from India's perspective.

- Imminent introduction in the U.S. and Europe of a regulatory framework for approving generic versions of biologicals considerably improves our sales and marketing prospects

Pharmacogenomics and Personalized Medicine: A large and diverse population coupled with high incidence of genetic disorders makes India an ideal setting for pharmacogenomics research. Growing interest in individualized therapy to improve drug efficacy has prompted huge investments in pharmacogenomics research. India's growing capabilities in research, clinical development and bio-manufacturing should give it a decisive edge in the development of personalized medicine.

Diagnostics and Theranostics: An offshoot of personalized medicine is the emergence of New Age diagnostics based on genetic and protein markers as well as other metabolite based bio-markers. Today's diagnostics track disease progression, drug response, and are designed to customise therapy in a differentiated manner. Theranostics - as such diagnostics are often described - are growing at an exponential pace, attracting sizeable investment in the Biotech sector.

Biometrics and Bio-IT: Drug research, as they say, is data rich but information poor. This is where Biometrics comes in. With nearly 20 percent of drug discovery program today based on genomics and the mounting pressure to shorten drug development time and cut costs, Biometrics has come into its own. With acknowledged strengths in computing software and services and notable cost-benefit advantages, India could significantly improve its share in the global market. Clinical data management represents the largest segment in this space. India is already a preferred hub for global data management, with several international CROs and MNC pharma companies choosing to locate their data management centres in the country.

Contract Research and Clinical Services: Partnerships with overseas companies has progressed beyond APIs and solid dosage formulations. The growing pressure on big Pharma to reduce the cost of new drugs has created an opportunity for contract research and clinical trials in lower cost environs like India and China. What started as, simple project-by-project outsourcing is giving way to enduring, long-term relationships, often involving shared IP. Service providers are slowly but surely transforming themselves into solution providers, enhancing their capabilities, developing proprietary technologies, and specializing in niche areas to stay ahead of the competition. Overall, the prospects of Indian contract research firms garnering a bigger share of the estimated $33 billion market have never seemed brighter.

In clinical development as well, India is already perceived as a favorable destination, thanks to growing compliance with internationally harmonized standards such as GCP plus inherent cost advantages and speed of patient enrollment . Indications are that the Indian CRO industry, currently growing at a rate of 40-50 per cent, could well become a multi-billion

dollar enterprise by 2015.

Phase 1-4 clinical trials apart, Indian companies would do well to exploit opportunities in "pre-clinical" as well as "proof-of-concept" studies. Proof-of-concept studies, undertaken in India ahead of expensive clinical trials in the U.S., are seen as an emerging strategy to bring in more predictability in drug development Likewise, lower clinical development costs in India can enable multiple indications to be clinically evaluated simultaneously, especially for diseases like cancer.

Stem Cells and Regenerative Medicine: The prevalent socio-economic sensitivities in the West provide a window of opportunity for Indian scientists and biotech companies to have a heard start in regenerative medicine. Still a new field, regenerative medicine promises innovative and affordable approaches to addressing the "double burden" of infectious and non-communicable diseases such as cancer and diabetes that plague developing countries, further stretching their already fragile health systems. Scientific and political challenges notwithstanding, stem cell research and technologies hold enormous promise, particularly in the Indian context.

Biofuels and Enzymes: Dwindling reserves of fossil fuel, mounting oil prices, and increasing quantities of greenhouse gases has accelerated the focus on promoting production and use of alternative fuels derived from renewable raw materials. In this process, industrial biotechnology plays a key role, with the use of a variety of enzymes helping to produce fuels from renewable biomass sources. Considering India's increasingly vulnerability on the energy security front, biofuels and industrial enzymes decidedly represent an area of opportunity for Indian biotech.

GM Crops and Agri Biotech: Prime national concerns such as poverty reduction, food security and employment generation provide the impetus for agri-biotech in India, which ranks next only to China in food production. That by itself makes it a huge market for biotechnology products. Excellent scientific infrastructure in agriculture, rich bio-diversity and low-cost manpower combine to provide the right environment for agro-biotech initiatives, including biologically engineered crops.

Challenges ahead
Several "positives" characterize the current Biotech scene, from the Indian perspective. These include the skyrocketing cost of new drug development, extended time to market, pricing pressures and funding challenges that increasingly shackle the industry in the West. Considering India's intrinsic strengths in Biotechnology and the strides that the industry has already made in a short time span, these developments can work to India's advantage. But several challenges still remain to be addressed should India aspire to joins the ranks of the truly powerful players in the industry:

- The need to further streamline our regulatory framework to meet global standards is imperitive. The sooner we have a well-equipped statutory national regulatory body to oversee all aspects of regulation the better
- More than any other high-tech business, biotech depends on close industry-academia linkages. The importance of a well-conceptualized, nation-wide framework that fosters systematic exchange of knowledge/information, networking, and understanding between academic and industry cannot be overemphasized.
- While government policies have been largely supportive, there's need for more innovative, substantive, and priority funding, and that includes funding from venture capital firms who somehow seem too coy of financing biotech initiatives
- Standards of biotech education and training vary vastly across the country, prompting the need for an independent statutory authority to lay down standards and ensure compliance.
- Concerted efforts are necessary to popularize biotechnology as a rewarding carrier; equally the need to revamp life-sciences curricula at the under-graduate and post-graduate levels to reflect contemporary advances in the field aligning them with contemporary advances in the field
- Finally, we need to move from an "imitative" culture toward a "patent" culture in our all R&D endeavors

In sum, given the inherent strengths of the Indian Biotech sector, the capacity and capability-building exercises underway, growing number of international bio-partnerships, and opening up of new opportunities, the industry is certainly set on a fast-growth trajectory. How successful we are in sustaining Ã¢â?¬â?? and building Ã¢â?¬â?? on this momentum would determine whether we would rank amongst the truly powerful players in this space two decades hence.