

Biotechnology, India

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Biotechnology in India holds a great promise in the future.

When Watson and Crick discovered the double helix structure of DNA in 1953, it was a major breakthrough in biology. The last five decades have seen some truly amazing developments in the field of biotechnology. We are on the threshold of a new and exciting era where basic sciences, powered with proteomics, genomics, metabonomics, high-powered computing and bioinformatics and increased focus on evidence-based medicine are poised to revolutionize the way we treat diseases.

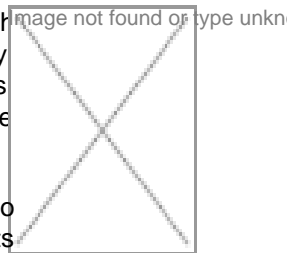
Simply defined, biotechnology deals with the application of biological knowledge and techniques pertaining to molecular, cellular and genetic processes to develop significantly improved products and services. Its applications range from agriculture, industrial and medical biotechnology.

As the regional head of a global pharmaceutical company, I would elaborate on biotechnology and bioinformatics as used in our pursuits of diagnosing diseases and curing them with newly developed drugs

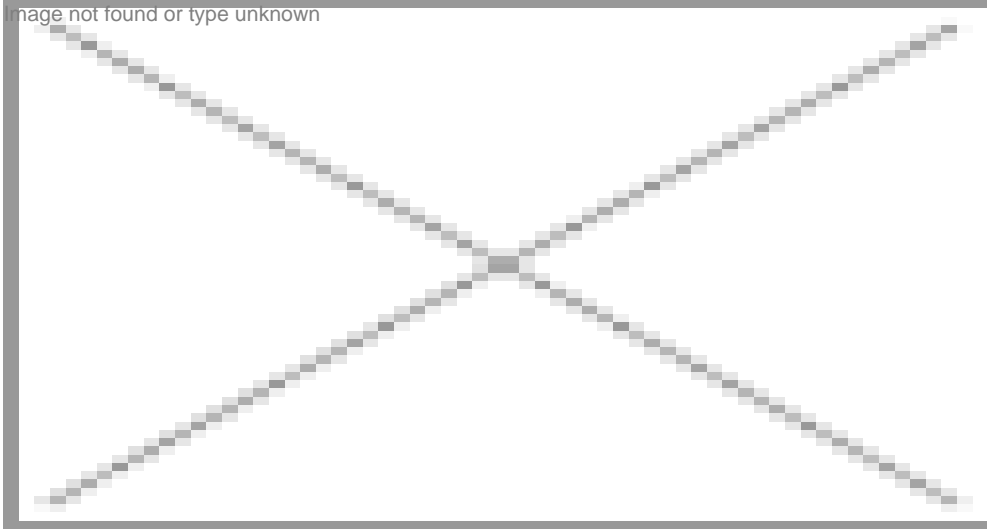
Where will biotechnology add value in drug discovery?

Biotechnology can potentially add value at every step in modern drug development—from Discovery Research to Commercialization.

For example at early stage in drug development, genetics plays a vital role in identifying new drug targets, disease



mechanisms and refining high throughput screens. Modern genetics is expected to even identify the right medicine for the right patient. In other words, not too far from now, we may have drugs tailor-made for individual patients to maximize efficacy and minimize side effects



Like genetics, metabolomics is expected to have a compelling impact on diagnosis and treatment of diseases. Metabolomics is the quantitative measurement of time-related multiparametric metabolic responses of multicellular systems to pathophysiological stimuli or genetic modification.

Research in biotechnology can also have huge applications in "diseases of the developing world". For example, scientists at the Imperial College in London are working on pioneering basic research to develop new methods to control malaria. The

approach is a fundamental change in strategy-to attack the parasite in the vector rather than the human subject.

Three concepts are being explored:

1. Determination of structure/function of parasite molecules regulating infection of mosquito so as to develop anti parasitic vaccines & drugs
2. Analysis of mosquito immune responses that kill parasites so as to identify genes needed to design genetically modified refractory insects
3. Methodology needed to construct GM mosquitoes and to drive the genes into natural insect population.

GSK's contribution in biotechnology

Recognizing its immense potential in discovery of breakthrough medicines, biotechnology is now a key investment area within GSK global R & D.

GSK biotechnology research has resulted in some major breakthroughs in drug discovery. Scientists at Glaxo Wellcome (now GSK) identified PPAR γ as the receptor for a group of drugs called Glitazones. This opened up a completely new way of treating diabetes with insulin sensitizing drugs.

Scientists at GSK have used pharmacogenetics to improve the risk benefit ratio for Ziagen, an antiretroviral drug. Ziagen is a highly effective Anti HIV medicine. But Hypersensitivity reactions occur in 5 percent of the patients. Scientists at GSK compared the DNA of patients who experienced hypersensitivity reactions with those who did not, looked for differences in genes that may be involved in the reaction and thereby identified patients at risk

A number of new vaccines, especially for the developing world, are either on way to the market or at late stages of development. Our breakthrough offering will be in the form of a cancer prevention vaccine called Cervarix, which will provide Indian women protection against HPV, which causes cervical cancer.

About 1lakh children die in India every year due to gastro enteritis caused by Rota virus. GSK's Rotarix offers an opportunity to save their lives. GSK also has a late stage vaccine candidate for malaria. If clinical trials find our confidence in the vaccine appropriate, it will start providing protection to the world's children from falciparum malaria in a few years from now. Work is also on for developing new vaccines for protection against TB, Dengue and HIV.

Bright future for Biotechnology in India

With such exciting prospects, it is not surprising that the global biotech industry is expected to grow in leaps and bounds.

Sales of biotech products are slated to reach over \$ 60 billion by 2015.

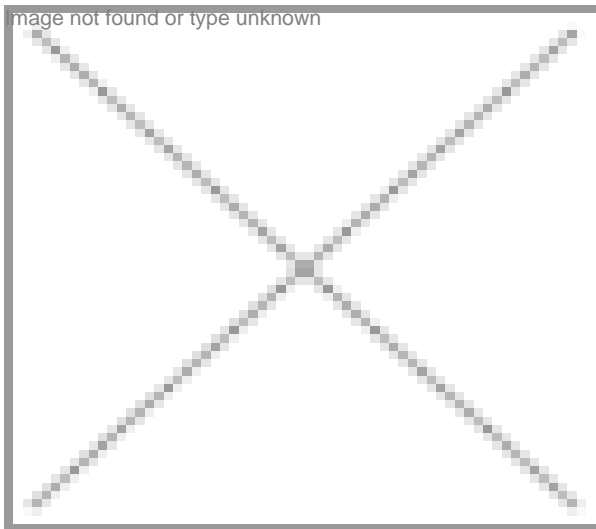
According to a recently concluded study, Indian biotech industry's R&D and services will reach a turnover of \$3 billion by 2010 and bioinformatics market will cross \$2 billion. The size of Indian pharmaceutical market is currently estimated to be \$4.5 billion. In other words, biotech and bioinformatics together are going to develop into a huge market in next five years, equivalent to today's pharma industry.

This truly presents an unprecedented business and career opportunity in the years to come, fully deserving to be called India's supernovas.

Some of India's strengths include:

- A knowledge pool in biosciences and engineering of over 3 million graduates, 700,000 post graduates and 15,000 PhDs
- A strong multinational presence offering Indian talent exposure to cutting age technologies and opportunity to work in state of the art research projects
- A significant presence in areas such as conventional generics and track record based on process engineering skills.
- Cost advantage
- A robust IT industry which has already established India's credentials as a viable investment destination, and
- Presence of a well-defined user industry, i.e. pharmaceutical industry

The recent introduction of Intellectual property law provides just the right kind of environment to encourage research in this highly potential area. What would be more important would be data exclusivity to provide even a better environment for scientists and the industry to invest in biotechnology.



The biotechnology sector in India is growing rapidly at a rate of over 40 percent annually. India is the largest producer of recombinant Hepatitis B vaccine in the world today. The country is also emerging as global player in recombinant Human Insulin. In addition, Indian vaccine market, which is over \$100 million, is growing at over 20 percent annually. As vaccines are one of the most cost-effective healthcare interventions, I expect the government of India to expand its programme of immunization in the years to come. When this happens, the Indian vaccine market will grow exponentially.

Clinical services are now a global opportunity for India with a strong competitive edge based on speed and quality of clinical development. GSK India is currently conducting 9 clinical trials for its parent. This number is likely to increase significantly in the future. GSK has plans to conduct clinical trials for Hep E vaccine with India in mind. Indian regulatory authorities have displayed mature understanding towards this project and as a result, we are getting excellent co-operation from them.

Bioinformatics and research services are yet another fast growing segment where a number of multi national companies are setting up their base in India. GSK set up its data management centre in Bangalore in 1996, much before outsourcing became a buzzword. Our teams at CDMCI handle data of our global trials and strictly conform to global standards such as ICH GCP.

I am optimistic about the country's rapidly growing strengths and capabilities in biotechnology. I am confident that it can emerge as a powerful growth engine for the Indian healthcare industry and help in its global aspirations.

S Kalyanasundaram

Managing Director,
GlaxoSmithKline Pharmaceuticals