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# 21st Century Biotechnological Research and Development Advancements for Industrial Development in India

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***Abstract*****—**Biotechnology is a discipline which explains the use of living organisms and systems to construct a product, or we can define it as an application or technology developed to use biological systems and organisms processes for a specific use. Particularly, it includes cells and its components use for new technologies and inventions. The tools developed can be further used in diverse fields such as agriculture, industry, research and hospitals etc. The 21st century has seen a drastic development and advancement in biotechnology in India. Significant increase in Government of India's outlays for biotechnology over the past decade has been observed. A sectoral break up of biotechnology-based companies in India shows that most of the companies are agriculture-based companies having interests ranging from tissue culture to biopesticides. Major attention has been given by the companies in health related activities and in environmental biotechnology. The biopharmaceutical, which comprises of vaccines, diagnostic, and recombinant products is the most reliable and largest segment of the Indian Biotech industry. India has developed its vaccine markets and supplies them to various countries. Then there are the bio-services, which mainly comprise of contract researches and manufacturing services. India has made noticeable developments in the field of bio industries including manufacturing of enzymes, biofuels and biopolymers. Biotechnology is also playing a crucial and significant role in the field of agriculture. Traditional methods have been replaced by new technologies that mainly focus on GM crops, marker assisted technologies and the use of biotechnological tools to improve the quality of fertilizers and soil. It may only be a small contributor but has shown to have huge potential for growth. Bioinformatics is a computational method which helps to store, manage, arrange and design tools to interpret the extensive data gathered through experimental trials, making it important in the design of drugs.

***Keywords*****—**Biotechnology, advancement, agriculture, bio-services, bio-industries, bio-pharmaceuticals.

## I. Introduction

FOLLOWING its independence, India has shown great success in developing a strong scientific base in the biotechnology sector through its five year plans. It has established major research and supported breakthroughs in the biotechnology industry sector in the 8th to 12th five year plans (1992-2017). For a country like India, biotechnology is a powerful enabling technology that can revolutionize agriculture, healthcare, industrial processing and environmental sustainability.

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The commitment of the Indian government in the biotech field "emerges out of compulsions and social commitments to minimize foreign dependence" [8]; the National Biotechnology strategy provides a policy framework and focuses on human resource development, academic and industrial infrastructure improvement and awareness building. It can provide self-sufficiency in food. Presently, biotechnology is a fast growing field and one of the most promising scientific and economic areas for success of the Indian economy and can revolutionize agriculture, healthcare, industrial processing and environmental sustainability. The manipulation of genetic material through techniques of modern biotechnology permits to develop genetically-modified organisms (GMO), which can be living genetically modified organisms (LMO) and non-living genetically modified organisms. GMO can be grouped into the following categories: transgenic crops, recombinant pharmaceutical products, genetically modified microorganisms, transgenic animals and industrial products. A more comprehensive categorization of biotechnology, based on its end-use has also been proposed. In this classification, products are described in one of the following biotechnology thematic subsets: healthcare biotechnology, agricultural biotechnology, industrial biotechnology and environmental biotechnology. Each one of these broad categories encompasses a range of products, activities and techniques [5]. Expenditure data on R&D on biotechnology are not available for several OECD countries even after having substantial business sector capabilities in biotechnology [15].

More comprehensive categorization of biotechnology can be done based on its end uses [19]. There is lot of scope to undertake research in various diversified fields under biotechnology including marine resources, agriculture, bioremediation, as well as ecology and the environment etc.

## II. Biotechnology Research and Development

The 21st century has opened various avenues for research aspirants in fields of agriculture, medicine and pharmaceuticals.

The National Biotechnology Board was set up in 1982 by Government of India, and became a full-fledged department, the Department of Biotechnology (DBT), under the Ministry of Science and Technology in 1986. At present in India, there are six major agencies responsible for financing and supporting research in the realm of biotechnology apart from other sciences. They are the Department of Science and

Technology (DST), Department of Biotechnology (DBT), Council of Scientific and Industrial Research (CSIR), Indian Council of Medical Research (ICMR), Indian Council of Agriculture Research (ICAR) and the University Grants Commission (UGC), as well as the Department of Scientific and Industrial Research (DSIR). DST, DBT and DSIR are part of Ministry of Science and Technology, while ICMR is with Ministry of Health, ICAR with the Ministry of Agriculture and UGC with the Ministry of Human Resource and Development. DSIR is the funding agency for CSIR and both of them independently fund biotechnology related research programs. In India, the developmental allocations are generally made for five years under the National Five Year Plans [18].

Reference [14] emphasized that the National Strategy for Development of Biotechnology focuses on strengthening academic and industrial research capabilities to commercialize the research. The Center for Plant Molecular Biology (CPMB) was established in 1990 by the DBT to provide advanced research in biotechnology. The Department of Biotechnology provides the support to most of the research work on crop biotechnology and GM crops. The government of India has also increased the plan expenditure for research. Establishment of the National Centre for Plant Genome Research (NCPGR) in 1998 was also was also a mile stone to support the research [13].

A large number of collaborative multi-institutional projects have been conducted in public and private sector institutes. The central government provides funds for most R&D efforts in public sector research institutes, universities and research centers. Agricultural universities receive substantial financial and infrastructure support from respective state governments and the Indian Council of Agricultural Research (ICAR), which are also involved in conducting research in biotech crops. The private sector initiated in biotechnology through the introduction of GM crops into India in 1995 [3]. Other areas of Agri-biotech research, besides the application of biotechnology to development of promising crop varieties, is related to the growing interest among public and private organizations to develop products like biodiesel, biofertilizers and biopesticides. Biodiesel and India's biofuels market is still at its infancy with only about 66 million gallons of ethanol being utilized annually [9]. It has been reported that profits for India's major biotechnologies companies, Biotech International, Excel and Multiplex, from the production and sale of biopesticides and biofertilizers have reached US$19.5 million [9]. Phosphate solubilizing micro-organisms have witnessed the highest growth among biofertilizers in India. The government policy initiatives to develop infrastructural facilities like biotech parks, a favorable intellectual property rights (IPRs) regime and encouraging a patent culture [6] are attracting investments from the private sector to develop crop biotechnology research in India. In spite of having 91% cotton area under GM varieties in India, regulation on the use of various other GM crops having have not been formulated properly, a situation that is adversely affecting research and development in the biotechnology sector [4].

The regulatory framework implemented by the Government of India has promoted the agricultural biotechnology industry and provided research funding through the Department of Biotechnology for private sector investment [17].

Various research oriented avenues leading to industrial growth have been developed and include transgenic crops, genomics and the application of markers in plant biotechnology. Development of transgenic crops has been encouraged through gene exchange, virus and anabolic system transfer of sequences from bacteria in plant biotechnology. The research in biotech crops can provide sustainable life and food security and conserve biodiversity, even at the time of variable climate and may also reduce environmental problems [10].

Biotechnology has widespread application in agriculture including crop improvement to accelerated breeding in animals. Biofertilizers and biopesticides also have increasing consumption and future industrial growth.

Reference [12] has reported the increased yield and net income and reduced cost of production of Bt cotton. Although the scientific regulatory authority approved the commercialization of Bt (*Bacillus thuringiensis*) eggplant in India in 2009, it is yet to be commercialized in the country due to the health, environmental and economic concerns associated with GM technology. This regulatory uncertainty is affecting research investments into the agri-biotech sector with negative implications on social welfare [11].

As far as biotech infrastructure is concerned, India has developed world class facilities for numerous biotech activities and techniques: "facilities for DNA sequencing, protein engineering, bioprocessing, crystallography, molecular graphics and modeling, PL3 and PL4 level containment for work on dangerous pathogens, prescribed glass/animal houses for transgenic animal/plant research, repositories of microorganisms important in agriculture, healthcare and industry, ex-situ and in-situ gene banks for crops and endangered medicinal and aromatic plants, medium and high throughput screening facilities for drugs and pharmaceuticals, biosensors, nuclear magnetic resonance machines, different mass spectrometers for various purposes, GM testing labs and recently micro arrays, automated DNA sequencing as well as robotic plasmid isolation equipment" [12]. India has Core Competence in Biotechnology Sectors [2].

1. Bioprocess Technology
2. Gene Manipulation of microorganism/animal cells
3. Extraction and isolation of plant/animal products
4. Recombinant DNA Technology
5. Traditional and Molecular Marker assisted breeding
6. Infrastructure in fabricating bio-reactors and following biotechnology sectors equipment

## III. Industrial Growth in Biotechnology

Fig. 2 shows the regulatory framework of biotechnology in India [16]. India is among the top 12 biotech destinations in the world and ranks second in Asia, after China. India is also the world's largest producer of the recombinant Hepatitis B vaccine.

India's large population, high health care expenditure, high growth in export demand and rise in medical tourism provides more opportunities to Indian biotech industries to explore for more development. Sufficient policy support has been extended through providing open excess policy in FY15, research and development funding and increased budgetary allocation in healthcare sectors by the Government of India. Growth of the Indian biotech industry has been recorded to 16.28% in FY14 and the financial outlay of the industry grew to US$7 billion from US$5 billion in FY15. This fast-paced growth is likely to continue; the industry is expected to increase in size to US$11.6 billion by 2017, driven by a range of factors such as growing demand, intensive R&D activities and strong government initiatives. With the increased clinical facilities, the scope for clinical trial, contract research and pharmaceutical manufacturing has also been expanded [1]. Table I shows the global share of Indian industry in different biotechnology services.

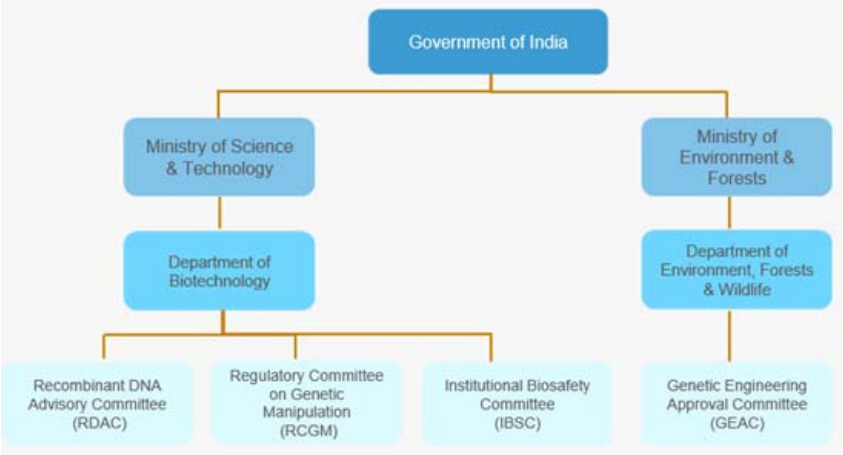


Fig. 1 Regulatory framework of Indian Biotech Sector [16]

TABLE I
INDIAN INDUSTRY SHARE IN DIFFERENT BIOTECHNOLOGY SERVICES [20], [21]

| Services | % Share, 2007-08 | | % Share, 2008-09 | | % Share, 2009-10 | | % Share, 2010-11 | |
|---|---|---|---|---|---|---|---|---|
| | Export | Domestic | Export | Domestic | Export | Domestic | Export | Domestic |
| Biopharma | 57.97 | 42.03 | 62 | 38 | 54 | 46 | 52 | 48 |
| Bio-services | 95.55 | 4.45 | 95 | 5 | 95 | 5 | 92 | 8 |
| Bio-Agri | 4.31 | 95.69 | 4 | 96 | 3 | 97 | 3 | 97 |
| Bio Industrial | 7.32 | 92.68 | 10 | 81 | 22 | 78 | 24 | 76 |
| Bioinformatics | 78.95 | 21.05 | 77 | 23 | 32 | 68 | 42 | 58 |
| | 55.81 | 44.19 | 59 | 41 | 53.04 | 46.96 | 51.32 | 48.68 |

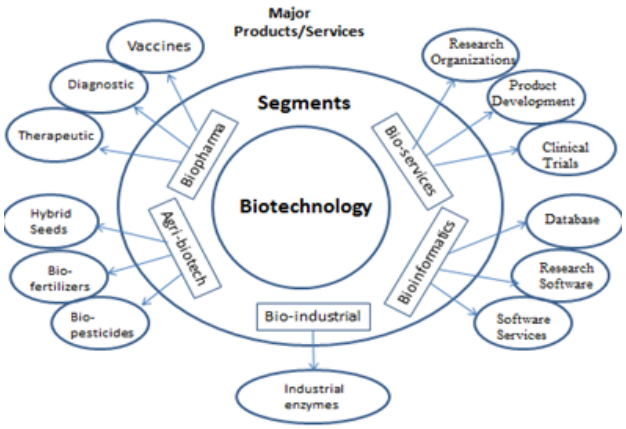


Fig. 2 Dimensions of Biotechnology

It has been observed that about 49% of biotechnology companies are agriculture based and has introduced their products in tissue culture and biopesticides. Almost 25% of those companies are active in health related activities and in medical sciences, while 26% have varied interests including environmental biotechnology. The biggest segment of Indian biotech industry is biopharmaceutical which includes vaccines, diagnostic, recombinant products.

The biotech industry mainly comprises of five distinct segments, viz. biopharma, agri-biotech, bioinformatics, bio-industrial and bio-services, as shown in Fig. 2. The biopharmaceutical are therapeutic or preventive medicines, derived from the natural materials present in living organisms, using DNA (rDNA) technology, it provides the vaccines, diagnostics and therapeutic use. The bio-services mainly include clinical research and CRO along with custom manufacturing delivered through Contract Research Organizations, Custom manufacturing and clinical Trials. Bio-agriculture is segmented in to hybrid seeds, transgenic crops, biopesticides and biofertilizers. Bio-industrial mainly comprises of enzymes manufacturing and marketing companies. Bio-informatics deals with the creation and

maintenance of database on various biological systems and provides information and analysis through available database, integrated research software and specialized software [1]. India has developed its vaccine markets, estimated in 2011, that almost 60% of world vaccines today are supplied by India. Biotech industry growth in India has been recorded as 18.5% annual rate in the 12th five year plan. Indian biopharma has become the largest segment of the biotech industry accounting about 62% of the total market share. With the private sector vaccines market growth of about 25 percent out of which 60% of the total volume of vaccines manufactured in India is exported. The India has the fastest diagnostics market growth in the world which is 20% and the molecular diagnostics has reached to 30-40% of total market share. The bio-services sector growth rate was 15.5% end of 11th five year plan. The healthcare sector has an annual growth rate of 10-12%. The healthcare sector accounts for 72%, mainly includes healthcare services i.e. hospitals, labs, physicians and other services. In the present day scenario, the traditional methods have been replaced by advance research assisted technologies which include the use of molecular markers for finding variable crop varieties, GM crops and improving the quality of fertilizers and soils. The share of agriculture in the biotechnology industry has made less contribution from 5% to 14% at the end of 11th five year plan and has not shown much growth in 12th five year plan. There are over 30 companies involved in Bt cotton seed marketing, which includes 8.4 million hectare of area under Bt cotton cultivation. The enzymes sector has shown a growth of above 11% in 12th plan and likely to grow further. The enzymes have numerous applications in the food, pharmaceutical, diagnostic and chemical processing industries. The Indian bioinformatics market, constituting 2% market share, is the smallest of the biotech industry segments its growth rate has been recorded 11.5% at the end of 11th five year plan. It also has much scope to grow [7].

## IV. Conclusion

There are sufficient initiatives in research have been taken by the Indian government which has provided sufficient indications for growth of biotechnology industry in India. Thus, biotechnology in India is entering a crucial phase and the path ahead is full of many opportunities and challenges.

A well-developed and coherent regulatory framework is essential for development of biotechnology industry in any country.

The biotechnology industry is growing but it is nowhere near the size and diversified nature of the industry in India. The number of firms involved in R&D is increasing but still small. The number of firms dedicated to R&D is very less.

Agricultural biotechnology also has lot of scope for development and this will affect the growth of biotechnology. Sustained efforts including bilateral/multilateral support and collaboration in capacity-building will benefit biotechnology industry growth in India.

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