INDIAN BIOTECHNOLOGY: THREE DECADES OF DEVELOPMENT

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Summary

This study aims to focus three decades journey of biotechnology in India. Biotechnology is three decade old in India; however this word is still modern and attractive for Indian research and media. Government promotes the manifold importance of the field of biotechnology in India as well industrial initiatives; subsequently Indian biotechnology is poised for a tremendous growth. Now India has entered advance stage of manufacturing activities and high-level biotechnology research programmes.

Introduction

The rapid economic developments in India now promote advance research and provide environment for high-level biotechnology initiatives. Indian government is devoted to enhance national technological capability and putting highest effort after freedom in all scientific and non-scientific fields. As everybody knows biotechnology is the technology of future shows the better platform for drug discovery, high cure of human health and quality environmental research for sustainable development of all kind of life. Indian government and industries are also paying their attention towards basic infrastructure of this high cost but valuable research. Indian government has an important role at the policy level to provide significant support and direction to the various activities in different fields of biotechnology.

The developments in the area of biotechnology are of particularly great interest in a developing country like India, where basic health cure facilities is not available for more than ¾ population, stage of agriculture with stagnating productivity and crops confronting many biotic and abiotic stresses, looks for growth avenues. Now India has entered in new arena of technological world, where we are recognized as well known manufacturer of rDNA drug, vaccines, enzymes pursuing high quality of research. This is the result of last three decade's efforts we had put for the development of Biotechnology in our country.

Early Years of Biotechnological Development

Biocon is India's leading biotechnology enterprise, established in 1978. biocon was the result of joint venture owned 70 percent by Kiran Mazumdar and 30 per cent by Leslie Auchincloss, owner of the small Irish global company Biocon Biochemicals.

The business was established in Bangalore and Ms Mazumdar was appointed Chairman & Managing Director. The company is an integrated biotechnology enterprise focused on the development of biotechnology and biopharmaceuticals serving partners and customers in over 50 countries[1].

The Centre for Cellular and Molecular Biology (CCMB) a pioneer organization in the field of biotechnology and molecular biology in India was set up as a semi-autonomous Centre in 1977 at Hyderabad, Andhra Pradesh. This institute became a full-fledged national laboratory during 1981-82 with its own Executive Committee and Scientific Advisory Council, and was dedicated to the nation on 26 November 1987 by the then Prime Minister of India late Shri Rajiv Gandhi. CCMB has published more than 1200 research papers mainly in reputed international journals and known one among the top 3 institutions in the country in terms of the impact factor earned from publications. For the development of science in India on a sound basis CCMB conduct training courses in advanced areas of biology, promote centralized national facilities for new and modern techniques in the inter-disciplinary areas of biology, interact with industry carrying out basic and applied work, and to collect and disseminate information significant to biological research[2].

To achieve the aim of integrated research for development and design base for microbial technology the Institute of Microbial Technology (IMTECH) was established in 1984 under the aegis of Council of Scientific & Industrial Research (CSIR). IMTECH scientists are dedicated to both basic and application-oriented research and focus to four major areas specifically:(i) Molecular Biology and Microbial Genetics (ii) Cell Biology and Immunology, (iii) Protein Science and Engineering (iv) Fermentation Technology and Applied Microbiology. Institute is undertaking basic to applied research and development programmes in established and newly emerging areas of relevant biotechnology including genetic engineering to develop and maintain gene pool resources and genetic stocks of microbial cultures and other cell lines. Biochemical Engineering Research & Process Development Centre (BERPDC) and The Microbial Type Culture Collection & Gene Bank (MTCC) are two privileged specialties of this institute. BERPDC undertakes strain improvement, feasibility studies of fermentation processes, media and process optimization, fermentation scale-up, downstream processing. MTCC is an affiliate member of the World Federation of Culture Collection (WFCC) and is registered with the World Data Centre for Microorganisms. The Main objectives of this national facility are to act as a depository, to supply authentic microbial cultures and to provide related services to scientists working in research institutions, universities and industries[3].

To keep a vision of development of the field of modern biology and biotechnology in India, Department of Biotechnology (DBT) was established in 1986, under the Ministry of Science Technology. The department has made significant achievements in the growth and application of biotechnology in the broad areas of agriculture, health care, animal sciences, environment, and industry through several R&D projects, demonstrations and creating infrastructural facilities for better research. More than 5000 research publications, 4000 post-doctoral students, several technologies transferred to industries

and patents filed including US patents, are the evidence of its dedication to development of science in the country. Department of Biotechnology (DBT) not only continuously interacting with more than 5,000 scientists per year in order to utilize the existing expertise of the universities and other national laboratories but also has close interaction with the State Governments particularly through State Science & Technology Councils for developing biotechnology application projects, demonstration of proven technologies, and training of human resource in States and Union Territories to create a strong platform for quality research work[4].

New initiatives in Next Decade

An autonomous institution, National Institute of Immunology (NII) was established in 1887 and supported by the Department of Biotechnology, Government of India for the development of immunology research. The Institute is dedicated to advanced research addressing the basic mechanisms involved in body defense, host-pathogen interactions and related areas. The research direction of institute mainly focused in four major areas; gene regulation, immunity & infection, molecular design, and reproduction & development. The institute provides platform for basic and applied immunology research with a view to contribute to the creation of an internationally competitive intellectual knowledge base as a sustainable source of pioneering modalities of potential use in health care and also maintains so many national and international patents. Some good technology has been produced by institute and transferred to industry. Bioinformatics Center (BIC) at NII set up by the Department of Biotechnology, as one of the ten distributed information centres under the Biotechnology Information System (BTIS) program is another achievement of the institute[5].

Bangalore Genei, a division of the Sanmar Speciality Chemicals Ltd, and a member of The Sanmar Group, Chennai was established in 1989 by a scientist couple. Bangalore Genei was the first to start manufacturing and marketing research biochemicals like restriction enzymes & other tools for DNA based R&D for biotech research in India. Today the GeNei™ brand is well recognized by leading research centers and academic institutions in the country and now a major supplier of restriction enzymes, DNA vectors and equipment needed for biotechnology research in South Asia[6].

Being a part of the 'Tata Institute of Fundamental Research' (TIFR), a young research center specializing in biological research National Centre for Biological Sciences (NCBS), was established in 1991 at Bangalore, Karnataka. Researchers at NCBS use advanced experimental and computational approaches to the study of molecules, cells and organisms. Institute mainly focus on basic research in the broad areas of biochemistry, biophysics & bioinformatics, cellular organization and signaling, genetics and development, and neurobiology; and also encouraging participates in a major initiative on physics in biology emphasizing the interface between biology and the physical sciences[7].

Centre for DNA Fingerprinting and Diagnostics (CDFD), an autonomous centre of the Department of Biotechnology (DBT), Ministry of Science and Technology, Government of India was established in 1995 aiming to decipher role of frontline areas of modern

biology for the benefit of society. The main research areas of CDFD involve DNA fingerprinting, diagnostics, genome analysis and bioinformatics. This institute has a clear vision to find out the complex answer of modern biology, especially in the post genomic scenario. In addition to DNA Fingerprinting and Diagnostics services provided by the centre, institute has initiated several new activities in curious areas of modern biology such as bacterial genetics, molecular pathogenesis, cancer biology and metastasis, computational biology, structural and functional genomics, immunology, gene expression and cell death, host-parasite interactions, cellular signaling, etc[8].

Bharat Biotech International Limited, Hyderabad is a multidimensional biotechnology company established in the year 1996 by Dr. Krishna M. Ella & Mrs. Suchitra K. Ella as the Founder Directors. Bharat Biotech was first bio-pharma company in India to manufacture injectables (small volume parentals) for the Korean market and a preservative-free vaccine for regulated markets. The company has an R&D centre at Genome Valley, Hyderabad with core competence in the fields of molecular biology, microbiology, virology, immunology, biochemistry, clinical research and industrial biotechnology[9].

Decade of Major Achievements

Shantha Biotechnics Ltd was established in 1993 as an initiative of Dr. K I Varaprasad Reddy with a dream to develop efficacious but cost effective vaccines and therapeutics that are within the easy reach of the common man. Shantha Biotechnics was first Indian company to develop, manufacture and market Shanvac-B, an r-DNA hepatitis-B vaccine in 1997. SHANVAC- B' an indigenously developed first Indian hepatitis B vaccine and Shantetra (combination of DPT & Hep B) are pre-qualified by WHO, Geneva for supplying to UN agencies globally[10]. The entry of Indian companies, with their own brands of recombinant products, has changed the scenario of the domestic market in India and now India known as the 'vaccine hub' of the world as many local companies are selling vaccine in the domestic and world market at affordable prices.

Monsanto, a St. Louis based agricultural company had establishes an R&D center at world-renowned The Indian Institute of Science (IISc) in Bangalore for plant genomics in 1998 and could able to successfully utilize India's strong knowledge base and its varied natural resources to develop numerous agri-biotech products. Department of Biotechnology (DBT) in April 1998 had approved Mahyco -Monsanto to conduct small trials of Bt cotton 100 g per trial.

1999 was the year when NCBS scientist founded Avesthagen, a genomics company. The principle founder of company was Dr. Villoo Morawala-Patell. Avesthagen. Being a science and discovery based life sciences company focus on biotechnology, bioinformatics, food, pharmaceuticals and clinical genomics. Today, the company has four main strategic business units. The units are (i) Biopharmaceutical (ii) Biotherapeutics (iii) Food for medicine (FFM) (iv) Agri-biotech activity ("seed for food")[11].

In addition to the Central Government initiatives, many state governments have also realized the benefits/importance of biotechnology industry. And then state governments of Andhra Pradesh, Tamil Nadu, Karnataka and Maharashtra announced biotech initiatives to formulate their policies, develop R&D centers to encourage the biotech industry in 2000. Some of these state specific biotech policies are as follows: Government of Andhra Pradesh, in collaboration with the ICICI Limited, has set up a Knowledge Park near Hyderabad then development of Genome Valley and Biotech Park with state-of-the art features, an area covering 600 sq. kms. The Government has initiated many business friendly policies such as 'Single Window Clearance' mechanism geared to relieve the problem of red tape. The Government of Tamil Nadu is facilitating in the setting up of the biotechnology enterprise zones (biovalleys) along the lines of Silicon Valley to exploit the bio resources of the state and they are determined to develop new biotech park, bioinformatics and genetics center in service of nation. The Maharashtra government is promoting biotech parks, R&D centers, and pilot plant facilities for underway contract research by putting equity stakes in such projects. The Karnataka government has announced a biotech policy to promote not only biotech but also bioinformatics sector. State government has shown interest in creating a biotechnology for incubation of new projects and promotion of the sector in the state. Three 'biotech parks' are emerging in the Karnataka state, namely 'University of Agricultural Sciences' in Banglore, 'Institute of Agri-biotech' in Dharwad and 'Institute of Biotechnology' in Karwar.

Reliance Group is the largest private sector enterprise in India incorporated Reliance Life Sciences in Mumbai in the year 2001. This institute has big set up for biopharmaceuticals research, molecular diagnostics and genetics, cell-based therapies, plant tissue culture, plant metabolic engineering, biofuels, biopolymers, biochemicals and clinical research. Reliance Life Sciences is providing new opportunities for research, process development, pre-clinical studies and human clinical trials[12].

Wockhardt limited launched its recombinant human insulin, Wosulin in September 2003 and became the first Indian company to launch recombinant human insulin in Asia. Company launched Biovac-B, a recombinant vaccine from their joint venture with the German biotechnology company, Rhein Biotech GmbH. During 2005, Wockhardt had launched a new generation hepatitis A vaccine in India, under the brand name Biovac-A in collaboration with Zhejiang Pukang Biotechnology Company Ltd of China[13].Few more important achievement can be discussed as Syngene International, country's first a drug discovery-based Custom Research Company (CRC) was promoted by Biocon in 1994, country's first Bionformatics company Strand Genomics formed by four IISc professors in 2000. This was the start of commercial Bioinformatics in India.

Research Councils of India

The Council of Scientific and Industrial Research (CSIR) was established in 1942. It is India's leading research and development organization with 40 laboratories and 80 field stations/extension centres spread all over the country. CSIR offers programmes in the

area of industrial biotechnology, agro-biotechnology and toxicant identification control etc. maintaining balance in basic research and market needs[14].

Indian Council for Medical Research (ICMR) is another major institution working in the area of biotechnology, which comes under the Ministry of Health. To govern 22 permanent institutes and 6 regional medical research centres, it is one of the major scientific working authorities to promote, co-ordinate and formulate biomedical and health research. ICMR carries out research in communicable diseases, contraception, maternity and child health, nutrition, non-communicable diseases and basic research[15].

Under the Ministry of Agriculture, Indian Council for Agricultural Research (ICAR) lead agricultural research in India and represents 48 ICAR Institutes, 5 Bureaux, 30 National Research Centres, 138 Substations of ICAR Institutes, 561 Krishi Vigyan Kendras (KVK), 41 State Agricultural Universities (SAUs), 1 Central Agricultural University and 4 Central Universities having faculty of agriculture. The Council is engaged in conducting research in the field of agriculture, soil and water conservation, animal husbandry, fisheries, dairying, forestry and also in agricultural education[16].

Market Scenario of Recombinant Products

Own brands of quality recombinant products, has changed the dynamics of the domestic market in India. The Indian government has granted marketing licenses for about 25 recombinant protein therapeutics. These include insulin, alpha interferon, hepatitis B surface antigen based vaccine, GM-CSF, G-CSF, blood clotting factor VIII, erythropoietin, streptokinase, human growth hormone and follicle stimulating factor. Medical proteins such as relaxin, rennin, the interleukins and tumor necrosis factor also offer market opportunities. Local companies have set up the expertise to develop and manufacture seven recombinant biotech products are: hepatitis B vaccine, streptokinase, human insulin, G CSF, erythropoietin, human growth hormone and interferon alpha 2b and rest all are imported and marketed in India. After launching Shanvac-B, an indigenously developed hepatitis B vaccine by Hyderabad-based Shantha Biotechnics, many other companies like Bharat Biotech, Biocon, Biological E, Cadilla, Dr Reddy's Labs, Intas Pharmaceuticals, Panacea Biotec, Serum Institute and Wockhardt have left their mark in developing and manufacturing recombinant products, now India is called 'vaccine hub'. Wockhardt, Biocon and Shreya Life Sciences are Indian leader of human insulin[16].

Biotechnology Parks

Biotechnology Parks support high quality biotechnology research in India. With a view to promote quality research in biotechnology and its applied fields central and state governments had taken initiatives to established Shapoorji Pallonji Biotech Park-Karnataka, ICICI Knowledge Park-Andhra Pradesh, International Biotech Park-Maharashtra, Lucknow Biotech Park-Uttar Pradesh, Ticel Bio Park and Golden Jubilee Biotech Park for Women Society-Tamil Nadu while 20 more biotech parks will be set up throughout the country as announced by government of India[18].

Conclusion

In recent years, the biotechnology sector in India is accelerating tremendous growth. Active government support and increased investment - both public and private led India to established, world-class infrastructure and skilled human resources. Nowadays India is becoming one of the most favoured destinations for collaborative R&D, bioinformatics, contract research, manufacturing and clinical research as a result of growing compliance with internationally harmonized standards such as Good Laboratory Practices (GLP), current Good Manufacturing Practice (cGMP) and Good Clinical Practices (GCP). In addition, a change in the production profile of the manufacturing sector with new molecules, enzymes and recombinant products enforcing employment and accelerated economy of India. Availability of biotech parks and industry friendly state biotechnology policies, rich biodiversity and natural resources, large pool of skilled manpower and major market for biotechnology products makes Indian biotechnology attractive globally.

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