

# LifeScienceWorld

Online magazine on Pharma & Biotech industry

Guest Desk March, 2013

## Opportunities for Research and Applications in Biotechnology



### Dr. B.M.Gandhi

In the last decade Asia has emerged as the major business growth market for biotechnology, full of potential with endless opportunities in biopharmaceuticals, pharmaceutical, Nutraceuticals and Functional Food industry. There is a gradual trend for global biotechnology companies to turn to Asian markets and local research institutes for R&D collaborations business interactions.

Major emerging markets especially China, India, Singapore, Thailand, Malaysia, Indonesia and Vietnam are attracting lot of investments in healthcare sectors including Therapeutics, Vaccines, Speciality Drugs and Modulators, Diagnostics, Medical Tourism etc. China, India and Singapore have already developed as major hub for R&D developments related to Biotech Industry

In India, the Biotech Industry in the last decade has registered an annual growth rate in the range of 15 – 20 % CAGR (compounded annual growth rate). With this rate, it is expected that Biotech Industry has a potential to grow from the present about US\$ 4 billion to US\$ 8 billion in 2015 and would further increase to 30% growth to reach US\$100 billion by 2025.

The Indian Government investments in S&T sector increased from about Rs. 10,000 crores during 8th Five Year Plan to 150,000 crores during 11th Five Year Plan, with the Department of Biotechnology (DBT) investing in biotechnology from Rs. 400 crores (US\$ 88 million) during 8th Five Year Plan to Rs. 15,000 crores (US\$ 3.6 billion) during 11th Five Year Plan, a 16 folds increase during the period.

The Indian Research and Development capabilities in biotechnology have received a big boost in its credibility with publications from the Indian scientists registering a jump from the 13th position in the world to 10th position.

### Research and Development:

The major areas identified for R&D include Genomics; RNA Biology; Proteomics; Metabolomics; Computational Biology; Systems Biology; Synthetic Biology; Regenerative Medicine and Tissue Engineering in Stem cell Biology; Novel Animal Models; Nano-Biology and Medicine. Priority areas have been identified to include Biotherapeutics; Vaccines and Adjuvant both for human and animals; Diagnostics; Biomarkers: Biosensors; Bioengineering;

Bioenergy; Bioequipments; Bioimplants and Medical Devices; Biosimilar Manufacturing; Nano-Biotechnology; Novel Protein Therapeutics; Transgenic Crops and Marker assisted breeding; Nutraceuticals and Functional Foods

Specific R&D efforts may be directed to improve understanding of basic biology and cellular and molecular pathways to identify new targets for vaccines and therapeutics; research on protein-protein interactions; interaction between the human immune system and the causative agents and expand research on anti-infective resistance mechanisms and develop approaches to overcome them; and targeted drug discovery including antagonists and agonists. Enabling studies may include use of genomics and bioinformatics tools in system biology mode for predicting common pathogen and host targets; simulation models for prediction technologies; developing tools for quick and sensitive diagnosis of diseases; and promote discovery and development of natural anti-microbial proteins, such as defensins

## **Translational research:**

Modern biotechnology in medicine and health care has strongest value in biopharmaceuticals, followed by *in vitro* diagnostics and vaccines. Emerging biotechnology applications in medicine and health care cell-based therapies; tissue engineering; application of stem cells; gene therapy; antisense and RNA interference (RNAi)-based therapies; therapeutic vaccines; pharmacogenetics; and nanomedicine.

Biotechnology sector, is leading to increased opportunities for innovation driven start-ups. Clinical and translational Science is important to convert knowledge to solutions. Applied research and product development experiments should target to develop multivalent and multiplex broad spectrum vaccines and drugs, develop appropriate animal models to support efficacy studies, novel delivery systems and temperature stabilization technologies; develop new classes of antibiotics; evaluate immunomodulators as adjunct treatment; evaluate novel adjuvant to increase potency of vaccines and reduce number of doses required for maximum protection; and develop universal expression frameworks like. RNAi and monoclonal antibody based therapeutics. Regenerative medicine and tissue engineering technologies stem cell research and therapy.

**Exciting areas**, being explored for further development are platform technology for drug discovery; drug delivery using the technologies of nano particles; broad spectrum activities; fusion technologies linking antiviral DNA sequences and anticancer DNA sequences; innovative therapeutic vaccines; adjuvant technology platform in combination with well established antigens and cell-line for large scale manufacturing; RNAi Technology Platforms

## **New Generation vaccines**

In India, a number of new generation vaccines are in different stages of development. Clinical trials are going on for recombinant cholera vaccine, live attenuated rotavirus vaccine, Mw tuberculosis vaccine and anthrax vaccine while rabies vaccine has already completed animal trials and is being taken up for human clinical trials. Other vaccines such as malaria vaccine, Japanese encephalitis vaccines, and tuberculosis are in the stage of preclinical toxicology. New initiatives are taken for Papillomavirus vaccine.

## **Therapeutic areas**

Leading therapy class would include oncology, antidiabetics, respiratory, lipid regulators, angiotensin inhibitor, autoimmune, HIV antivirals, platelet aggregation inhibitors and Alzheimer's. Disease conditions being explored for new product opportunities are oncology, neuroscience, diabetes; central nervous system disorders such as

ADHD, nocturnal hypertension, Parkinson, Alzheimer and pain; bio implants including prosthetic hips and knees; biomaterials; oncology and autoimmune diseases including hematology and inflammation; development and use of high throughput screening, x-ray crystallography and medicinal chemistry; new molecular targets directed toward cancer recurrence and metastasis; anti-infectives and cosmeceuticals; developing antiviral proteins. By modelling intelligent designs;

There is a further need to develop novel therapeutics having different mode of action as well as to currently used pharmaceuticals in areas of particular clinical need, e.g., Influenza, Inflammation, multi drug resistance, central nervous system disorders and prosthetic joints, platform technology,

**Supplementary facilities** require expanding *in vitro* and *in vivo* screening resources; preclinical services including pharmacology and toxicology, improve bioavailability; characterization and evaluation of candidate products; expanding clinical trial capabilities; manufacturing platforms for rapid and cost-effective production of therapeutics; and designing adaptive diagnostic systems that allow for simple and rapid incorporation of additional targets.

## Diagnosics

In-vitro diagnostics is a huge global market. The core diagnostic and therapeutic segment comprising primarily of pharmaceutical, [medical device and diagnostics](#) companies is estimated at \$25 billion and is expected to grow by 10 percent annually. Personalized medicine, based on individual's genetic variation is attracting a huge market. Advances in genomics, proteomics, metabolomics, aided by human genome information helps in development of "targeted" diagnostics and therapeutics with improved efficacy of treatments and health outcomes. In India, though a number of diagnostics including that for *Japanese encephalitis*, HIV-I & II, hepatitis-C, leishmaniasis, alpha-feto protein, reproductive hormones, dengue, hepatitis-A have been launched in the market, there is a huge scope for development of other diagnostics and 3rd or 4th generation technologies using genetic markers, platform and biosensor technologies.

## Agriculture

A number of transgenic have been developed for crop improvement around the globe and large areas are already under cultivation. In India, Bt cotton is commercialized and over 13 transgenic are under different stages of development including that for mustard hybrid developed with barnase / barstar gene; potato with high protein content (Ama1 gene) under field trial; transgenic tomato with reduced oxalate content. Other products under development include cotton for insect and viral resistance; rice for biotic and abiotic stress; sugarcane for insect resistance; mungbean; virus resistance; and tomato for virus resistance. DBT has identified five city clusters and virtual network centres for advanced targeted research and multi-institutional functional genomics programmes. In the areas of biofertilizers, technologies have been commercialized and products are available in market for mycorrhizal biofertilizers and biopesticides.

Modern biotechnology provides large opportunities in primary production and the agro-food sector mainly in breeding and propagation of crops, livestock and fish, using genetic markers, genetic modification and embryo transfer; feed additive production; veterinary and food diagnostics, genetically modified crops and food; veterinary vaccines, enzymes for food production etc.

**Industrial and environmental technologies** like bioremediation; biodegradation; bioleaching; and metagenomics studies using fingerprinting microbial communities are widely being explored. Modern biotechnology in industrial production processes, energy and the environment provide opportunities for enzyme-

based technologies for better textile finishing and textile dyes; pulp and paper manufacturing; detergents; development of biodegradable plastics/biopolymer; antibiotics, amino acids, drug compounds; bioethanol production; new bio efficient technologies for, industrial waste management, development of new products from the waste materials including packaging for treating industrial effluents.

## **Collaborations**

Global alliances play a pivotal role in public health high impact technologies and product partnership opportunities in stage drug discoveries. India has already entered into international partnerships for development of vaccines, biodesigns and affordable healthcare. Global partnerships with number of countries is already been used to foster relationships in terms of joint R&D, fellowships and human resource development. Possibilities are increasing for our biopharmaceutical industries to develop business relationships with regional companies' for middle to late stage developments and distribution of new molecular entities to the global market.

## **Role of Funding agencies**

In India R&D in biotechnology is funded mainly through public funding under the Ministry of Science and Technology, Ministry of Health and Family Welfare and Defence Research and Development Organization. Only 10% funding for research comes from private sector. The Department of Biotechnology (DBT), through its various initiatives has launched funding programs for human health, animal health, agriculture, food technology and green energy for developing safe and affordable technologies and products in both basic and translational space for industries and academic institutes. To support these initiatives programmes have been launched human resource development and infrastructure has been strengthened.

## **Biopartnership with PPP**

Major programmes have been launched to support R&D with participation and interaction of academics with industries under the Private-Public-Partnership to translate products to boost economic growth. Technology Development Board (TDB) (DST) helps translate indigenous research into commercial products and services; The Small Business Innovation Research Initiative (SBIRI) (DBT) supports the high-risk pre-proof-of-concept research and late stage development in small and medium companies lead by innovators; The New Millennium Indian Technology Leadership Initiative (NMITLI) (CSIR) provides a boosts to the nationally industry originated projects; and Pharmaceutical Research and Development Support Fund (PRDSF) by Drug Development Promotion Board (DDPB) (DST) supports research in all systems of medicine including setting up of facilities. A Public Sector Biotechnology Industry Research Assistance Council (BIRAC) has been set up by DBT as enabling platform to transform innovation for affordable product development. Innovation, accessibility, high impact technologies, quality bio-manufacturing and affordability are considered as key measures for bio economy.

## **Scientific and innovation awards**

For creating scientific and innovation leaders, opportunities have been created for excellence in R&D in life sciences and a number of awards have been instituted which includes: National Bioscience Awards for Career Development (DBT); Innovative Young Biotechnologist Award (DBT); National Woman Bioscientists Awards (DBT); Third World Academy of Sciences (DBT); Biotech Product, Process Development & Commercialization Awards (DBT); Better Opportunities for Young Scientists in Chosen Areas of Science and Technology (DST); Fast Track

Scheme for Young Scientists(DST); Distinguished Biotechnologist Award (DBT); Biology Scholarships (DBT); and Cutting-edge Research Enhancement and Scientific Training award (DBT).

## **Fellowships**

New fellowships have been instituted to support joint programmes and re-entry grants like Ramanujan Fellowships (DST); Ramalingaswami Fellowship (DBT); Swarnajayanti Fellowship (DST); Visiting Scientist from Abroad (DBT); DBT - Welcome Fellowship (DBT); Tata Innovation Fellowship (DBT); DBT- Stanford Fellowships for Biodesigns (DBT); JC Bose National fellowships (DST). Young Scientists are being encouraged for fast track research grants; rapid travel grants; small science meetings; career development awards; associateship for specialized training of young scientists in niche areas of biotechnology in foreign laboratories.

## **Infrastructure**

In the last five years a number of new universities and technology institutes have been established which includes regional centres, centres of excellence, IITs, NIPERs, national universities, and specialized centres for translational research, molecular medicine, biomedical genomics, stem cells and regenerative medicine, animal biotechnology, agri food, marine biotechnology etc. National facilities are created for high containment pilot production and testing, large animal houses, testing for GMOs, LMOs, GM crops, repositories, DNA and stem cell banking and bioparks and bioincubators.

## **Challenges:**

Even though S&T agencies have made all efforts to promote translational research and transfer of technologies in terms of PPP programmes, this culture is not visible in most of research institutions and university level. The young budding scientists and large number of faculty are hotbeds for emerging fields in biotechnology, nanotechnologies, drug discovery sciences and likely to generate Intellectual Property Rights (IPRs), patenting and start-up businesses. Innovation and entrepreneurship should become incorporated into the mission statements of our major research institutions / universities as of fundamental values. To bring in culture of innovation, resources should focus on basic sciences and interdisciplinary disciplines required for technology transfer, entrepreneurship and innovation with emphasis on patent laws, studies of inventions and inventors and nature of contracts, deals, finance, public and private sectors.

The sequencing of the genetic code of certain living organisms including humans led to identification of genes involved in a number of diseases and those in the production of specific materials, physiological processes and technologies and generated a huge volume of data and information. The challenge is integration the vast amount of data being obtained in the complex context of the cell and organisms control systems.

Advances in biotechnology pose grave challenges to biological arms control for the coming decades. The increasing capabilities of the biological sciences and the global spread of the underlying technologies raise the prospect of misuse of these technologies by small groups or individuals with the necessary technical competence. Biological and Toxin Weapons Convention is apprehensive of development of dual-use technologies in the areas of genetic engineering, biotechnology and microbiology, for high growth of products and processes that are capable of being used for purposes inconsistent with its objectives and provisions. Issues need to be addressed for biosafety and biosecurity of the agents, products and processes.

In therapeutic area the identification of the right patients for the right treatments is a challenge in face of large volume of the genomic data and new molecular therapies effective in limited range of cancer patients.

The emerging bio-similars may have several challenges and disadvantages to compete regulations and market.

In recent years, Biotechnology has experienced an unprecedented revolution. The techniques that have been developed up until now, particularly in Genetics, are opening up a wide range of new lines of research and promising applications. The speed with which science and technology advance in the booming information age often makes it difficult to follow, understand and appreciate their advantages. Public awareness and acceptance is a major challenge.

Dr. B. M. Gandhi,

Former Advisor, Department of Biotechnology

Currently, CEO, Neo BioMed Services

[www.neobiomed.com](http://www.neobiomed.com)