

**BIOTECHNOLOGY**  
**The Indian Scenario for Research,  
Capacity Building and Regulatory  
Framework**

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# OUR MISSION

- Realise full potential of biotechnology
- A well directed effort and significant investment for generation of products, processes and technologies
- Enhance efficiency and productivity and cost effectiveness of :
  - Agriculture
  - Nutritional Security
  - Molecular Medicine
  - Environmentally sustainable technologies

# Support for Biotechnology

- Department of Biotechnology
- Department of Science and Technology
- Council of Scientific and Industrial Research
- Indian Council of Medical Research
- Indian Council of Agricultural Research
- Department of Energy
- Ministry of Environment and Forests
- Department of Space
- Ministry of Defence

# Department of Biotechnology: Perspective

## Department of Biotechnology

- Set up in 1986
- Central Coordinating and policy making Government organisation
- Promotes research and development in biotechnology in the country

## Mandate

- Developing critical mass of skilled human resource.
- Accelerated research in priority areas of research and development.
- Providing financial support research institutes / universities and academies of India.
- Setting up of state-of-the-art infrastructure facilities for research.
- Regulatory policies

# Broad categories of support

- Research & Development and Biotechnology applications
- Demonstration and Technology Transfer
- Industrial Biotechnology
- Human Resource Development
- International Collaboration
- Infrastructure facilities and programme support
- Vaccine Research & Production
- Bioinformatics
- Bio safety
- Patents

# Thrust Areas

- Medical, Vaccine and Diagnostics
- Genomics, Proteomics
- Stem Cell Research
- Agricultural and Food
- Bioresource Development and Utilization (Plants, animals and microbes)
- Environmental Biotechnology
- Product and Process Development
- Bioinformatics
- Biotech Incubators / Parks

# Responsibility of institutions

- National Institute of Immunology, (NII), New Delhi
- National Centre for Cell Science (NCCS), Pune
- Centre for DNA Fingerprinting and Diagnostics (CDFD), Hyderabad
- National Brain Research Centre (NBRC), Gurgaon
- National Centre for Plant Genome Research (NCPGR), New Delhi
- Institute of Bio-resource and Sustainable Development (IBSD), Imphal
- Institute of Life Sciences (ILS), Bhubneshwar
- International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi
- Bharat Immunological and Biologicals Corporation Ltd., (BIBCOL), Bulandshahr

# Flagship programmes supported by the Government :

## Genome sequencing and gene mining:

Crop	<i>Microorganisms</i>	Animal
Rice, Sugarcane	<i>Helicobacter pylori</i> , <i>Mycobacterium</i> ,	Buffalo

## Vaccine Development Programme:

**Rabies:** World's first DNA Rabies vaccine. Phase III clinical trials for animals completed.

**Anthrax:** Phase I/II clinical trials initiated.

**Cholera:** Indigenous recombinant oral cholera vaccine, Phase II clinical trials underway.

**Malaria:** Phase I clinical trials initiated.

**Rotavirus:** Phase I clinical trials underway

**JEV:** Vaccine technology transferred to industry, Preclinical development Under process

# Flagship programmes supported by the Government :

## Transgenic crops with pest and disease resistance and enhanced nutritional quality

- Protein rich potato ready for large field trials
- Insect resistant potato, brinjal, cabbage, tomato – limited field trials being carried out
- Insect resistant rice, pigeonpea, mustard, groundnut – limited field trials being carried out

## Bioresource conservation and utilization

- National Bio resource Development Board (NBDB) established
- Bio prospecting of bioactive genes and molecules

## Bioremediation:

- Technologies developed for treatment of dye industry waste water using phyto remediation; petroleum sludge and crude oil spills using microbial consortia; treatment of starch factory waste water; desulphurization of fossil fuels etc.

# Technology Transfer

Fifty three technologies transferred to the industry in the areas of medical, plant tissue culture, medicinal and aromatic plants, biofertilizers and biopesticide, environment, animal and aquaculture, microbial and enzyme related.

Seventeen technologies are already in the market

# Capacity Building

## Objective

- To create skilled human resource in biotechnology through specialised courses for research, industry and academic sectors.
- To provide industrial training at various levels – research students, scientists, technicians, et

## **Human Resource Development Through:**

- Post graduate teaching programmes
- Post MS / MD and PG Diploma
- Ph. D Fellowships JRF / SRF
- Post – doctoral Fellowships
- Scholarship for CBSE toppers in biology
- Biotechnology Overseas Associateship
- Visiting Scientist from broad Programme
- Short term and Long term training courses
- DBT–TWAS Biotechnology Scholarships
- Ph. D and Post doctoral for researchers of Third World countries

# Status

- 67 Universities supported for M. Sc./M.Tech., Ph.D., Post doc Programmes in Biotechnology
- Special programmes of M.Sc. in areas of agriculture, medical, neuroscience, bio informatics
- 600 students trained each year; 3500 trained during last five years
- Over 100 Ph.D Fellowships granted during last two years
- 75 Post Doctoral Fellowships granted in 54 R&D institutes during last two years

# THE INTELLECTUAL POOL

**120 NATIONAL RESEARCH INSTITUTES  
25,000 SCIENTISTS**

**~300 LIFE SCIENCES COLLEGES  
500,000 GRADUATES PER ANNUM**

**~ 120 MEDICAL COLLEGES  
17,500 MEDICAL GRADUATES PER ANNUM**

**~ 200 BIOTECH COMPANIES  
EMPLOYING 25,000 SCIENTISTS IN R&D**

**>100 TEACHING HOSPITALS  
EMPLOYING MEDICAL & PARAMEDICAL PROFESSIONALS**

# Bioinformatics

- A National Bioinformatics Network is evolved for sustainable utilization of the biological data resources.
- Sixty one centres are developed and six interactive computer graphics facilities have been created.
- Five graduate diploma and 5 M.Sc. / M.Tech / Ph.D courses in Bioinformatics are being supported
- Virtual Private Network established connecting major institutions

# Thrust Areas :

- Provide bioinformation network among scientists in organisations involved in R&D and manufacturing activities
- Build information resources, prepare databases on biotechnology and to develop relevant information handling tools and techniques
- Assess information requirements; create and improve necessary infrastructure; provide informatics based support and services in biotechnology and allied areas

- Undertake research on advanced methods of computer-based information processing for analysing the structure and function of biologically important molecules
- Evolve programmes on education and training for handling biotechnology information and its application to biotechnology R&D
- R&D towards development of new tools and generation of knowledge through use of Biotechnology information resources such as genetic and proteomic data

# Biotech Facilities

- National containment cum Quarantine facility for transgenic plants at NBPGR, New Delhi
- National facility for virus diagnosis and quality control of TC plants established at IARI, New Delhi with 5 satellite centers
- Microarray facilities set up for genomics at CDFD, Hyderabad and NBRC, Gurgaon
- Super computing facility on Bioinformatics and computational Biology at Indian Institute of Technology, Delhi
- NMR facility for biomedical & biological research at TIFR, Mumbai
- 700 MHz NMR facility at IISc., Bangalore and NBRC, Gurgaon
- International Depository Authority for micro – organisms, IMTECH, Chandigarh

# Biotech Parks

## **Support Provided**

Genome Valley in Hyderabad

Biotech City, Lucknow

Biotech Park, Chennai

Women Biotechnology Park in Chennai funded by the Government

Venture Capital Funding for Biotech Parks has been provided;

Soft loans and Equity Capital investment are available through Technology Development Board

# Biosafety Regulations in India

- The release of transgenic crops is governed by India's Environment Protection Act 1986. The act provides framework for the protection and improvement of environment
- Rules and regulation for the manufacture, use / import, export and storage of hazardous microorganisms, genetically engineered organisms or cells were notified under EPA on December 5, 1989

- In 1998 Revised Guidelines were prepared for Research in Transgenic plants for Toxicity and Allergenicity evaluation of transgenic seeds plants and plants parts”
- These Guidelines provide information on level of approvals for conducting research in transgenic plants, category of experiments and testing procedures for toxicity and allergenicity

## **Competent Authorities dealing with GMOs in research and commercial application**

- Recombinant DNA Advisory Committee (RDAC)
- Institutional Biosafety Committee (IBSC)
- Review Committee on Genetic Manipulation (RCGM)
- Genetic Engineering Approval Committee (GEAC)
- State Biotechnology Coordination Committee
- District Level Committee

# Areas of competence

## Biotechnology in India: advantages and enabling factors

- Critical mass of skilled scientific manpower and knowledge base
- State-of-art infrastructure extending across the country
- A legal and regulatory system for recombinant DNA product
- Low infrastructure and operating costs
- Targeted growth in development of:

Vaccines	Diagnostics
Bio-therapeutics	Clinical research
Transgenic crops & foods	Bio-informatics
Bioremediation	Bioprospecting

# Areas of Competence (contd.)

- Increased Capacity in handling sterile fermentation processes
- Skills in handling microbes and animal cells
- Capacity in downstream processing and isolation methods
- Skills in extraction and isolation of plant and animal products
- Competence in plant and animal breeding
- Infrastructure in fabricating bioreactors and processing equipment

## **Biotech facilities**

- Facilities for Breeding and Supply of experimental animals
- DNA sequencing facilities
- Mass Spectrometer facilities
- Repositories of germplasm and accession lines of crops, microbes, marine germplasm, medicinal plants etc.
- Bioinformatics Information Network

# Contract Research

## Compound Discovery & Development

- Screening requirements of the top 10 pharma companies will increase from 10-15 million primary screens per year to 200 million within 1-2 years

## Process Development & Synthesis

- India's expertise in chemical synthesis can be utilized for development of cost-effective processes for new drugs and intermediates

## Clinical trials

- One of the areas with greatest potential

## Advantage India : Clinical Trials

- Large and heterogeneous population and prevalence of wide spectrum of disease conditions offer wide patient-resource.
- Low clinical trials cost in India ( US\$ 25 million) .
- India has the 2<sup>nd</sup> highest number of qualified doctors in the world.
- Patient enrollment rate for Phase III studies could be upto 6 times faster in India than in the Western countries.
- Conformity to ICH and GCP quality guidelines
- Effective data management by CROs by leveraging IT strengths of India.

# Government Support for Biotechnology Industry

- **FUNDING**
  - **Technology Development Board**
  - **Schemes for promoting indigenous technologies**
    - **Home grown technology programme**
    - **Technopreneur promotion programme**
    - **Programme aimed at technological self reliance**
  - **Sector specific venture fund (DBT and SIDBI)**

# Investment incentives in Indian Biotechnology Industry

- 100% foreign equity investment is possible in manufacturing of all drugs except recombinant DNA products and cell targeted therapies.
- DBT provides a “single window processing mechanism” for all mega biotech projects involving FDI (Foreign Direct Investment) of US\$22 million or more under the Foreign Investment Implement Authority (FIIA) with its Fast Track Committee (FTC) existing in DBT.
- Depreciation allowance on plant & machinery raised from 25 to 40%.
- Customs duty exemption on goods imported in certain cases for R&D.
- Customs & excise duty exemption to recognized Scientific & Industrial Research Organizations (SIRO)
- 150% weighted tax deduction on R&D expenditure
- 3 years excise duty waiver on patented products.
- 100% rebate on own R&D expenditure.
- 125% rebate if research is contracted in public funded R&D institutions.
- Joint R&D projects are provided with special fiscal benefits

# Glimpse of products from Indian Biotech Companies

- Drugs**
  - Statins, Gemfibrozil, enalapril, ranitidine, streptokinase, GM-CSF, Epo, interferon antidepressants, antibiotics (b-Lactams, polyketides, fluoroquinolones) antivirals, antiretrovirals, antifungals, antimalarials, NSAIDS, steroids, peptide hormones, insulin (recombinant), anticancer drugs, antipyretics.
- Diagnostics**
  - Classical RIA, ELISA immunodiagnostics, HIV, Hepatitis.
- Vaccines**
  - 20 different kinds (tissue, cell based and recombinant), DNA vaccine, SPF eggs for vaccines
- Health aids**
  - Vitamins, tonics, parenterals, cord blood
- Traditional Medicine**
  - Ayurveda, Unani, Siddha and homeopathic products
- Agribiotech**
  - Hybrid seeds, bio-pesticides, bio-fertilizers, hybrid cotton, tobacco, sugarcane, soya, GM plants under development and infield trials (cotton, rice, potato, cassava) bovine growth hormone.
- Bioinformatic products**
  - Biosuite (TCS), Avadis (Strand), Oncomime (IOB)
- Clinical Research**
  - CROs (Quintiles, iGATE, VIMTa...)

# Commercial r - DNA products

- r DNA Hepatitis 'B' vaccine World's first cesium chloride free Hepatitis 'B' vaccine
- Recombinant streptokinase
- Erythropoietin
- $\alpha$ ,  $\beta$ ,  $\gamma$  – interferon
- Contract manufacturing of *Haemophilus influenzae* B vaccine
- Human insulin
- Human Growth Hormone
- Human Interleukin
- HIV diagnostic kits being exported