Role of Biotechnology In Pharmaceutical Drug Development

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ABSTRACT

Biotechnological methods have become an important tool in pharmaceutical drug research and development. Biotechnology derived drugs are applied in cancer therapy, HIV, AIDS and AIDS-related and autoimmune diseases, helps in diagnostic investigations.Biotechnology products is used as blood substitutes, clotting factors, etc. There are many steps are required to biopharmaceutical drug development like , discovery, product characterisation, formulation, delivery, packaging, development, preclinical and clinical studies. New therapeutic approaches such as RNA interference, nanotechnology, antibody production by hybridoma technology , production of human and animals vaccines for cancer, polio, tuberculosis, etc. with the help of enzymes linked immuno-sorbant assay (ELISA), PCR based technique and RIA Assays, recombinant DNA technology or genetic engineering, monoclonal antibodies, immunoglobulin , Antisense technology to treat genetic diseases. Live, attenuated vaccines, inactivated vaccines, subunit vaccines, toxoid vaccines, conjugate vaccines, DNA vaccines, recombinant vector vaccines etc play very important roles in current commercial drug research and development. With the help of biotechnology , pharmaceutical industry can not only develop new products, new processes, methods and services also improve existing ones. Today approximately 18 % of drug revenues are derived from biopharmaceuticals. In India biotech industry is ranks 2nd globally by number of units. In future it can be expected that the relevance of biopharmaceuticals will further increase.

Keywords: RNAi ; recombinant DNA; vaccines therapy; drug development.

INTRODUCTION

Biotechnology is a technique which uses the living systems and organisms to develop or make useful products, or "any technological application that uses biological systems, living organisms or their by products derivatives, to make or modify products or processes for specific uses".[1,3]

Biotechnology has contributed to the discovery and manufacturing of traditional small molecules, nano particles and different pharmaceutical drugs is called biopharmaceuticals. biopharmaceutical drugs are generated through researches in cell biology, genetics and recombinant DNA technology By the use of modern biotechnology manufacturing of existing medicines become relatively easy and cheap. The first genetically engineered medicines designed to treat human diseases like diabetes. Example, in 1978 synthetic humanized insulin was first developed by Genen'tech which is widely used to treat diabetes by inserting its gene combine with a plasmid vector into the E.coli. Then the resulted genetically engineered bacterium (E.coli) is enabling to produce huge quantities of synthetic human insulin at relatively low cost[13,14]. The application of biotechnology to basic science like gene therapy, human genome project have improved our understanding of applied biology and as our scientific knowledge of normal and disease conditions has increased, It also helps to develop new medicines to treat previously untreatable and life threatening diseases has increased[14]. Recombinant DNA (rDNA) and monoclonal antibody (MAb) have the exciting opportunities for new pharmaceuticals development, new approaches to drug delivery[7].

 Drug discovery is the process of discovering or designing the potential medicines or drugs. In the past most drugs have been discovered either through isolation of the active ingredient from traditional remedies or by unexpected discovery. But the modern biotechnology applications are concern with understanding the metabolic pathways of disease that are caused by pathogen or other reasons and also understanding of these pathways by using molecular biology ,cellular biology as well as biochemistry techniques.

Drug development are the activities that are undertaken after a compound is identified as a potential drug as a medicine to determine appropriate and safe formulation[10,11].

The semi-original approach to pharmaceutical drug development[12]

1. Enzyme or Receptor of Interest.
2. Isolation or Characterization/Purification of Target Molecule.
3. Protein microsequencing . .
4. Gene cloning or sequencing. (the target protein expressed at high levels.)
5. High-Throughput Screening assays are established against target protein.
6. Identify lead inhibitor confirm role in specific disease process.
7. Chemical Structure-Activity analysis is done to determine
   a) Therapeutic Index
   b) Pharmacokinetics

Determining which genes are the best suitable for drug discovery through "Target Validation" is perceived as a major rate-limiting step for drug discovery. So, the chosen gene should have the following properties.

1. Improved efficiency
2. Increased productivity
3. reduced failure
4. Intellectual property

Target Validation Approaches for drug development include:

1. Identification of best suitable gene.
2. Isolation of protein of interest.
3. Target validation.
4. Drug identification
5. Clinical development.

Applied or related matters in the field of pharmaceutical drug development and medicines are as follows

1. Biotechnology derived drugs are applied in various life threatening diseases like cancer therapy, HIV, AIDS and AIDS-related and autoimmune diseases.
2. Biotechnology also helps to diagnose several abnormal biological processes.
3. Biopharmaceutical products is used as blood substitutes, clotting factors, etc.
4. Human insulin (approved in 1982) and human growth factor were the first biotechnological products that are applied for human therapy.

Due to new biotechnology has infinite possibilities of its application in the field of genetic engineering and hybridoma technology, the progress in healthcare has been very rapid.

APPLICATIONS

Following are the some application of biotechnology in field of pharmaceutical drug development, diagnosis and treatment of several diseases[48].

1. Production of Antibody – B and T lymphocytes produces antibodies that are protein molecules in the body which can develop an immune system. by hybridoma technology one can produce antibody is biochemically pure and it is called monoclonal antibody. These antibodies gives protection to the body against microorganisms. These also used for development of drugs as well as detection of animals and plants diseases.
2. Production of several human and animals vaccines – One of the application of biotechnology is to produce human and animal vaccines for cancer, polio, tuberculosis, etc.
3. Diagnosis of many infection diseases – Biotechnology makes an easy, early, quick and correct diagnosis of many infectious diseases like AIDS, cancer, foot and mouth diseases, tuberculosis with the help of many diagnostic kits and tools like Enzymes Linked Immuno-sorbant Assay (ELISA), PCR based technique and RIA Assays.
4. Hormones enzymes and chemicals as biopharmaceuticals –biotechnology products such as insulin, penicilline, streptomycin, kanamycin, tertracycline, growth hormones, proteases, amylase, pectidases, etc..
5. Antibiotics and vitamins production – antibiotics such as penicillin, aminoglycosides, tetracyclines etc have been developed by genetic engineering technique.
6. Gene Transfer – genetic diseases can be treated by inserting the gene of interest into body by using recombinant DNA technology or genetic engineering.[44,48]

ROLES OF BIOTECHNOLOGY

Some specific roles of biotechnology in the field of pharmaceutical sciences as following:

RECOMBINANT DNA (RDNA)

Every DNA molecule composes the genes that reproduce cells and maintain life. Each DNA consists of two strands that are linked by

bases adenine (A), guanine (G), cytosine (C) and thymine (T). Each DNA codes for the information for the production of the 23 amino acids thus proteins . The DNA molecules are selectively hydrolyzed in presence of endonucleases. As a result , molecules of two different DNA joined to form recombinant DNA. Other techniques such as replication, separation, identification helps to produce of large quantities of purified DNA fragments . rDNA technology eliminates a specific piece of DNA outside a large complex molecule. Restriction endonuclease and DNA ligase can join two different pieces of DNA together at the specific sites within the molecule. Non-human cells (e.g. special strain of E. coli) can be used to manufacture proteins that are identical to those produced in human cells. rDNA technology used to diagnose many diseases by small pieces of DNA to search a cell with viral infection or genetic ,infectious diseases, cancer, genetic defects and disease susceptibility.

MONOCLONAL ANTIBODIES

After entry of any antigen molecule into the body, an immune response begins by proliferating line of β-lymphocytes and secretes an immunoglobulin molecule to fit a single antigenic determinant of an antigen or part of it. the expression of a single β-lymphocyte produces monoclonal antibodies. Hybridoma technology produces large quantity of identical, monospecific antibodies by the fusion of β-lymphocytes with immortal myeloma cells to form hybridoma cells which are then maintained in cultures to produce large amounts of antibodies. The monospecific immunoglobulins produced by the specific line or clone can be selected from the hybrid cells.

IMMUNOGLOBULIN F

The immunoglobulin F (i.e. IgG) subclass molecule has the molecular weight 150-180 kD have two polypeptide chains i.c heavy and light chains connected by the di-sulphide bonds.Each chains have the constant and the variable domains. The amino acids of the constant domain conserved specific class of immunoglobulin (e.g. IgGi, IgM) whereas the variable domains of antibodies are heterogeneous in nature which gives antibodies its binding specificity and affinity .

HUMAN ANTI-MOUSE ANTIBODIES

The patient exposed to the foreign monoclonal antibodies develops noticeable levels of antibody responses within two to four weeks. Over doses of it can causes a typical allergic reaction like chills, urticaria, wheezing etc. The antibody is rapidly cleared from the serum .It have been derived from mice and this man-made antibodies can overcome the lack of intrinsic antitumour activity as well as immunogenicity of many murine monoclonal antibodies. They can potentially activate human immune system through their human constant regions where as the smaller fragments control immunoglobulin binding sites F(ab)2 and Fab′ do not contain the lower binding domain of the molecule. The smaller sized molecule tends has less immunogenic but may have greater tumour penetration ability than the larger structure.

GENE THERAPY

An inherited or acquired defect can be corrected when exogenous genetic materials(self renewing stem cells) have been transferred into end-state differentiated somatic cells to introduce a new function or property into cells especially in some life threatening diseases such as cystic fibrosis, hemophilia, sickle cell anemia and diabetes. As the stem cells can selfrenew, the inserted gene will remain in place throughout subsequent generation of differentiated cells or tissue population. Gene therapy is used to treat adenosine deaminase deficiency (ADA) and severe combined immunodeficiency syndrome (SCID) that causes death in childhood or adolescence .

NUCLEOTIDE BLOCKADE or ANTISENSE TECHNOLOGY

Antisense technology is deals with the function of specific proteins and intra cellular expression. The sense sequence is the nucleotide chain contains that contains information for protein synthesis i and the nucleotide chain, complementary to the sense sequence is called the antisense sequence. Antisense drugs have the ability to identify and bind to the nucleotide sense sequence of specific messenger RNA (mRNA) molecule to prevent the synthesis of unwanted proteins or destroying the sense molecules in the process. When the antisense RNA is introduced into a cell, the specific gene of interest is cloned in an expression vector in the wrong orientation by cloning technique and the complementary mRNA has been created to match an abnormal mRNA. As a result the two mRNA strands make a complex together, translation ,thus the disease-producing protein production is prevented. Antisense drug such as Fomivirsen sodium injection is used for the treatment of cytomegalovirus (CVM) retinitis in patients with AIDS. Efavirenz is used to treat anti-HIV drug as it is a non-nucleoside reverse

transcriptase inhibitor. Clotting factors such as recombinant anti-hemophiliac factor is used to treat the classical hemophilia A (which occurs in deficiency of clotting factor VIII).[9]

THE ROLE OF BIOTECHNOLOGY IN DEVELOPING VACCINES

A vaccine is a nontoxic biological preparation which is given to humans to make them immune against diseases especially infectious diseases. The human body's immune system of a human body recognises the vaccine as being 'foreign' agents and destroys it, but also 'remembers' the structure of the foreign matter. When the body then actually encounters the specific disease or virulent form of a foreign agents, the immune system recognises it and will be ready to fight against the infection. The way of disease-causing microbe infects body cells, how the immune system of the body reacts, physical characteristics of the microbe and also where the vaccine is going to be used etc are considered for routes to develop a vaccine [45,46].

a) Live, attenuated vaccines

These types of vaccines contain a stain of the disease-causing microbe that has been weakened or attenuated, therefore it cannot cause disease but can punctual the immune system to remember it and have less chances to mutate back to its virulent form and cause disease. As the live attenuated vaccines provide a very strong immune reaction, only one or two doses can give lifelong immunity. These vaccines are used against viral diseases like measles, mumps and chickenpox. It is better to avoid a live attenuated vaccine on a person with a weakened immune system (HIV-positive individuals or patients receiving chemotherapy) for safety. These vaccines should store in a refrigerator to stay potent, limiting their use in some developing countries. There is also the remote possibility that the weakened microbe might mutate back to its virulent form and cause disease.

b) Inactivated vaccines

In inactivated vaccines the disease-causing microbe is killed with chemicals, heat or radiation and not just weakened and the microbe can therefore not mutate back to its virulent form to form diseases. This type of vaccine does not produce such a strong immune reaction, so additional immunisation ('booster shots') are necessary. Inactivated vaccines are freeze-dried, so they can be stored easily – making them better for use in developing countries. Examples of inactivated vaccines are those against cholera, bubonic plague and hepatitis A.

c) Subunit vaccines

These vaccines do not include the entire disease-causing microbe, but only the antigens that stimulate the immune system the most. Antigens behave like 'markers' on the surface of a microbe and recognised by the immune system's T-cells to bind. In the laboratory by using recombinant DNA technology one can make the antigens from the microbes. This type of the vaccine is called a recombinant subunit vaccine, example: vaccine against the hepatitis B virus.

d) Toxoid vaccines

These vaccines are used against bacteria that secrete toxins like diphtheria and tetanus. The toxoid vaccine is generally formed by treating the toxin with formalin and the toxin is harmless. The toxoid vaccine signals the immune system to produce antibodies against the toxin to bind to the toxin and block its action.

e) Conjugate vaccines

The outer coating of polysaccharides hides the antigens (markers) on the surface of the Many harmful bacteria so that the immature immune system of a child or baby cannot recognise it. Now it is possible to connect antigens or toxoids from a microbe that an immature immune system can recognise to the polysaccharides and making a conjugate vaccine. Example: The vaccine against Haemophilus influenzae type B (Hib).

f) DNA vaccines

Although these vaccines are still in the experimental phase but these only use the genes of the microbe that code for the antigens of that microbe. At first, these genes enter the body; they are taken up by body cells, then instruct the body cells to produce antigens. At last the antigens then stimulate the immune response. The DNA vaccines follow some simple steps to produce and store. Example: vaccines against herpes and influenza.

g) Recombinant vector vaccines

Recombinant vector vaccines use an attenuated virus or bacterium as a vector to carry the DNA of the disease-causing microbe into the body. By infecting body cells the vector virus delivering the DNA to the body cells. These type of vaccines can be monovalent i.c immunizes against one disease

or multivalent i.c. immunizes against more than one disease, or two or more strains of the same disease-causing microbe.[47] Example: vaccines against HIV, rabies and measles.

RNA INTERFERENCE (RNAi)

The RNA interference (RNAi) for target-specific gene silencing through short interfering RNA (siRNA) is a diagnostic tool of pathogenesis of a disease and also now the method of choice for target validation in cell culture systems in vivo and in vitro. The identification of this molecular pathway is the concern of RNAi therapy and target gene-specific siRNA-delivery technology in vivo especially for the development of the next generation of drugs such as anticancer therapies, drugs to treat wide range of diseases, including viral infections and cancer.[22] In future it is possible to develop efficient "double-specific" drugs, comprising of siRNAs with target gene specificity and nanoparticles for siRNA delivery as well as target organ specificity[23].

RNAi is a significant tool for target validation, target identification, hit selection, lead optimisation and development of animal models. RNAi for in vivo target validation shows that administration of RNAi reagents to human patients is useful for the treatment of various diseases by inducing sequence-specific degradation of mRNAs, RNAi can transform short double stranded RNA molecules to silence target genes and in all multicellular organism RNAi occurs by an intracellular mechanism.

The process are

A. Cells take the double-stranded RNA molecules and thaen these RNAs developed by intracellular protein complexes known as Dicer and in every multicellular organism (RISC).

B. The dicer cuts the larger double-stranded RNA molecules into smaller molecules (20-22 nucleotides in length) and then they are loaded into RISC.

C. In RISC, the double stranded RNA molecule unwind with one of the two strands remaining associated with RISC and the other unnecessary fragments are released and degraded.

D. The strand that are connected with RISC can direct the RISC to target mRNAs by sequence-specific base pairing.

E. RISC has the endonucleolytic activity that cuts the target mRNAs to make them unable to translate into proteins and susceptible to further degradation.

Any silencing on the gene is formed through the cleavage as well as degradation of the mRNA.

Some of the double- stranded RNA molecules can activate the interferon alpha pathway to cause non-specific cellular stress responses .These non-specific inhibitory effects is reduced by using the least concentrations of RNAi reagent, research the effects of multiple independent RNAi reagent in every target gene and well-designed, carefully controlled experiments.

The impact of RNA on drug discovery

RNAi has the efficiency of target validation and target identification. RNAi-derived data initiated or make advance drug discovery projects by giving the key functional data that demonstrates functional effects in cell lines or relevant primary human cells. There are many criteria like such as target class and drug ability, therapeutic rationale, market size and strategic fit, risk analysis and IP position are important and over-ride even the most solid target validation data that influence whether a target will advance beyond the initial stages of drug discovery. At present, RNAi technology also apply to other steps like assay development and hit selection in drug discovery[24].

Nanotechnology

Nanomedicine is the application of nanotechnology in medicine which gives abundant possibilities in healthcare including drug delivery and tissue engineering as well as could enable entirely novel classes of therapeutics at the atomic and molecular scale to treat many vulnerable diseases.[25,26]

Nanoparticles can deliver conventional drugs, recombinant proteins, vaccines and more recently nucleotides. Nanoparticles and other colloidal drug delivery systems can modify the kinetics, body distribution and drug release of an associated drug. Nanobiotechnology also helps to design tissue or cell specific targeting drugs and reduction of many adverse drug reactions by a controlled release. Nanoparticles in the pharmaceutical biotechnology sector can improve the therapeutic index and thus provide solutions for future drug delivery problems for new classes of biotech drugs that includes recombinant proteins and oligonucleotides[27].

GLOBAL FACTORS UNDERLYING BIOTECHNOLOGY TODAY

1) A rapid aging of the population base of nations including the Europe, Asia and America , such as approximately 75

million surviving senior citizens in America are   rising in numbers, require a growing level of health care.
2) It is the global aim to develop effective vaccines.
3) Major pharmaceuticals firms tiring to get hold of biotech drug companies.
4) There are massive investments in biotechnology research in Singapore, China and India, often with government sponsorship—for example, Singapore's massive Biopolis project.
5) Increasing use of research related to synthetic biology.
6) Highly advanced biotechnological approaches such as gene therapies have the ability to cure patients from life threatening diseases.
7) Fast growth is shown in the overall prescription drug markets in emerging nations, especially China, India and Brazil.
8) An increased focus on the drug discovery and manufacture of new drugs for rare diseases[21].

GLOBAL ECONOMIC STATUS OF BIOTECHNOLOGICAL DRUG DEVELOPMENT
1. Globalization enhances industrial reforms and economic benefits.
2. Trade is now seamless across the countries and thus creates more wealth.
3. Socialist world are stand for transformation.
4. Although some religious fundamentalism and terrorism obstructs the process of globalization.
5. Relationship with other large and small countries is vital for sustenance and growth of economy.
6. Biopharmaceutical unions can create good relation among neighbor countries.
7. Today approximately 18 % of drug revenues are derived from biopharmaceuticals.[9]

 Indian situation in Biotechnology combined with pharmaceutical sectors
1. Biotech industry is ranks 2nd globally by number of units.
2. It is presumed that the biotech industry will be the leading industry by 2020.
3. India is considered in world's top 11 biotech powers.

4. The Biopharmaceutical industry has been grown by 74% in the last 2 years.
5. In future, by 2010, Biotech industry was aimed to generate $5 billion and offered one million jobs.[9]

METHODOLOGY OF DRUG DEVOLOPMENT
A) Discovery
1. Identify enzyme-Receptor of Interest.
2. Isolation of Target Molecules.

 B) Product characterisation
1. Characterization/Purification of Target Molecule
2. Protein Micro sequencing.
3. Gene Cloning/Sequencing. Target Protein Expressed at High Levels.
4. High-Throughput Screening Assays Established against Target Protein.
5. Identify Lead Inhibitor Confirm Role in Disease Process.
6. Chemical Structure-Activity Analysis
7. Tested for its .molecule's size, shape, strengths and weaknesses, preferred conditions for maintaining function, toxicity, bioactivity, and bioavailability

C) Formulation, delivery, packaging and development.
 D) Pharmacokinetics and drug disposition.
 E) Preclinical toxicology testing
1. Uses results from in vitro experiments (cell cultures) and in vivo animal models
2. Acute Studies
3. Repeated Dose Studies
4. Genertic Toxicity Studies
5. Reproductive Toxicity Studies
6. Carcinogenicity Studies
7. Toxicokinetic Studies

 F) File an Investigational New Drug application
1. If company/lab decides to pursue human studies, must submit an IND to the Food and Drug Authority
2. IND is effective 30 days after receipt by the FDA
3. IND must provide pre-clinical data to justify testing in humans
4. About 85% of all IND applications move on to begin clinical trials

G) Bioanalytical testing
Bioanalytical laboratory work supports most of the other activities in the drug development process and is essential for proper characterization of the molecule, assay

development, developing optimal methods for cell culture or fermentation, determining process yields, and providing quality assurance and quality control for the entire development process as well a s for supporting preclinical toxicology/pharmacology testing and clinical trials

H) Clinical trial

Clinical studies are categorised group according to their objective into four types or phases

i)Phase I Clinical Development (Human Pharmacology) –
1. The Cost of this stage is about $10M or more
2. Inspect the drug safety, pharmacology, determine drug regimen
3. Participants are screened for harm caused by the medicine
4. It Involve 20-100 patients
5. Phase I shows the drug to be reasonably safe , it is proceed to next step.

ii)Phase II Clinical Development (Therapeutic Exploratory)
1. The Cost of this stage is Cost about $25-35M
2. this trial Confirm safety, determine efficacy, set up dosage of Phase III trials
3. 100-300 patients suffering from the illness are recruited for testing
4. This stage concerned with Placebo controlled and double-blinded trial.

iii)Phase III Clinical Development (Therapeutic Confirmatory)
1. The Cost of this stage is cost about $100M or more
2. The main aim of this stage is to establishes safety and effectiveness in large group of volunteers over the long term
3. This stage concerned with double-blinded, placebo controlled, involve 500-3000 patients every months-years in wide range of sites
4. Minimal risk for the patient should be maintained
5. Rare side effect of treatment can be identified in this stage
6. This stage is very expensive but ESSENTIAL for FDA approval
7. While phase III studies are in progress, arrangements are made for submitting the Biologics License Application (BLA) or the New Drug Application (NDA). BLAs are reviewed by the FDA's Center for Biologics Evaluation and Research (CBER). NDAs are also reviewed by the Center for Drug Evaluation and Research (CDER).[42]

File an NDA with the FDA
1. FDA reviews all drugs and their reports and finally clears them for marketing
2. For New Drug Applications – typically 120,000 pages of data are require to submit.
3. 12 months are requiring for FDA to review all the study reports.
4. Often, more data is required to evaluation, even, sometimes clinical trials need to be repeated.

iv) Phase IV (post-market surveillance studies)
These are post-approval trials that are sometimes a condition attached by the FDA and a follow-up trial after a drug is released to the public.

The process of drug development is not stopped immediately after an NCE begins human clinical trials. Long-term or chronic toxicities, capability to cause cancer (carcinogenicity testing), effects on systems not previously monitored (fertility, reproduction, immune system, etc.) should be tested to move a novel drug into the clinic for the first time.

If a compound passes these tests with an acceptable toxicity and safety profile, and it can further be demonstrated to have the desired effect in clinical trials, then it can be submitted for marketing approval in the various countries where it will be sold.

FUTURE PROSPECTS

Biotechnology derived drugs are applied in various life threatening diseases like cancer therapy, HIV, AIDS and AIDS-related and autoimmune diseases as well as diagnose several abnormal biological processes. Antibody production by hybridoma technology, Production of human and animals vaccines for cancer, polio, tuberculosis, etc. With the help of Enzymes Linked Immuno-sorbant Assay (ELISA), PCR based technique and RIA Assays, we can diagnose AIDS, cancer, foot and mouth diseases, tuberculosis, etc. Biotechnology product is the insulin, penicilline, streptomycin; kanamycin, tetracycline, growth hormones, proteases, amylase, pectidases, etc. are the examples of biopharmaceuticals. Recombinant DNA

technology or genetic engineering, monoclonal antibodies, immunoglobulin, Antisense technology to treat genetic diseases. Live, attenuated vaccines, inactivated vaccines, subunit vaccines, toxoid vaccines, conjugate vaccines, DNA vaccines, recombinant vector vaccines etc. are used to treat many diseases or make a person immunizes against more than one disease, or two or more strains of the same disease-causing microbe that causes HIV, rabies ,measles etc. RNAi is a significant tool for target validation, target identification, hit selection, lead optimisation and development of animal models. RNAi for in vivo target validation shows that administration of RNAi reagents to human patients is useful for the treatment of various diseases. RNAi technology also apply to other steps like assay development and hit selection in drug discovery. Nanobiotechnology also helps to design tissue or cell specific targeting drugs and reduction of many adverse drug reactions by a controlled release. There are many steps are required to biopharmaceutical drug development like, discovery, product charecterisation, formulation, delivery, packaging, development, preclinical and clinical studies .Today approximately 18 % of drug revenues are derived from biopharmaceuticals. In India biotech industry is ranks 2nd globally by number of units. Biotechnology helps the pharmaceutical industry to develop new products, new processes, methods and services and to improve existing pharmaceutical aids. Although, biotechnology has the significant promise to the future but certain amount of risk is associated with this area. So, biotechnology must continue to be carefully regulated so that the maximum benefits should be received with the least risk. In future it can be expected that the relevance of biopharmaceuticals will further increase.

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