



RAMA
UNIVERSITY

www.ramauniversity.ac.in

Faculty of Engineering &
Technology
Production of
Biopharmaceuticals BBT-614

Submitted by-
Mrs. Namrata Singh
Assistant Professor,
Department of Biotechnology

Introduction

UNIT -1

Introduction to pharmaceutical products, biopharmaceuticals and pharmaceutical biotechnology

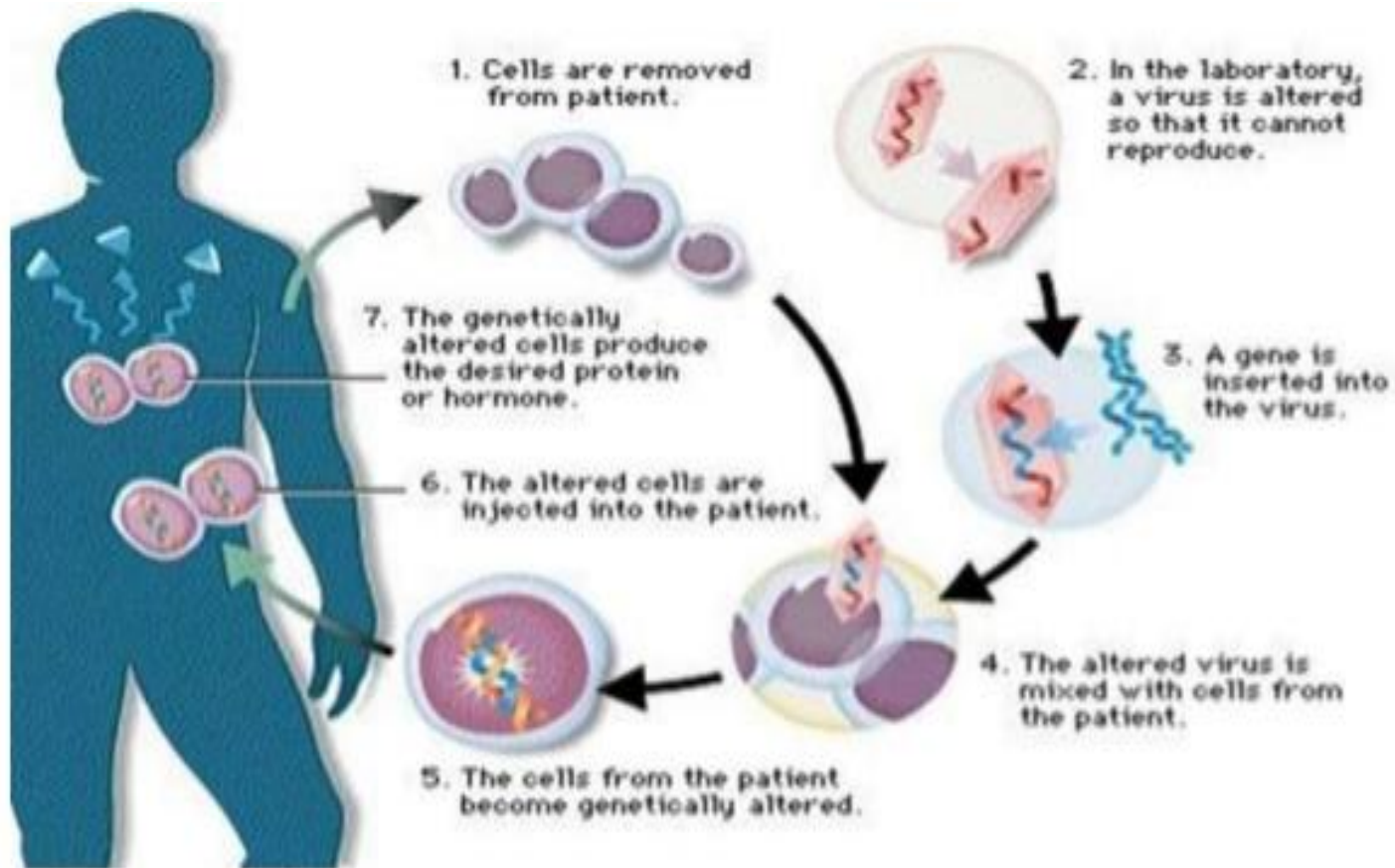
- It is the area of biology that uses living processes, organisms or systems to manufacture products or technology intended to improve the quality of human life. Depending on the technology, tools and applications involved, biotechnology can overlap with molecular biology, bionics, bioengineering, genetic engineering and nanotechnology.

History

- People have been harnessing biological processes to improve their quality of life for some 10,000 years, beginning with the first agricultural communities. Approximately 6,000 years ago, humans began to tap the biological processes of microorganisms in order to make bread, alcoholic beverages, and cheese and to preserve dairy products. But such processes are not what is meant today by biotechnology, a term first widely applied to the molecular and cellular technologies that began to emerge in the 1960s and '70s. A fledgling "biotech" industry began to coalesce in the mid- to late 1970s, led by Genentech, a pharmaceutical company established in 1976 by Robert A. Swanson and Herbert W. Boyer to commercialize the recombinant DNA technology pioneered by Boyer, Paul Berg, and Stanley N. Cohen. Early companies such as Genentech, Amgen, Biogen, Cetus, and Genex began by manufacturing genetically engineered substances primarily for medical and environmental uses.

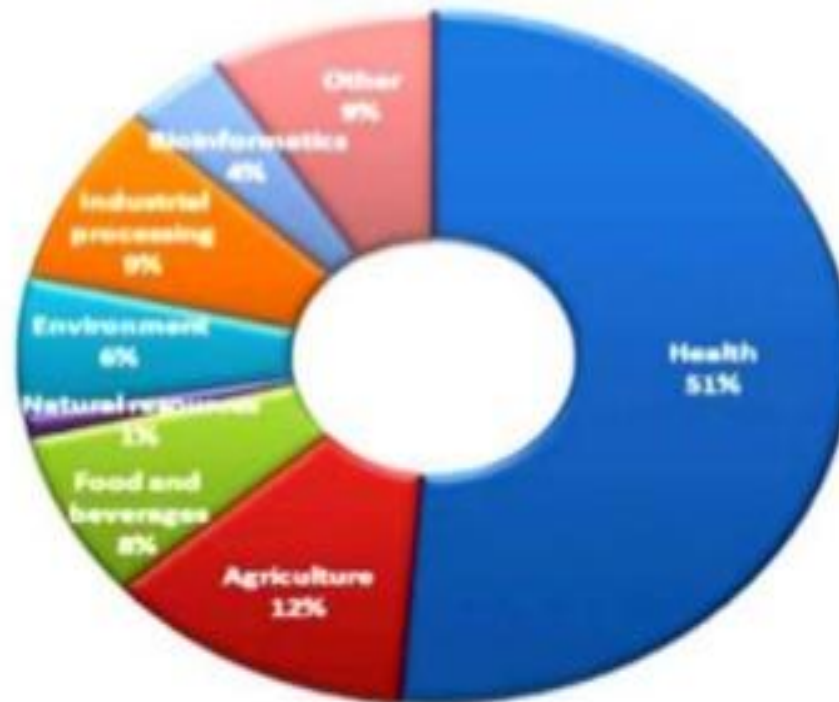
- Pharmaceutical biotechnology is a relatively new and growing field in which the principles of biotechnology are applied to the development of drugs. A majority of therapeutic drugs in the current market are bio formulations , such as antibodies, nucleic acid products and vaccines.

Pharmaceuticals Biotechnology



- Biotechnological methods have become an important tool in pharmaceutical drug research and development. The most relevant indications are oncology, metabolic disorders and disorders of the musculoskeletal system

Percentage of Biotechnology Firms by Application



EXAMPLES:

- INSULIN:

An hormone used diabetes mellitus

- GENE THERAPY:

The common function of gene therapy involves the use of functional DNA to replace muted DNA

- CLOTTING FACTORS:

Use in treatment of hemophilia where there is absence of clotting factors in patient's body

- HUMAN SERUM ALBUMIN:

One of the most blood protein use in the treatment of burns

- ENGINEERED ENZYME:

Used to treat variety of conditions that is due to enzyme deficiency

Types of Biopharmaceuticals

Unit -2

- ▶ Hematopoietic Growth Factors
 - ▶ Monoclonal Antibodies
 - ▶ Vaccines
 - ▶ Thrombolytic Agents
 - ▶ Interferons
 - ▶ Hormones
 - ▶ Blood Factor
-

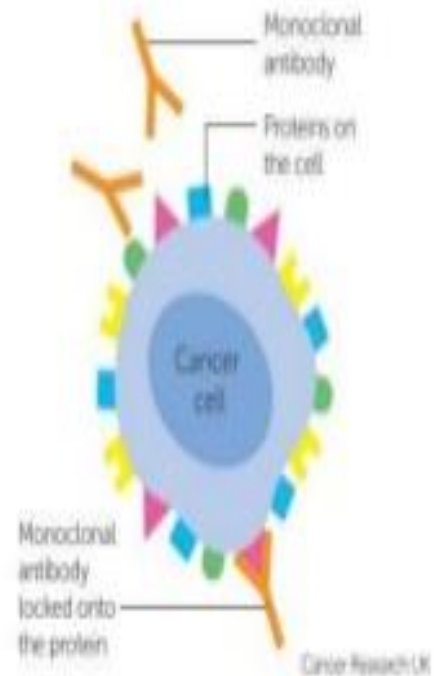
Hematopoietic Growth Factor

- ▶ Group of proteins that causes blood cells to grow and mature.
- ▶ e.g. Erythropoietin:
 - Glycoprotein hormone that controls erythropoiesis
 - Produced by the endothelial cells of the kidney
 - Absence = Anemia



Monoclonal Antibodies

- ▶ Antibody produced by the single clone of B cells
- ▶ Produced by using "Hybridoma Technology"
- ▶ Popularly known as Magic bullet
- ▶ Used for the treatment of rheumatoid arthritis, cancers.



Vaccine

- ▶ Biological product of microorganism that have 2 characteristics:
 - ✓ Intact Immunogenicity
 - ✓ No pathogenicity
- ▶ They can be prophylactic or therapeutic
- ▶ e.g. **HBV vaccine**
 - ✓ Subunit vaccine composed of only surface proteins produced in the yeast cells.



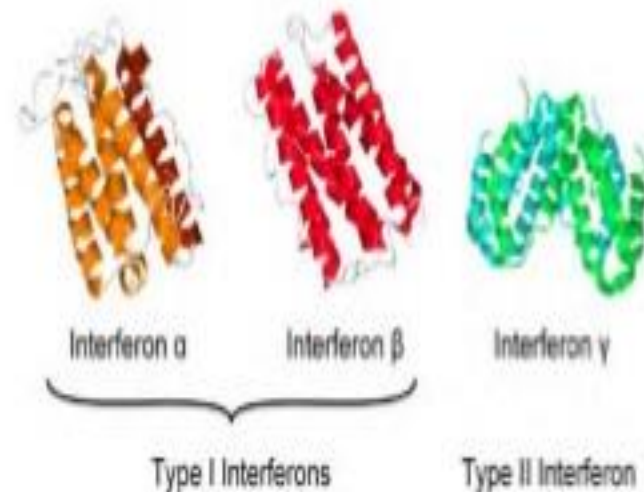
Thrombolytic Agents

- ▶ Proteins involved in the breakdown of blood clots
- ▶ Anti-coagulants
- ▶ e.g. Tissue plasminogen activator
- ✓ Serine proteases
- ✓ Found on endothelial cells
- ✓ Absence = Acute MI



Interferons

- ▶ Are proteins which are produced by the cells of the immune system in response to viruses or tumors.
- ▶ e.g. IF-alpha , IF-Beta, IF-Gamma
- ▶ They assist the immune response by:
 - ✓ Inhibiting viral replication
 - ✓ Activating NK cells and macrophages
 - ✓ Increasing antigen presentation to lymphocytes



Harmones

- ▶ Chemical messengers that transfers the information and instructions b/w cells in animals and plant cells
- ▶ e.g. **Insulin**
- ✓ Produced by the Islet of Langerhans in pancreas
- ✓ Lack of insulin = Diabetes



Blood Factor

- ▶ Component of the blood
- ▶ e.g. Factor VIII
- ✓ It is also known as Anti-hemophilic Factor
- ✓ Synthesized and released in the blood stream
- ✓ Absence = Hemophilia



Biopharmaceuticals Manufacturing

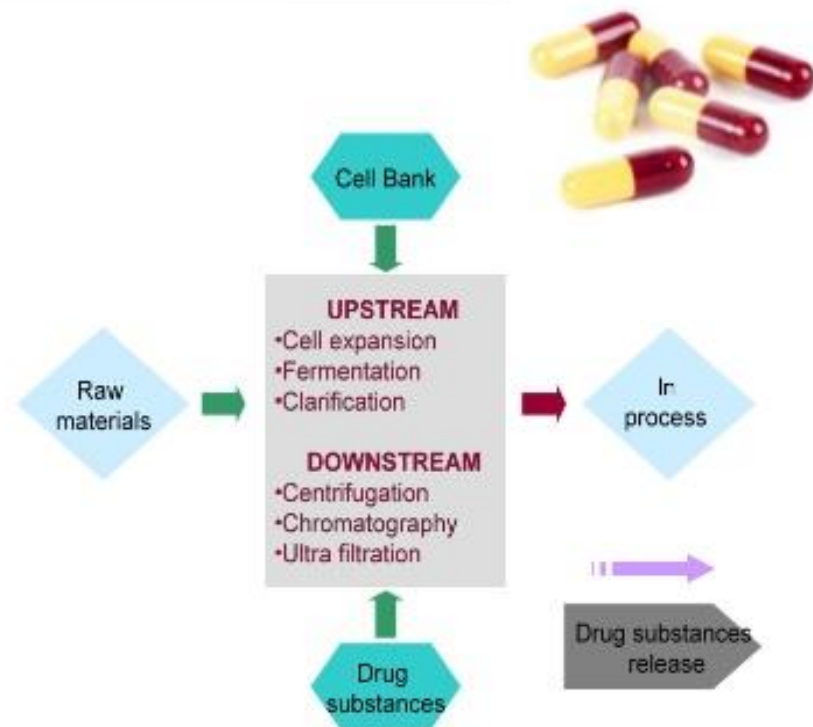
- ▶ Biopharmaceuticals may be produced from:
- ▶ Microbial cells (e.g., Recombinant E. Coli or yeast cultures)
- ▶ Mammalian cell lines (cell culture)
- ▶ Plant cell cultures (plant tissue culture)
- ▶ Moss plants in bioreactors of various configurations
- ▶ Whole plants (plant-made pharmaceuticals).



Drug Substance Production

Protein therapeutics-
therapy using protein-
based drugs

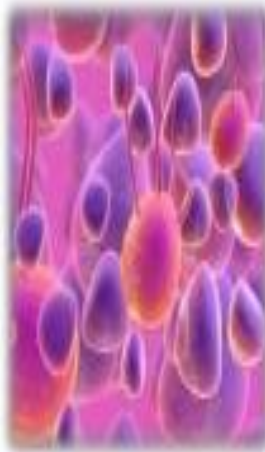
Especially monoclonal
antibodies and
recombinant proteins,
have emerged as the
hottest approach in
targeting and treating a
number of diseases.



Conventional Drug Vs Biopharmaceuticals

Conventional Drug

- ▶ Multiple effect
- ▶ Short Acting
- ▶ Non-Immunogenic
- ▶ Species independent
- ▶ Small molecules



Biopharmaceutical Drug

- ▶ Specific effect
- ▶ Long acting
- ▶ Immunogenic
- ▶ Species dependent
- ▶ Large molecules



Advantages of Biopharmaceuticals

- ▶ Highly Effective
- ▶ Highly Specific
- ▶ Fewer Side effect
- ▶ They are not Carcinogenic
- ▶ Safe
- ▶ Easy Commercial Production



Applications

- ▶ Production of different biopharmaceutical products:
- ▶ **Humilin** (Recombinant Insulin)
- ▶ Recombinant glycosylated Protein
- ▶ **Streptase** : Streptokinase
- ▶ **Epogen and EpoREL** : Commercially produced erythropoietin hormone
- ▶ Monoclonal Antibodies: **Rituximab, Ceutximab**, used against various lymphomas
- ▶ Biopharmaceuticals produced by rDNA technology: Recombinant vaccine, including **Recombivax HB** (HBV).



Conclusion

- ▶ Biopharmaceuticals are medicinal product manufactured using biotechnology.
- ▶ Have potential to cure diseases.
- ▶ With Emerging technologies, different biopharmaceuticals like Monoclonal Ab, Recombinant therapeutic proteins, vaccines, enzymes, hormones, growth factors etc are manufactured.
- ▶ Fewer side effects and more potent effect on target cells.
- ▶ Thus biopharmaceuticals have profound influence on molecular medicine.