



**BP 605 T. Pharmaceutical Biotechnology (Theory)**

# **Introduction to Pharmaceutical Biotechnology**

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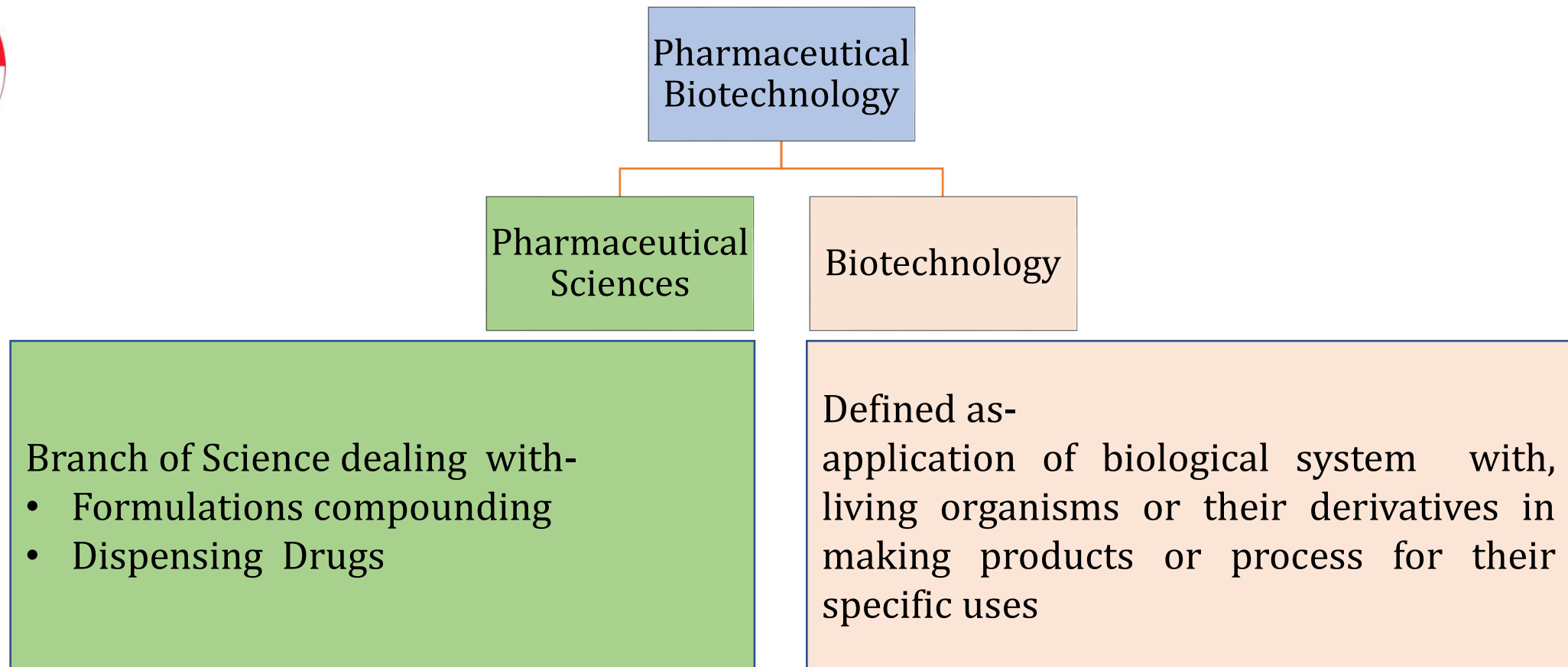
# Overview

Definition and Introduction

Steps of development of Bio-formulations

Biotechnology derived pharmaceutical products

Recombinant DNA Products



- ✓ Relatively new and growing field in which the principles of biotechnology are applied to the development of drugs.
- ✓ The aim is to design, produce drugs that are adapted to each persons genetic make up, which can give the maximum therapeutic effect.



# DEVELOPMENT OF BIO-FORMULATIONS

Bio-formulations are developed through several stages:

- Understanding the principles underlying health and disease
- The fundamental molecular mechanisms governing the function of related biomolecules
- Synthesis and purification of the molecules
- Determining the product shelf life
- Stability
- Toxicity and immunogenicity
- Drug delivery systems
- Clinical trials
- Patenting
- Commercialization



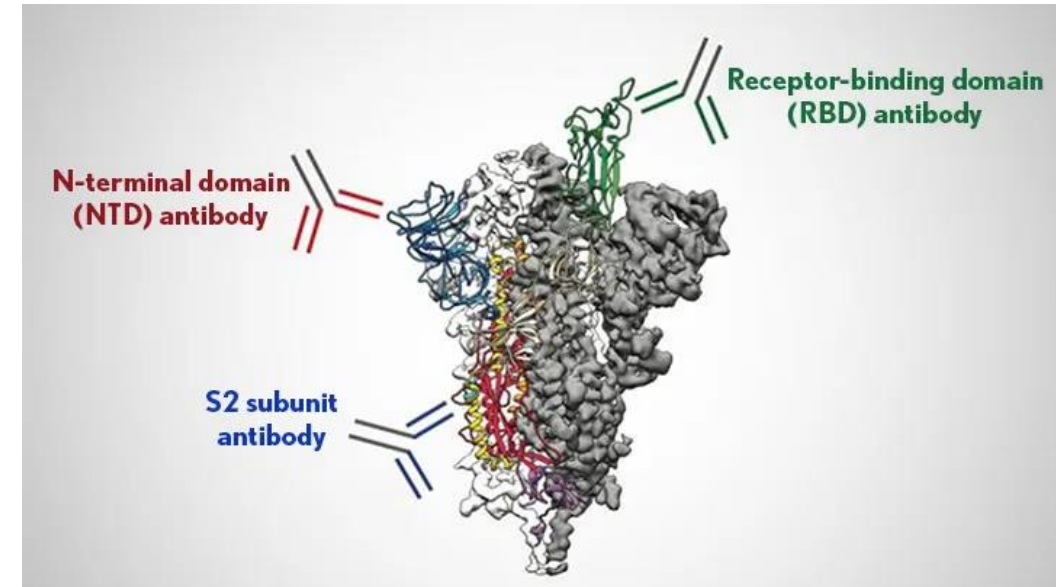
# BIOTECHNOLOGY DERIVED PHARMACEUTICAL PRODUCTS

- ✓ A majority of therapeutic drugs in the current market are bio-formulations
  - Proteins
  - Monoclonal Antibodies
  - Antibody fragments
  - Peptides
  - Antisense oligonucleotides
  - Vaccines
  - Recombinant DNA Products
- ✓ **Genetically modified organisms** that can be used in industrial production



# PROTEINS

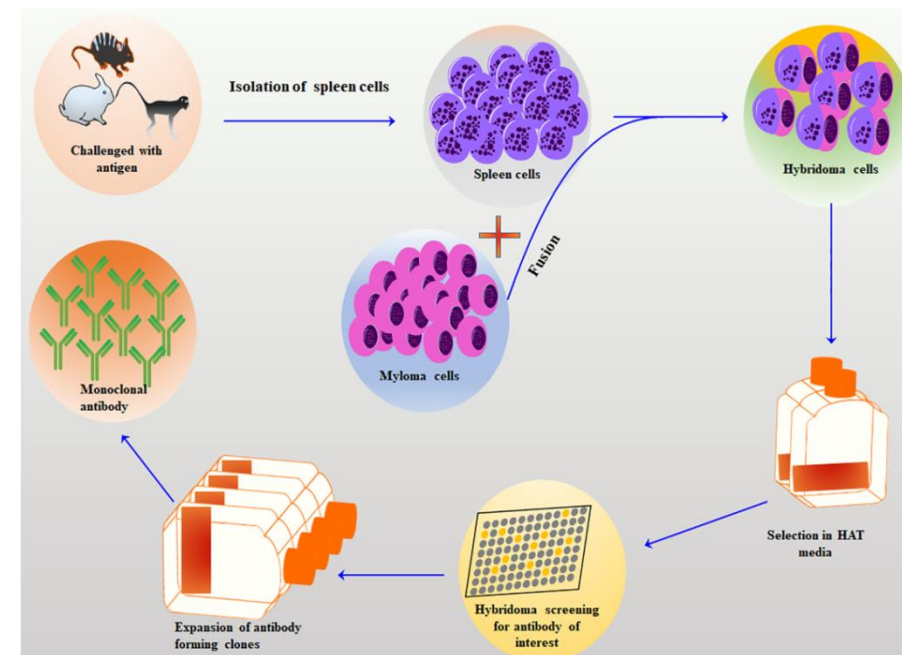
- ✓ Proteins, made of amino acids are large, complex molecules that do most of the work in cells
- ✓ Required for the structure, function, and regulation of the body's tissues and organs.
- ✓ Protein biotechnology is emerging as one of the key technologies of the future for understanding the development of many diseases like cancer or a myloid formation for better therapeutic intervention.





# MONOCLONAL ANTIBODIES

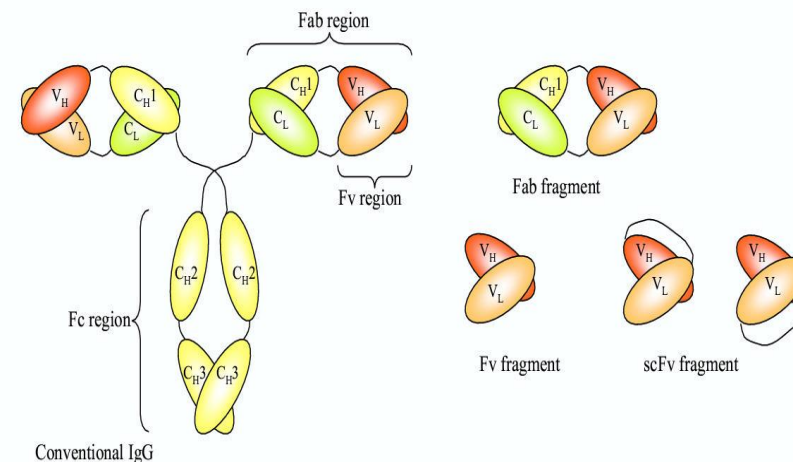
- ✓ Antibodies are proteins that are produced by white blood cells and are used by the immune system to identify bacteria, viruses, and other foreign substances and to fight them off.
- ✓ Monoclonal antibodies are one of the most exciting developments in biotechnology pharmaceuticals.
- ✓ Example: Avastin, Trastuzumab (Herceptin) etc. monoclonal antibodies against cancer





# ANTIBODY FRAGMENTS

- ✓ Antibody fragments (FABs) are proteins that form part of the antigen recognition site.
- ✓ FABs are produced in genetically modified bacteriophages, bacteria, fungi, or plants and, consequently, can be produced in large quantities at a fraction of the cost of traditional antibodies.
- ✓ Substitutes the function of Monoclonal antibodies.
- ✓ Advantages are being smaller in size can have better penetration
- ✓ Example: Ranibizumab (Lucentis®) for treatment of macular degeneration.

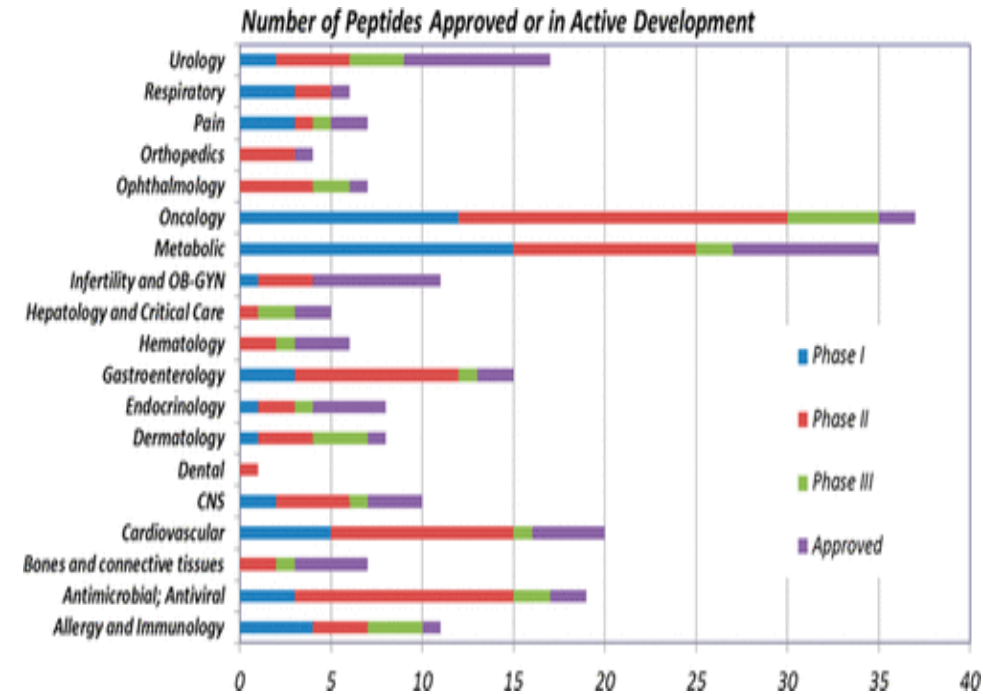






# PEPTIDES

- ✓ Peptides are the stretch of amino acids that are relatively shorter than proteins.
- ✓ Can be an excellent complement or even preferable alternative to small molecule and biological therapeutics.
- ✓ Relatively lesser toxic
- ✓ Advantages are being smaller in size can have better penetration if designed properly

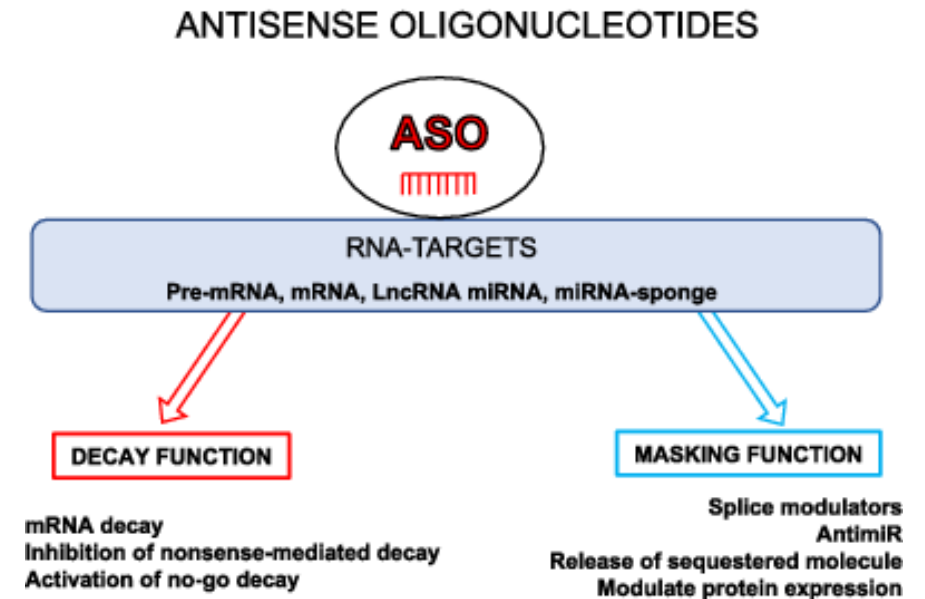




# ANTISENSE OLIGONUCLEOTIDES

- ✓ Antisense therapy is a form of treatment that uses antisense oligonucleotides (ASOs) to target messenger RNA (mRNA).
- ✓ Capable of altering mRNA expression through a variety of mechanisms
  - Ribonuclease H mediated decay of the pre-mRNA,
  - Direct steric blockage,
  - Exon content modulation through splicing site binding on pre-mRNA

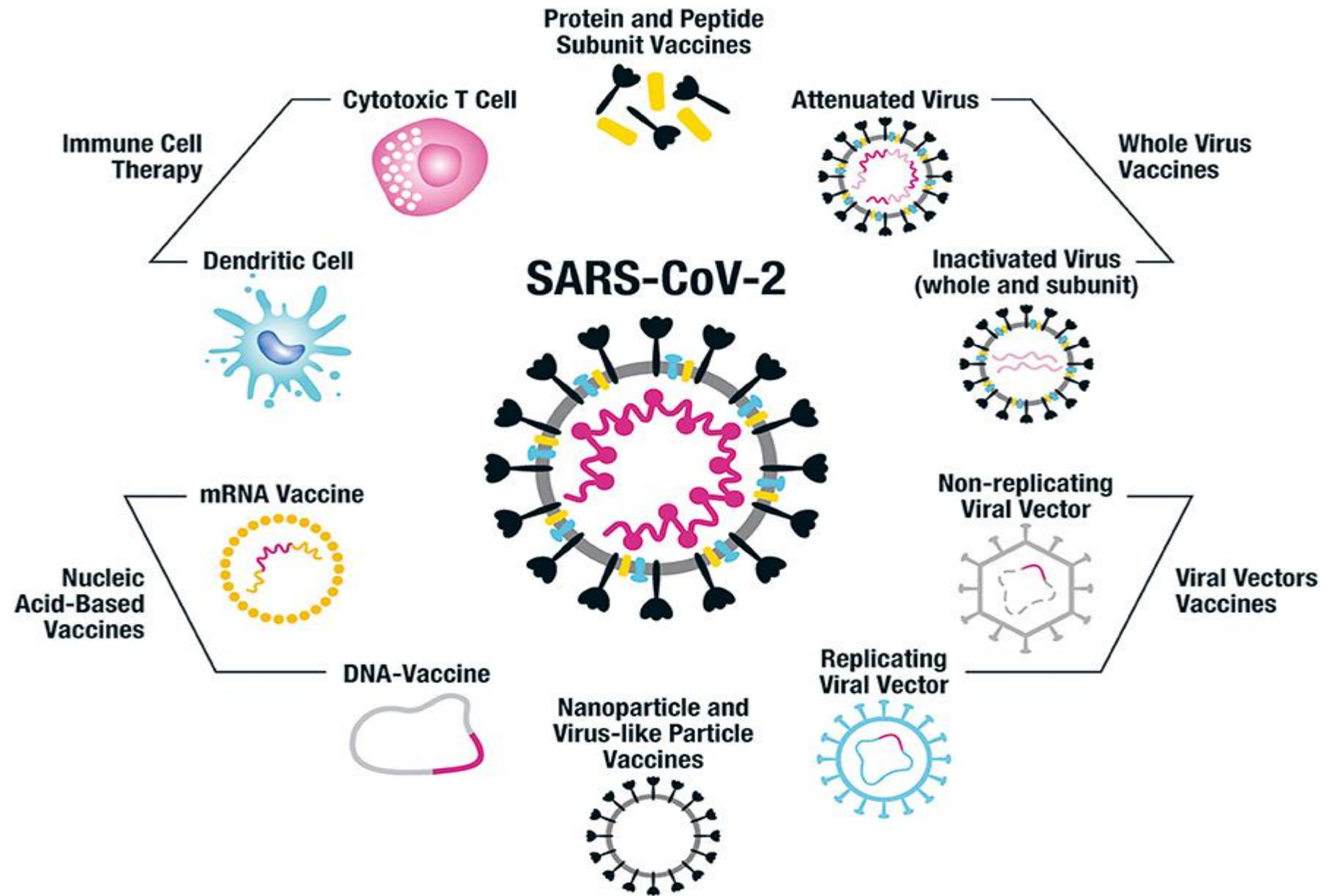
Example: Fomivirsen (marketed as Vitravene), was approved by the U.S. FDA in August 1998, as a treatment for cytomegalovirus retinitis.



TOWARDS PERSONALIZED MEDICINE 



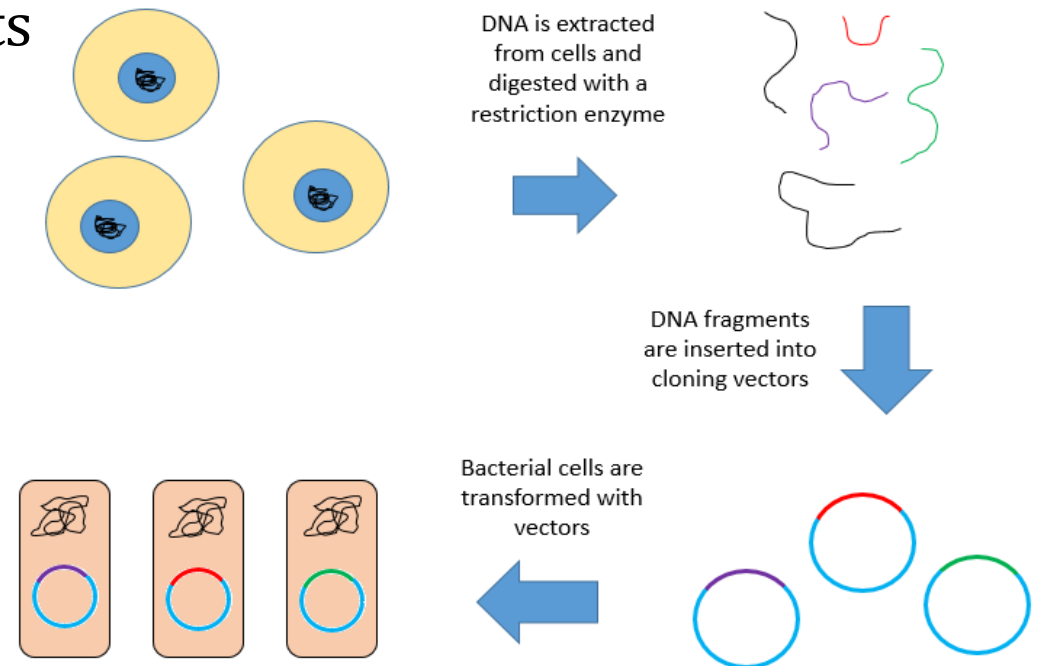
# VACCINES





# RECOMBINANT DNA PRODUCTS

- ✓ Recombinant DNA is the genetically engineered DNA created by recombining fragments of DNA from different organisms.
- ✓ Some of the Recombinant DNA Products includes:
  - Recombinant DNA Vaccines
  - Recombinant DNA Drugs
  - Recombinant DNA Enzymes
  - Recombinant DNA Growth Hormone
  - Recombinant DNA Insulin
  - Recombinant DNA Proteins
  - Recombinant DNA Yeast

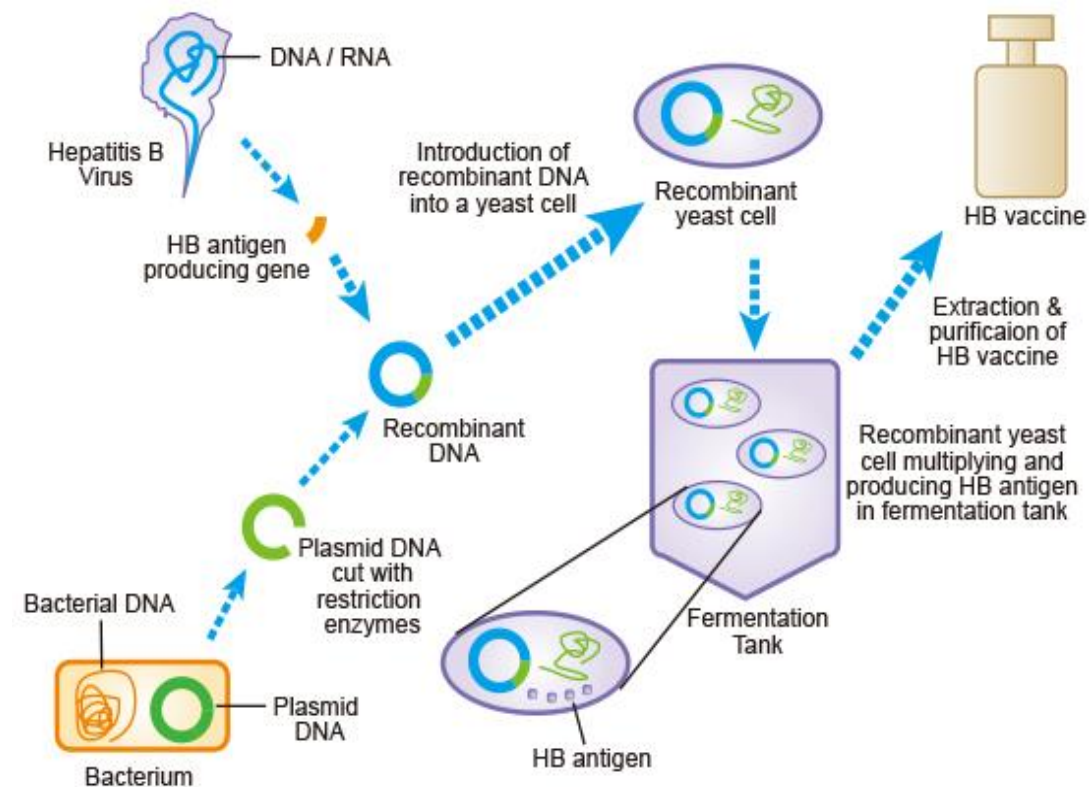




# RECOMBINANT DNA VACCINE

✓ A recombinant vaccine is a vaccine produced through recombinant DNA technology. This involves inserting the DNA encoding an antigen (such as a bacterial surface protein) that stimulates an immune response into bacterial or mammalian cells, expressing the antigen in these cells and then purifying it from them.

Example:-Hepatitis B infection is controlled through the use of a recombinant hepatitis B vaccine







# SOME IMPORTANT BIOTECHNOLOGY DRUGS AND VACCINE

Generic name	Product name	Name of company	Year of discovery
Human insulin	humulin	Eli Lilly	1982
sometrem	protropin	Genetech	1985
Digoxin Immune Fab	digibind	Burrough well come	1986
Interferon- $\alpha$ -2a	Roferon-A	Hoffman –La- roche	1986
Interferon- $\alpha$ -2b	Intron-A	Schering-Plough	1986
Hepatitis-B vaccine	Recombivax-HB	Merk	1986
somatotropin	humatrope	Eli Lilly	1987
Haemophilus- B conjugate vaccine	Hib titer	Praxis biologics	1988
Hepatitis –B vaccine	Engerix -B	Smithkline Beecham	1989
Interferon-Y-Ib	actimmune	Genetech	1990



For Query

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