

# Pharmaceutical Biotechnology

References:

- Crommelin /Pharmaceutical Biotechnology

- Ansel

## Topics:

- ✓ Introduction
- ✓ Techniques used to produce Biotech products
- ✓ Formulation of Biotech products
- ✓ Shelf life of proteins
- ✓ Delivery of proteins
- ✓ Pharmacokinetics of proteins

## Introduction

Biotechnology encompasses any techniques that **use living organisms** like micro-organisms, isolated mammalian cells in the production or modification of products having beneficial use.

The **classic example** of biotechnologic drugs was proteins obtained from recombinant DNA (rDNA) technology.

Biotechnology now encompasses the use of tissue culture, living cells or cell enzymes to make a defined product.

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rDNA and monoclonal antibody (MAb) technologies have provided exciting opportunities for the development of more pharmaceuticals and approaches to **the diagnosis, treatment, and prevention of disease.**

Also, it is:

Any technique that uses living organisms or substances from those organisms to make or modify a product, to improve plants or animals or to develop microorganisms for specific uses (**Organismic Biotech**).

Cloning is an example of organismic biotech, which is process of producing a new organism from cells or tissues of existing organism.

Ex. In 1997 cloned sheep – “Dolly”

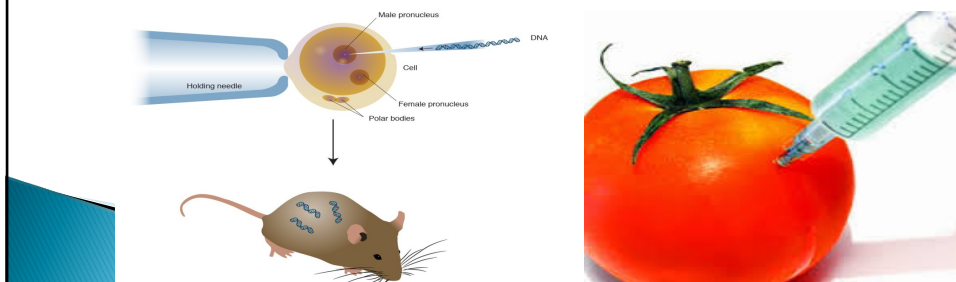


## Molecular Biotech

Changing the genetic make-up of an organism or altering the structure or parts of cells.  
as in ex. **The genetic engineering**

## Transgenic

Results of Gen. Eng. Are said to be “transgenic”  
Genetic material in an organism has been altered



## As applications:

Medicine  
Agriculture  
Environment  
Food

## Medicine

- Some new developments delve into the hereditary material of humans known as **gene therapy**.
- Biopharmaceutical : drug or vaccine developed through biotechnology

- ▶ The first of the novel biotechnologic pharmaceuticals were proteins, but eventually an increasing number will be smaller molecules, discovered through biotechnology-based methods that will determine just how proteins work.

- ▶ **Biosimilars**, also known as follow-on biologics, are biologic medical products whose active drug substances are made by a living organism or derived from a living organism by means of recombinant DNA or controlled gene expression methods.

## Biotechnology Products are different From others?



**Synthetic Drugs** are small molecules with relatively easy synthesis like Aspirin

**Extraction Biologics** are complex and large molecules, may obtained from animal source like Insulin, Heparin and calcitonin or Human source like HGH, Coag. Factors and Albumin

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## Biotech drugs or Biopharmaceuticals



Are complex and large molecules, may be obtained using different techniques with better yield & safety like Insulin, Heparins , HGH, Coag. Factors, Albumin and calcitonin

By Use of micro-organisms (procaryotic or eucaryotic) genetically modified for production of these complex molecules. After purification, the products are used in human or animal therapeutics

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