2022/2023

Fifth Stage

Second Semester/ Pharm Biotechnology

# Pharmaceutical Biotechnology

## (General introduction)

## Lecture One

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# Topics of Course:

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

***References:***

***- Crommelin / Pharmaceutical Biotechnology***

***- Ansel***

# General Introduction

- ✓ Biotechnology implies the use of microorganisms, plants, and animals or parts thereof for the production of useful compounds.
- ✓ Consequently, pharmaceutical biotechnology should be considered as biotechnological manufacturing of pharmaceutical products.

## Historically >>>>>

- ✓ Fermentation of yeast used to produce spirits, vinegar and leavened bread.
- ✓ Yogurt was produced by lactic acid bacteria in milk.
- ✓ Molds were used to produce cheese.
- ✓ Enzymes from yeast can convert sugar to alcohol, butanol, acetone and glycerol.
- ✓ Fermentation used to produce AB.s, Vit.s, amino acids, Enzymes, steroids …etc

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

# As important branches of biotechnology:

- Organismic Biotechnology
- Molecular Biotechnology

# Organismic Biotech

Any technique that uses living organisms or (substances from those organisms) to:

- Make or modify a certain product.
- Improve plants or animals properties
- Develop microorganisms for specific uses.

**As in cloning technique**

**Cloning** is an example of organismic biotech, which is process of producing:

a new organism from cells or tissues of existing organism.

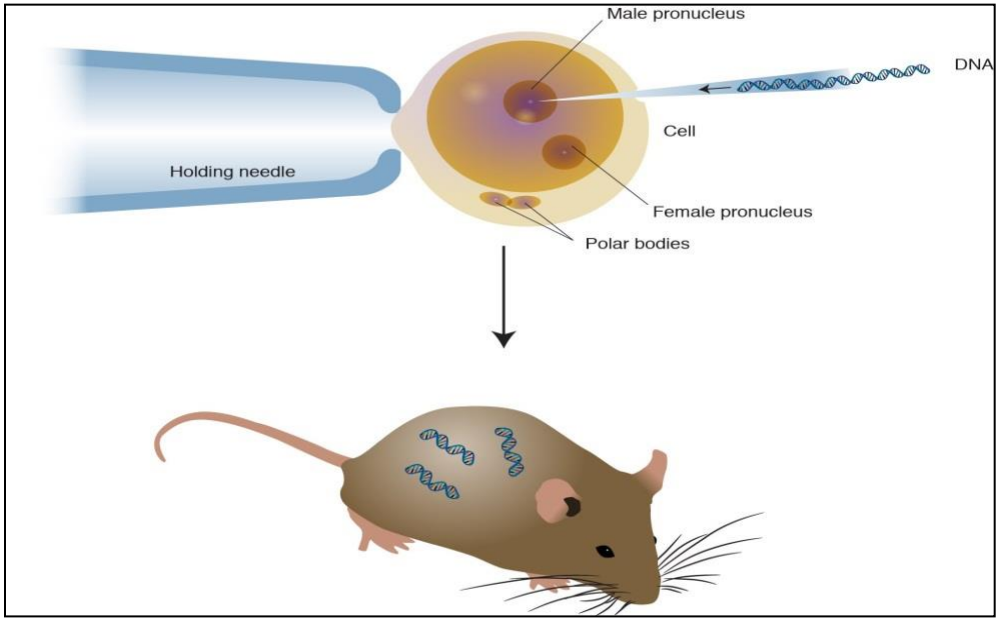

Dolly was **cloned from a cell taken from the mammary gland of a six-year-old Finn Dorset sheep and an egg cell taken from a Scottish Blackface sheep**. She was born to her Scottish Blackface surrogate mother on 5th July 1996.

# Molecular Biotech

Changing the genetic make- up of an organism or altering the structure or parts of cells.

as in ex. **The genetic engineering**

# Results of Gen. Eng. Are said to be **“transgenic”**




# Applications of Biotechnology

-Human and animal Medicine (Red biotechnology)
- Agriculture and food (Green biotechnology)
- Environment (Grey/White biotechnology)

# Biopharmaceutical

- Also known as a biologic(al) medical product, or biologic,
- Is any a pharmaceutical drug product (**manufactured in, extracted from, or semisynthesized)** from biological sources.
- Different from totally synthesized pharmaceuticals.

They include vaccines, blood, blood components, allergenics, somatic cells, gene therapies, tissues, recombinant therapeutic protein, and living cells used in cell therapy.

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.

# Gene therapy

Is an experimental technique that uses genes to treat or prevent disease.

In the future, this technique may allow doctors to treat a disorder by inserting a gene into a patient's cells instead of using drugs or surgery.

# Biotechnology Products are different From others?

**Conventional Drugs**

May be synthetic or naturally derived (semisynthetic), are mostly small molecules with relatively easy production like aspirin, acetaminophen, some antibiotics …

# Extraction Biologics

Are complex and large (macro) molecules, may be obtained or semi-synthesized from biological sources like:

- Insulin (bovine and **porcine** pancreas)
- Heparin (firstly, Canine **K9** liver cells then bovine, **porcine** intestinal mucosa)
- Calcitonin (Salmon)
- Gelatin (bovine and **porcine**)
- HGH, Coag. Factors and Albumin (human)
- Gonadotrophins (Urine of menapausal and pregnant women)

# Biotech drugs or Biopharmaceuticals

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

By Use of micro-organisms (procaryotic) or eucaryotic cells, genetically modified for production of these complex molecules.

**After purification, these products are used in human or animal therapeutics.**