B. Pharm. VI Semester 2022
Pharmaceutical Biotechnology

Introduction to Pharm. Biotechnology

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Definitions and understanding of Biotechnology

- Biotechnology” term - by Hungarian business man “Karl Erkey” in 1919 for mass production of pigs.
  - “Bio” means life – live organism/ processes/ products/parts
  - “Technology” means application of scientific knowledge/principles for Industrial purpose and/or benefit of humankind.

- **Def. 1.** The utilization/application of biological processes, organisms or systems/parts to produce products/improve process that are anticipated to improve human lives.
- **Def.2. A**pplication of biological systems and organisms to technical and industrial processes. (FDA)

Pharm. Biotechnology

- **Def. 1.** A field of applied biology that uses micro- and macroorganisms and hybridomas or their processes to create or modify pharmaceuticals or related services.
- **Def.2.** Principles of **biotechnology** are applied to the development of drugs/diagnostics such as
  - Biopharmaceuticals and Similar biologics (Biosimiliars)
  - Vaccines/ Antisera/Blood products/ Blood Substitute
  - Diagnostics- e.g. DNA fingerprinting

Biotechnology as an interdisciplinary area

- Interdisciplinary” – Combined approaches of different subjects and disciplines to redefine problems outside of normal boundaries and reach solutions based on a new understanding of complex situations.
- What is **Multidisciplinary** then ????
- **Biotechnology** is an interdisciplinary science including not only biology, but also subjects like mathematics, physics, chemistry and engineering.
- It is a blend of various technologies applied together to living cells for production of a particular product or for improving upon it.

History

Ancient Biotechnology
- A. History of Domestication and Agriculture
- B. Ancient Plant Germplasm
- C. History of Fermented Foods and Beverages
    1. Fermented Foods
    2. Fermented Beverages

Classical Biotechnology
- A. Biotech Revolution: Old Meets New

Foundations of Modern Biotechnology
- A. Early Microscopy and Observations
- B. Development of Cell Theory
- C. Role of Biochemistry and Genetics in Elucidating Cell Function

Nature of the Gene
- A. Early Years of Molecular Biology
- B. First Recombinant DNA Experiments
    1. Biotech Revolution: Breaking the Genetic Code
- C. First DNA Cloning Experiment
    1. Cause for Concern? Public Reactions to Recombinant DNA Technology

Traditional Biotechnology	Modern Biotechnology
It refers to the traditional techniques of using living organisms to yield new products or modify foods or other useful products for human use.	The diversity of microorganisms and development of genetics expanded the potential of traditional biotech, and ultimately led to the development of modern biotechnology.
Examples of early biotechnology include recombinant DNA techniques, tissue culture, and mutagenesis.	Examples of modern biotechnology include DNA profiling, genome analysis, transgenesis, DNA cloning, tissue engineering, etc.
Breeding animals and crops to make cheese, yoghurt, bread, beer and wine. Microorganisms are used to produce various products such as enzymes for use in laundry detergents.	Modern biotechnology techniques are used in many areas such as food, agriculture, forestry, healthcare, environment, minerals, and industrial processes.
It involves use of natural organisms to create or modify food or other useful products for human use.	It involves manipulation of genes and living tissues in a controlled environment.

The Indian Biotechnology industry

- *Valued at $64 bn in 2019 will reach $150 bn target by 2024-25.*
- *62% BIOPHARMACEUTICALS (includes Vaccines)*

  18% BIO-SERVICE

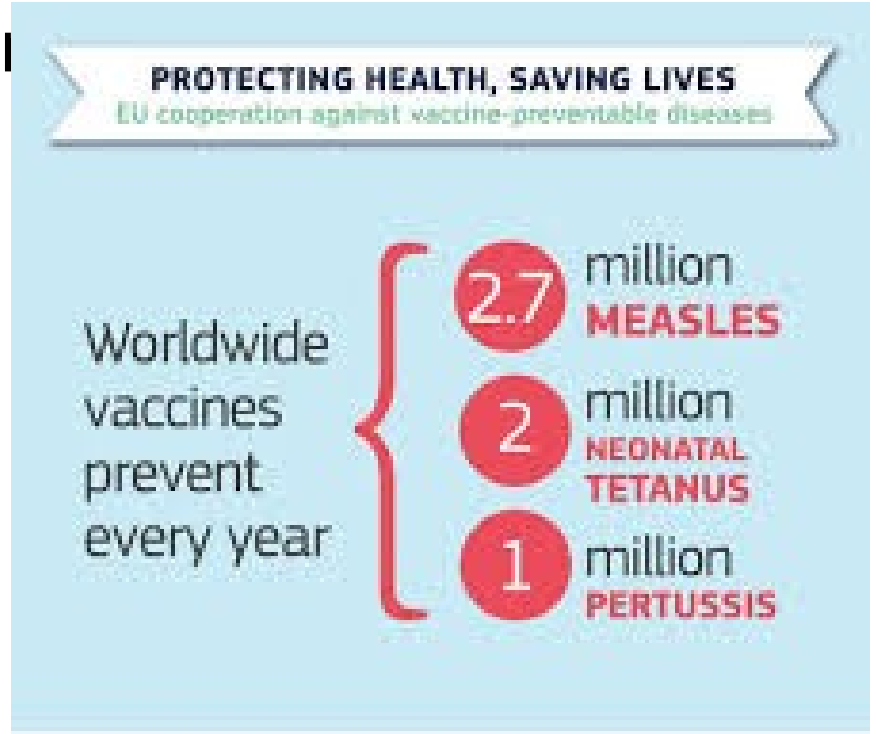
  15% BIO-AGRICULTURE

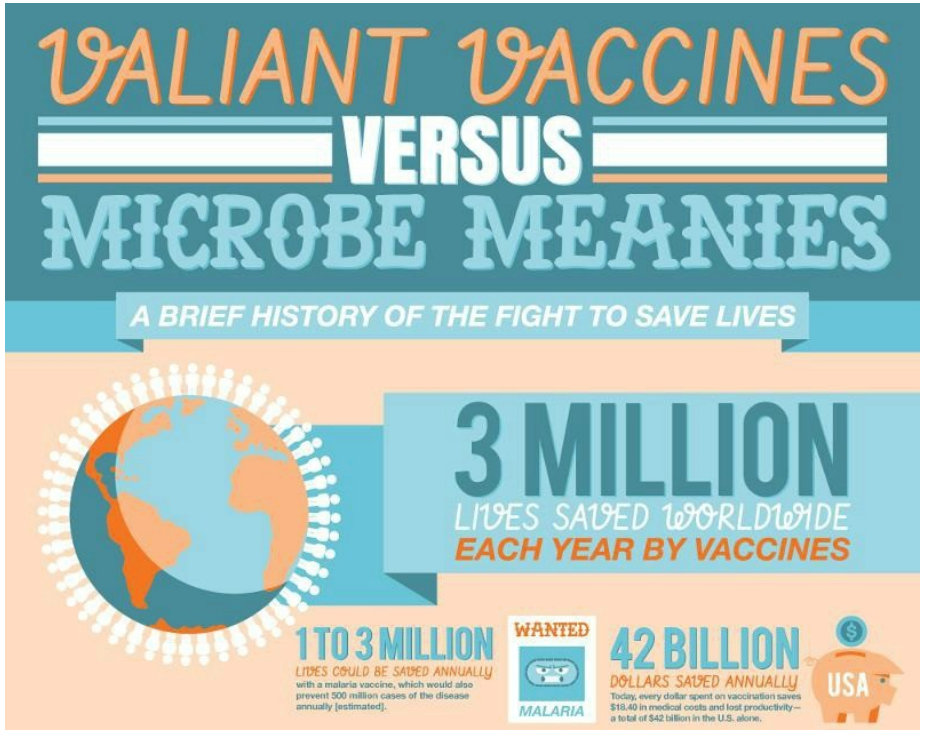
  04% BIO-INDUSTRIALS

  01% BIOINFORMATICS, SYSTEM BIOLOGY
- Bio-services accounted for 18% of the Biotech industry as India is becoming a leading destination for clinical trials, contract research, and manufacturing activities, which is further fueling the growth of the bio-services sector.

Global Impact of biotechnology in healthcare

- Vaccines- According to 2018 estimates, **60 percent of the global health vaccines (supply to UNISEF)** are produced in I





Biopharmaceuticals

S.No.	Molecules	Therapeutic applications
1	Human insulin	Diabetes
2	Erythropoietin	Treatment of anaemia
3	Hepatitis B vaccine (recombinant surface antigen based)	Immunization against Hepatitis B
4	Human growth hormone	Deficiency of growth hormone in children
5	Interleukin 2	Renal cell carcinoma
6	Granulocyte Colony Stimulating Factor	Chemotherapy induced neutropenia
7	Granulocyte Macrophage Colony Stimulating Factor	Chemotherapy induced neutropenia
8	Interferon 2Alpha	Chronic myeloid leukemia
9	Interferon 2Beta	Chronic myeloid leukemia, Hepatitis B and Hepatitis C
10	Interferons Gamma	Chronic granulomatous disease and Severe malignant osteopetrosis
11	Streptokinase	Acute myocardial infarction
12	Tissue Plasminogen Activator	Acute myocardial infarction
13	Blood factor VIII	Haemophilia type A
14	Follicle stimulating hormone	Reproductive disorders
15	Teriparatide (Forteo)	Osteoporosis
16	Drerecogin (Xigris) alpha	Severe sepsis
17	Platelet Derived Growth Factor (PDGF)	Bone marrow induction and osteoblasts proliferation

Biosimiliars- similar biologics

Product name	Active drug	Indications
Glaritus	Insulin glargine	Diabetes mellitus
Grafeel	Filgrastim	Neutropenia
Epofer	Epoetin alfa	Anemia
Adfar	Adalimumab	RA, Crohn's disease
Erbitux	Cetuximab	Colorectal carcinoma
Krabeva	Bevacizumab	Colorectal cancer
Herceptin	Trastuzumab	Breast cancer
Intacept	Etanercept	RA
Abcixirel	Abciximab	Autoimmune disease
Relibeta	Interferon beta-1a	Multiple sclerosis
Relipoietin	Epoetin alfa	Anemia, autologous blood transfusion, chronic kidney failure, HIV
Shankinase	Streptokinase	Arterial occlusions, deep vein thrombosis, pulmonary embolism
Razumab	Ranibizumab	Wet macular degeneration, macular edema, degenerative myopia
Terifrac	Teriparatide (parathyroid hormone)	Postmenopausal women with osteoporosis who are at high risk for fracture

Regenerative medicine

- Multi-disciplinary field that involves basic sciences, cell therapeutics and bio-engineering techniques to enhance he functionalities of tissues or organs. Eg. **Stem Cell Research**

Medical technology

- Healthcare devices and imaging methods that aid clinical diagnosis, monitoring and therapy for patients.

Natural product drug discovery

- Natural products have been an important source of active drugs and lead compounds. Around 75% of all anti-infectives and 60% of all anti-cancer drugs that were approved from 1981 to 2002 had natural product origins.

Synthetic Biology

- The synthesis of complex, biologically based (or inspired) systems which display functions that do not exist in nature.

1. Alexion Pharmaceutical's Soliris, at more than half million dollar a year, is the world's **single most expensive drug**. This monoclonal antibody drug treats a rare disorder in which the immune system destroys red blood cells at night. The disorder, paroxysymal nocturnal hemoglobinuria (PNH).

2. **Alipogene tiparvovec** (marketed under the trade name **Glybera**) is a gene therapy treatment that compensates for lipoprotein lipase deficiency (LPLD), which can cause severe pancreatitis. In July 2012, the European Medicines Agency recommended it for approval, the first recommendation for a gene therapy treatment in either Europe or the United States.

3. **Zolgensma** (onasemnogene abeparvovec-xioi) for all children under age 2 who are confirmed by a genetic test to have an inherited condition called spinal muscular atrophy. one-time infusion that takes about an hour. sold by the Swiss drugmaker Novartis, is a gene therapy that treats a defective gene that weakens a child's muscles so dramatically that they become unable to move, and eventually unable to swallow or breathe. Most expensive drug therapy (2.1 Million)

Colours of Biotechnology

Red biotechnology	**Medicine** **Drugs, diagnostics, regenerative medicine (stem cells), gene therapy**
White biotechnology	Industrial processes low cost, energy efficient and pollution free process
Grey biotechnology	Environment biodiversity maintenance and contaminants removal
Green biotechnology	Agriculture Genetically modified crops, biopesticides, biofertilizers,
Blue biotechnology	Sea resources For product/industrial processes

THANKS

Welcome to the world of Pharmaceutical Biotechnology
(Pharmaceutical Sciences + Biotechnology)