BIOSAFETY OF MEDICAL BIOTECHNOLOGIES

Medical biotechnology is a branch of medicine that uses living cells and cellular materials to analyze and then create pharmaceutical and diagnostic products.

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The field of medical biotechnology has grown rapidly in recent years, leading to the development of innovative methods necessary for the prevention, diagnosis and treatment of diseases. If the current rate of growth continues, medical biotechnology will soon become one of the mainstays of health science.

But, with the advent of numerous achievements in the field of medical biotechnology, new questions regarding safety of new technologies introduced into medical practice arise

Cell and genetic engineering are main biotechnological methods today.

Cell engineering involves modification or generation of new cells from those that already exist.

Genetic engineering involves manipulation by artificially changing the genotype of an organism

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Methods of genetic and cellular engineering are used to study humans, oncological diseases, and diseases related to the immune system

CRISPR (or CRISPR-Cas9) technology uses a unit called Cas9, which acts as "molecular scissors" and can cut DNA into specialized DNA regions, or CRISPRs, which are used in medical biotechnology as a **genome-editing tool**.

This allows scientists to change DNA and gene functions, and that is known as genetic engineering.

Applications of CRISPR include correcting genetic defects, treating diseases, preventing its spread, improving crops, and much more.

BUT CHANGING THE GENOME COMES WITH A NUMBER OF ETHICAL ISSUES

THE POSSIBILITY OF GENE MUTATION AND THE UNCERTAINTY ASSOCIATED WITH THIS PROCESS MAKE CRISPR ONE OF THE MOST CONTROVERSIAL FIELDS OF THE BIOMEDICAL SCIENCE.

CRISPR CAN PROMOTE TUMORS AND CANCER WHEN DNA MUTATIONS ARE OUT OF CONTROL.

THE REAL RATIO OF BENEFITS AND HARMS OF CRISPR REMAINS UNCLEAR.

Recombinant DNA technology

Recombinant DNA technology involves combining DNA molecules from two different species with subsequent introduction of new DNA into the host organism. This host organism can produce new genetic combinations for further use.

Application areas of recombinant DNA technology include biopharmaceuticals, medicine, and agriculture

Application of recombinant DNA technology:

HIV detection – DNA technologies are used to detect HIV in humans.

Gene therapy – it is used to correct genetic defects that cause hereditary diseases.

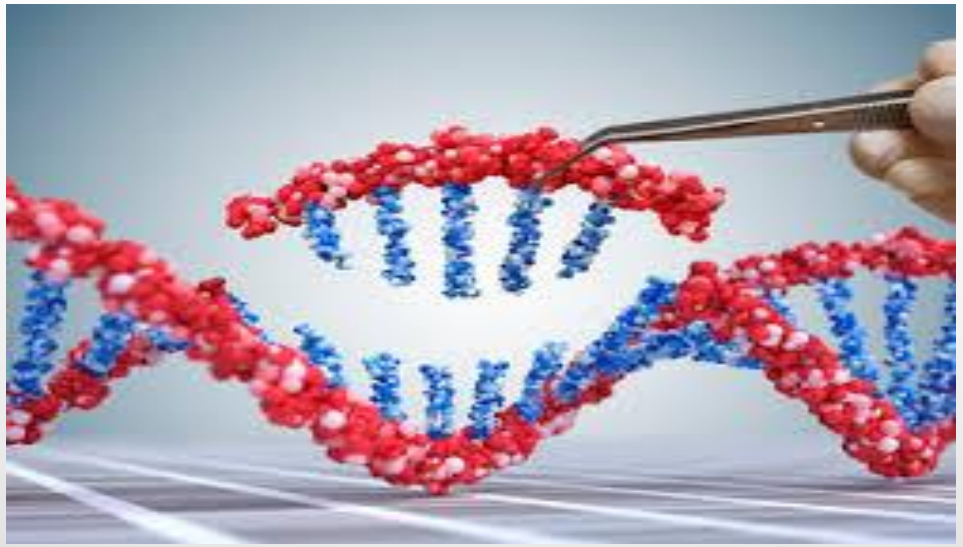
Clinical diagnostics - an example is the ELISA method, which uses recombinant DNA technology.

Agriculture – it is widely used to create genetically modified organisms.

Pharmacy - recombinant DNA technology is used for the production of medications.

Gene therapy is an experimental technique that uses **genes** to treat or prevent disease.

Gene therapy will treat the disorder by introducing a **gene** into the patient's cells instead of using medications or surgery.



Gene therapy is designed to introduce genetic material into cells **to compensate abnormal genes** or create a useful protein.

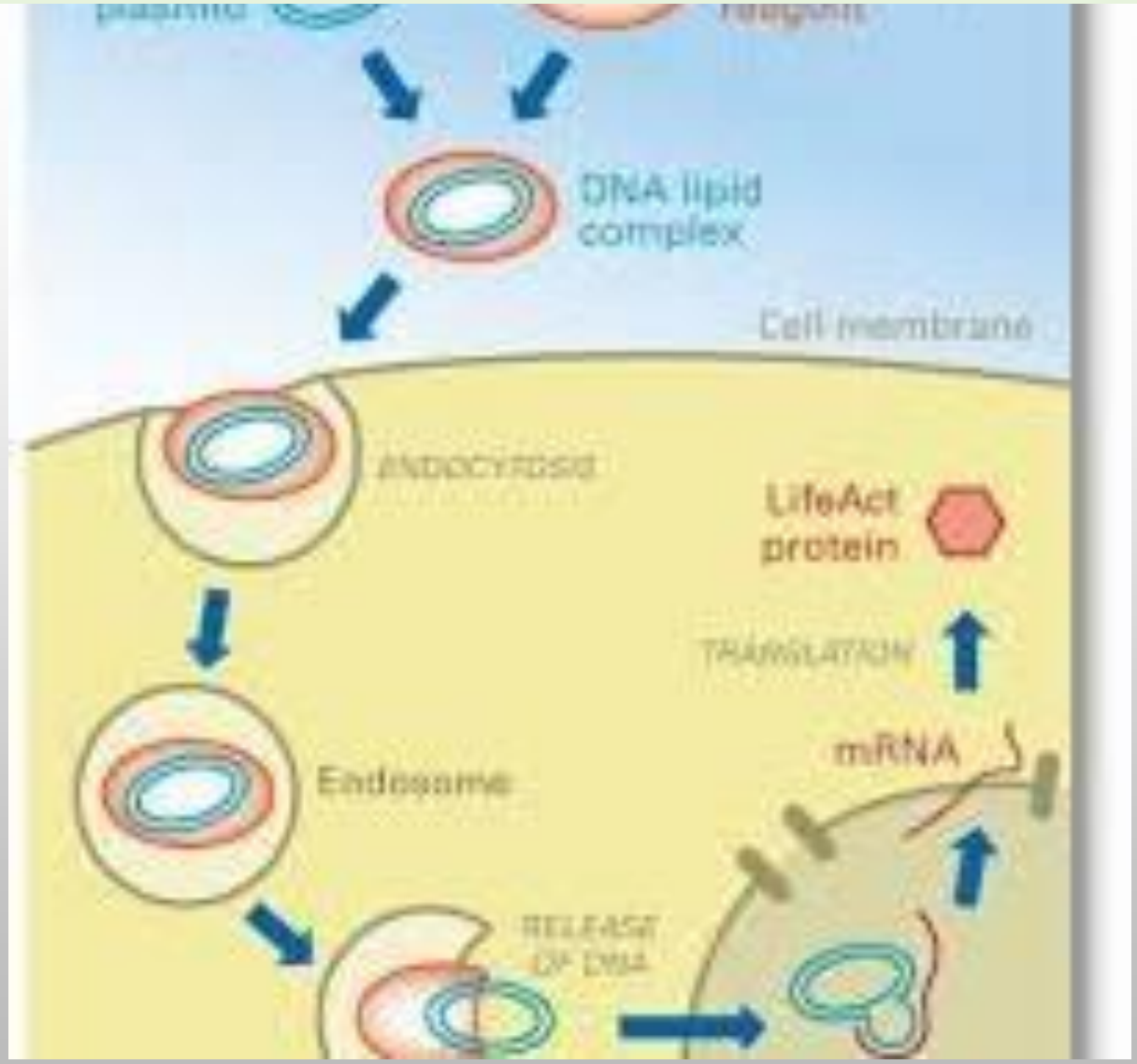
If a mutated gene causes an essential protein to be defective or missing, gene therapy can help **insert a normal copy of the gene to restore the protein function.**

Transfection is the process of introducing nucleic acid into eukaryotic cells by a non-viral method
This leads to a change in the phenotype by introducing a foreign nucleic acid.

TISSUE NANOTRANSFECTION

TISSUE NANOTRANSFECTION (TNT) WORKS BY INTRODUCING GENETIC CODE INTO SKIN CELLS, CONVERTING THEM INTO DIFFERENT TYPES OF CELLS NEEDED TO TREAT A DISEASE.

THIS BIOTECHNOLOGY CAN WORK WITH OTHER TYPES OF TISSUES BESIDES THE SKIN, THE POTENTIAL FOR SUCH GENE THERAPY IS HUGE.



The value of genetic engineering for medicine is significant. Products of genetic engineering have become an integral part of medical practice: medications for rare diseases treatment, production of vaccines, reagents for diagnostics, etc. The introduction of genetic technologies into medical practice opens up prospects for improvement and creation of new methods of treatment and diagnosis. On the other hand, together with numerous achievements in this field and medical biotechnology, the issue of biorisks arises.

1. **First of all, it is interbreeding and loss of biodiversity. Genetically modified species can hybridize with traditional representatives already known to us. This can have unintended consequences for other organisms that depend on altered ecosystems.**

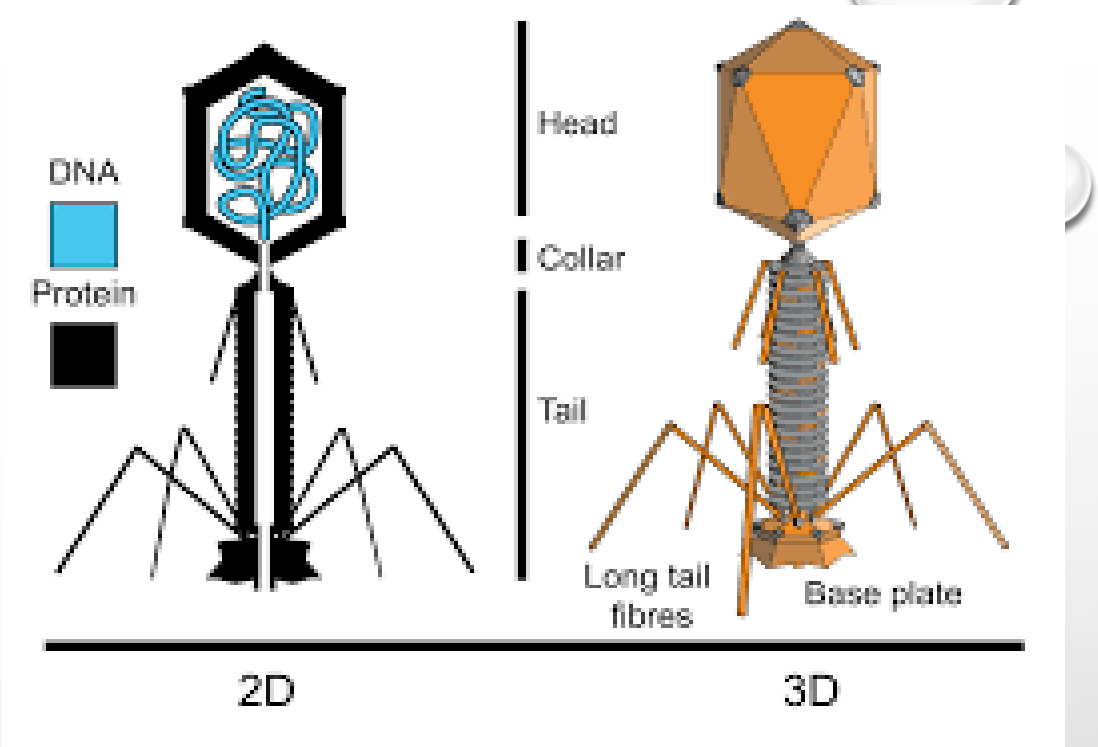
2. **Another potential risk associated with GMOs is the development of superweeds and superbugs that are resistant to pesticides and other control methods. And as a result - an increase of chemicals use that will cause greater damage to the environment.**

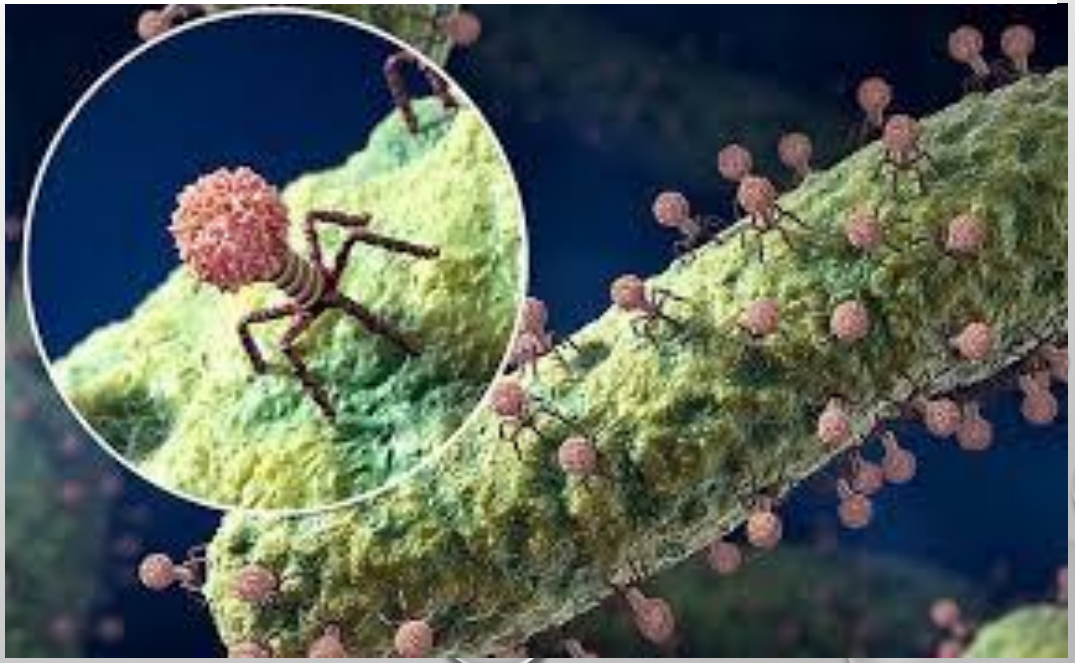
3. **Another major concern is the likely impact of GMOs on human and animal health. GMOs can cause allergic reactions or have unwanted side effects that were not observed during testing.**

4. **As a result of the rapid use of GMOs, there is a growing movement for labeling that would demand companies to disclose whether their products contain such ingredients. Consumers have the right to know what is in the food they choose and to make informed decisions about consumption**

Phagotherapy is not a new method of treatment. The essence of the method is to use bacteriophages to attack bacteria.

Using bacteriophages in this way has an important advantage: they attack only bacteria and do not harm flora and fauna. Bacteriophages are an organic part of life and are widespread in the biosphere and represent a natural way of controlling bacterial growth.





The use of bacteriophages in therapy is limited because of

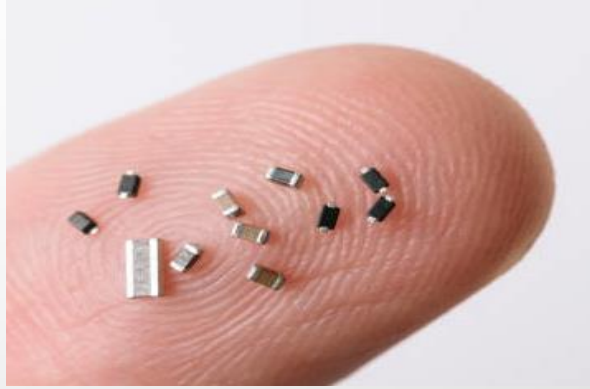
- Insufficient study of the interaction of living systems,
- The nature of the immune response of the body to phage particles
- Phage particle toxicity
- Incomplete knowledge of the role of the organs of the reticulo-endothelial system in the removal of phage particles from the vascular bed,
- The presence of toxins in insufficiently purified preparations of bacteriophages
- Imperfect methods of cleaning bacteriophage preparations from toxins and other related substances
- There are no effective methods for isolating mutant phages that can avoid capture by the reticulo-endothelial system.

Effective use of bacteriophages in medicine should be justified by a detailed understanding of their nature and features of interaction with the host bacterium, high-quality production of bacteriophage preparations, appropriate preclinical and clinical tests that confirm the absence of toxic properties and safety of bacteriophage preparations in accordance with modern regulatory standards.

Biochips.
Biochips are not electronic devices.
The main function of this chip is to perform hundreds of biological reactions in a few seconds.

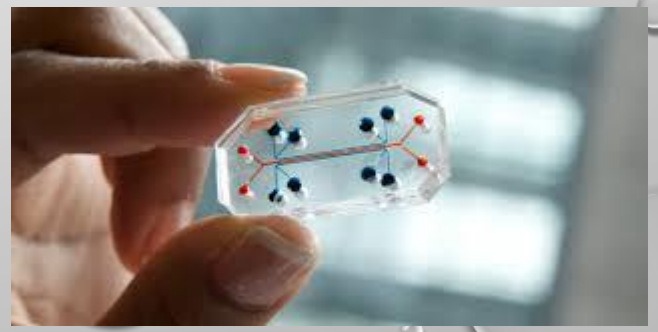
Disadvantages of biochips
They are expensive
They can be implanted in the human body without consent
They can cause serious privacy concerns

- **DNA Microarray**
It is a large number of small spots of DNA that are fixed on a strong surface. It is used to measure the expression levels of a large number of genes. Each DNA tag contains probes (picomoles of a specific gene) to determine the relative amount of nucleic acids in the target.
- **Microfluidic Chip**
They are a substitute for biochemical laboratories. Used for a large number of reactions, such as DNA analysis, molecular biological procedures and other biochemical reactions. These chips are extremely complex as they contain thousands of components. Its development and implementation in practice requires significant human resources.
- **Protein Microarray**
These chips are used to track the activity and interaction of proteins, and to study their functions on a large scale. The main advantage is that they can monitor a large number of proteins simultaneously. They are automated, fast, economical, highly sensitive and consume less samples. Protein chip technology was relatively simple to develop, with DNA microarrays becoming the most common.



Advantages of biochips:
They are very small in size, but powerful and fast.
They can perform thousands of biological reactions in a few seconds.
Biochips can help in the treatment of various diseases.

Fluorescent biochips are the most common. They are more widely implemented in laboratory practice. But on the other hand, they have disadvantages.



Risks of using fluorescent biochips may include:

Toxicity of materials: some materials used in fluorescent biochips (such as dyes or nanoparticles) can be toxic to cells or the body.

False-positive or false-negative results: the accuracy of biochips can vary which can lead to errors in diagnosis or testing.

Photodegradation: fluorescent dyes can degrade when exposed to light, affecting experimental results.

Sensitivity to environmental conditions: fluorescence can vary depending on external factors such as temperature, pH or the presence of other chemicals.

Cost and complexity: production and use of such biochips can be expensive and require specialized equipment.

Cell engineering

***CELL ENGINEERING* is a branch of science with the task to create new cells and obtain tissues, organs and organisms from cellular material.**

"Cellular" because manipulations are carried out with individual cells, and "engineering" - new cells are constructed based on their hybridization, reconstruction and cultivation.

The advantages of cell engineering are that it allows you to experiment with cells, rather than with whole organisms, and even produce tissues and organisms with specified properties from cells. Thus, in the above example, bone tissue and bones are grown from stem cells isolated from bone marrow or adipose tissue.

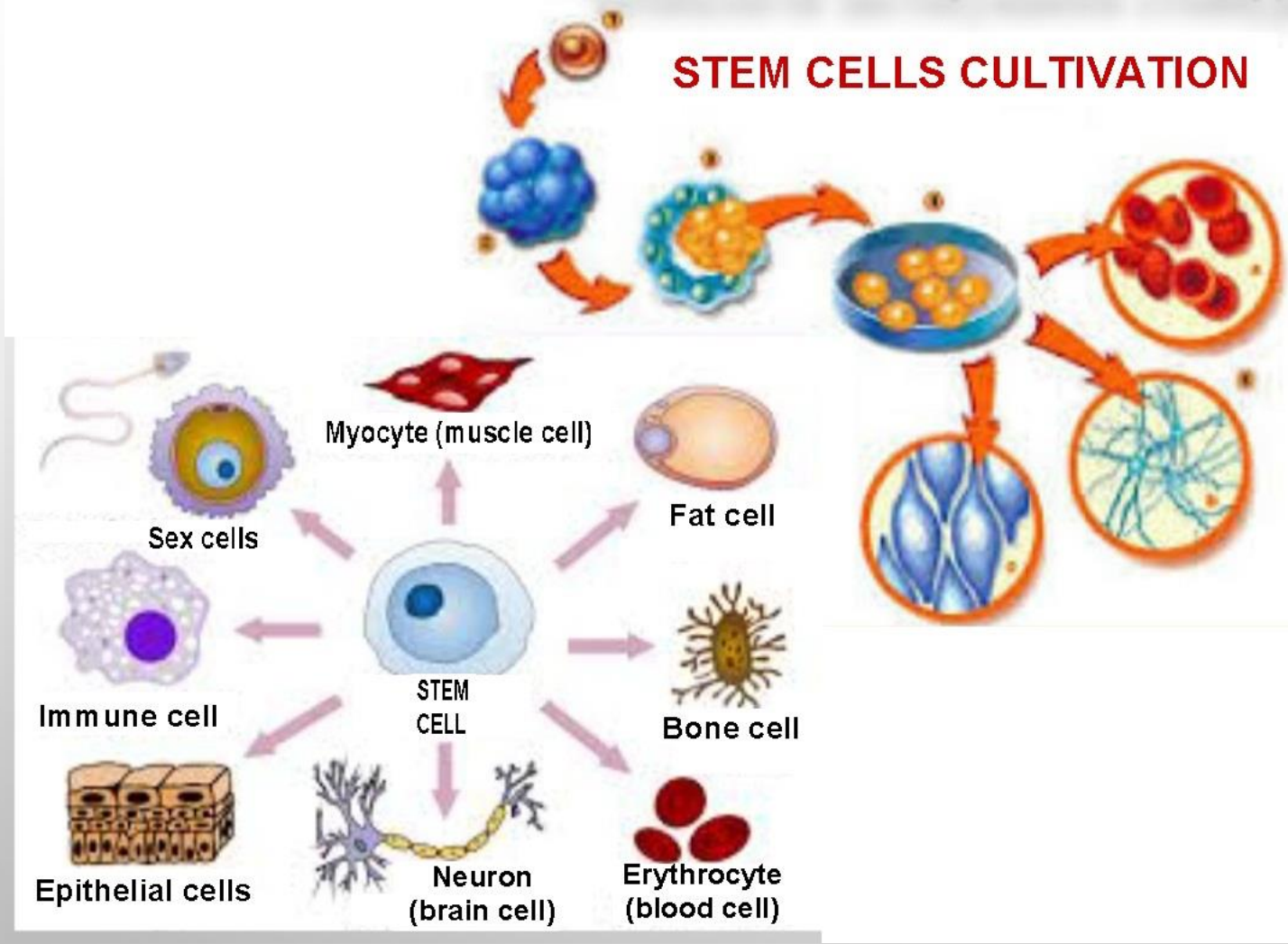
Until recently, cell engineering was considered only as a method of biotechnology or a branch of genetic engineering. The beginning of the rapid development of cell engineering dates back to the 1960s, when the first hybrid cells (B. Ephrussi, G. Harris, P. Carlson) and the first methods of cell construction were created.

Tissue engineering

Tissue engineering is about creation of frameworks, cells, and bioactive molecules for functional tissues. The purpose of tissue engineering is to combine functional structures that restore, maintain or improve damaged tissues or whole organs.

In addition to medical applications, non-therapeutic applications include the use of tissues as biosensors to detect biological or chemical threats, and tissue chips that can be used to test the toxicity of experimental medications

Technology of stem cells use



Stem cells are considered to be the progenitors of body cells. They differ from other cells by

- the lack of specific specialization
- capability for multiple division and maturation
- the ability to transform into blood components
- the ability to become elements of any tissue

Stem cells are cells capable of self-reproduction through division. However, during the division, two new stem cells are not formed, but asymmetric division occurs creating two different cells. One of the newly formed cells is a duplicate of the mother cell and retains the same characteristics, thus a new stem cell is formed. The second cell, created as a result of asymmetric division, develops into a specialized cell, thus it differentiates.

Stem cells can further mature by differentiating into different cell types and provide an important basis for the formation of complex tissues and organs such as heart and kidneys. The mechanism of asymmetric cell division allows you to simultaneously maintain the pool of stem cells and create new cells for differentiation.

Risks associated with the use of stem cells in medical procedures may include:

Tumor formation: stem cells, especially embryonic stem cells, have the potential to turn into tumors if their growth is not controlled.

Immune rejection: the body can reject stem cells if they are recognized as foreign, especially if they do not come from the patient's own cells.

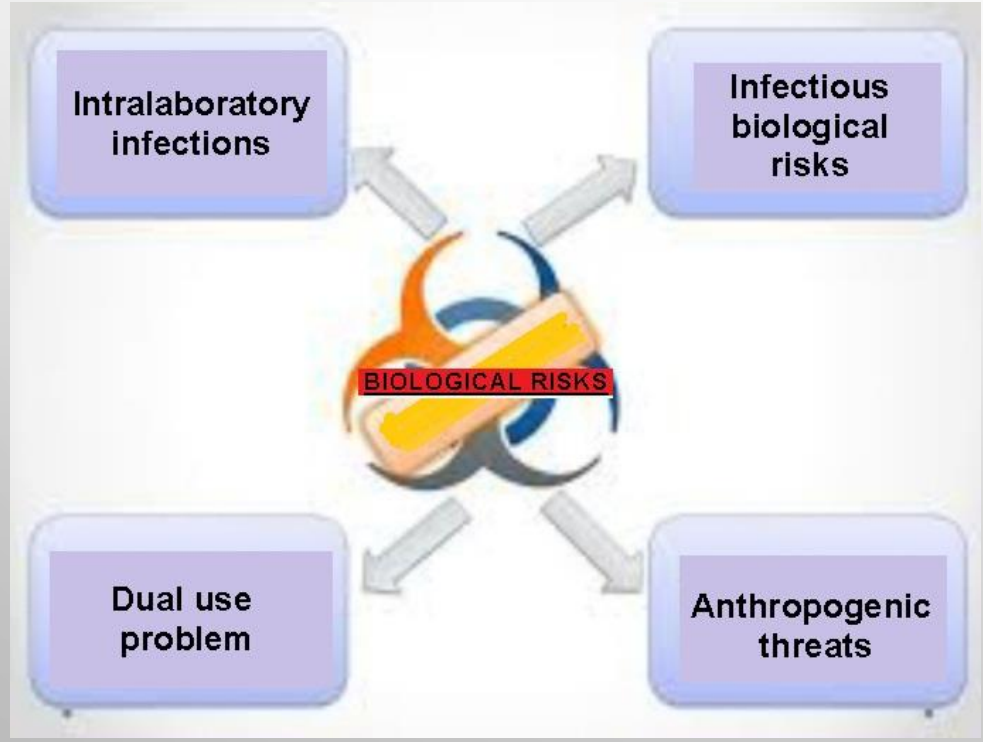
Infection: any surgical procedure or cell implantation carries a risk of infection.

Unintended differentiation: stem cells may not always differentiate into the intended cell type, leading to unwanted tissue growth.

Ethical issues: ethical controversies can arise, especially regarding the use of embryonic stem cells.

Unproven therapies: some clinics offer stem cell therapies that have not been thoroughly tested, which can lead to unforeseen complications.

Every day, biological scientists in their routine activities encounter a large number of biological objects, which are either studied or used as delicate and reliable tools during various studies. The list of laboratory animals, micro-organisms, viruses, cultures tissues and cells of various origins that exist in research laboratories is extremely long. Work on each of these objects exposes the researcher to certain risks, which, obviously, must be minimized. A wide range of measures to protect against hazards that arise when working with biological objects or materials are matters of risk.



Biological risk is the risk associated with biological hazards, which can be considered as the possibility that the hazard will have negative consequences for human existence and health, property and the environment under specific conditions.

Ensuring an adequate level of biosafety and biosecurity in the laboratory is based on the concept of biological risk management. Laboratory biological safety measures are an important component of laboratory practices aimed to protect health and life of medical and biological laboratory workers, public safety, animal health and welfare, and environmental safety from accidental or intentional exposure to biological pathogenic agents. These measures are planned and effectively implemented through risk assessment programs and through development of a safety culture necessary to secure workplaces in biological laboratories and biological industries.

There are two types of BIOLOGICAL SECURITY which fundamentally differ in support systems:

BIOSAFETY itself
- protection from pathogens and other harmful effects of the "biological factor" as a by-product of biotechnological production
- protection against the malicious use of a "biological factor".

On the other hand, the influence of dangerous biological factors on a person through the living environment.

Biohazards when working in laboratories.

1. The highest level of biological risks exists when **working with pathogenic microorganisms**.

2. Work on the **isolation of a genetic material and its use, especially of highly pathogenic pathogens,** is also associated with a high risk of biological hazards.

3. The danger is the release of a **pathogenic agent into the air**, contamination of personnel or the environment.

4. Biological material in laboratories is **a potential source of biological weapons**, and biological and medical facilities can be used to illegally develop and manufacture biological weapons for terrorists.

1. Transformation of social reality with the help of biotechnology, invasion of the life evolution can cause a threat to human existence, and create the possibility of inevitable and serious negative consequences of rapid biological progress.

2. Medical biotechnologies can be used for non-therapeutic or despicable purposes and lead to destructive consequences causing possible threats to security, freedom and even to human nature itself.

3. Using the opportunities of biotechnology creates a problem of unequal access.

4. The use of medical biotechnology creates a problem of freedom restriction. The purpose of despicable use of biotechnology products may be to establish social control (at school, at home, at work).

5. Globalization and concentration of trade in products of genetic technologies "under the umbrella of giant companies" cover various fields of application - from agriculture to medicine, that leads to centralized control and distribution of biotechnology products.

Thus, if it is possible to approach the development of biotechnology in medicine responsibly, without integrating biotechnological aspects into the processes of technology interaction with nature and to ensure social control over the development of biotechnology,

THEN IT IS POSSIBLE

to create all the prerequisites for the safe use of such technologies and make a leap in the evolution of civilization.

THANK YOU FOR YOUR ATTENTION

1. **What do you know about the use of biochips in medicine and the associated risks?**

2. **As is well known, stem cells assist in treating various diseases, but their application carries certain risks.**

3. **The use of genetically modified products is a widely discussed topic. In your opinion, what is the balance between the benefits and potential harms of using GMOs?**

4. **All new technologies that can be used in human life may be both beneficial and potentially unsafe. For example, tissue engineering – what secrets does it hold?**