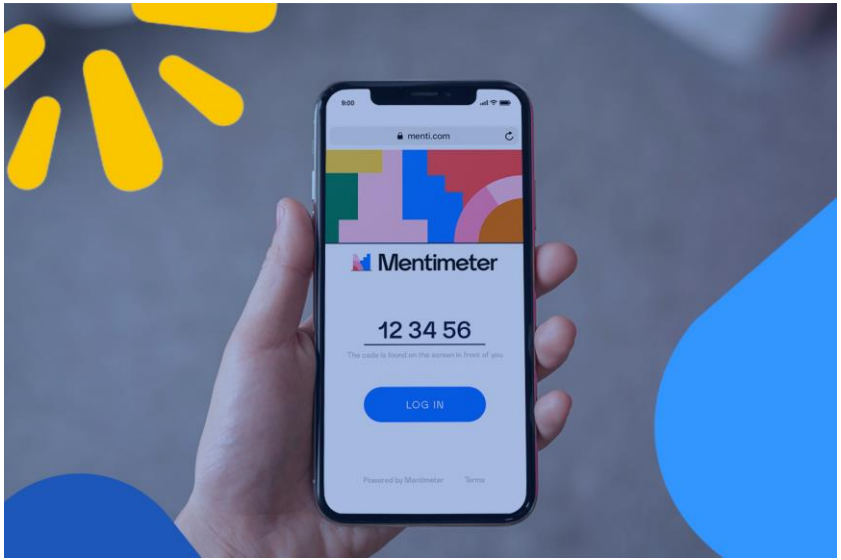
EURIZON H2020 project, grant agreement 871072

EURIZON FELLOWSHIP PROGRAMME: “Remote Research Grants for Ukrainian Researchers”

BIOSAFETY OF BIOMEDICAL PRODUCT TECHNOLOGIES

Overview: Biosafety in biomedical product technologies refers to the measures and practices implemented to ensure the safety of biological products throughout their lifecycle, from development and manufacturing to clinical use and disposal. This encompasses the protection of researchers, patients, and the environment from potential risks associated with biological materials.

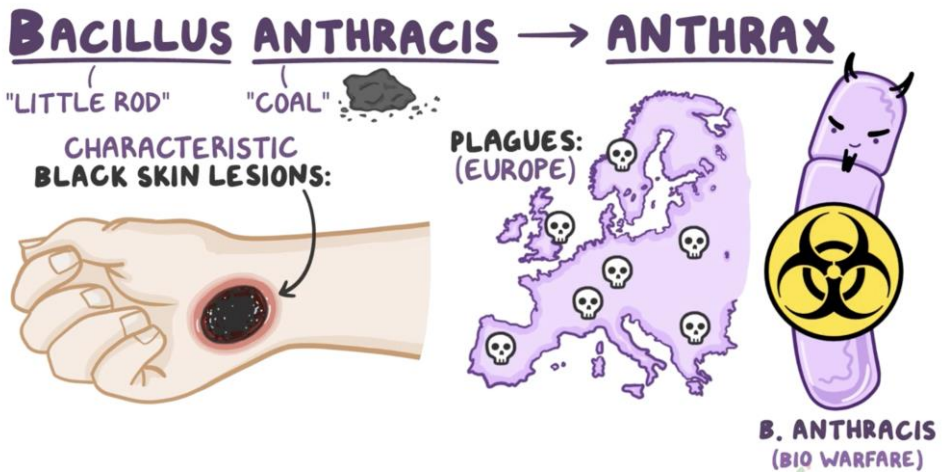
INTRODUCTION



Gary Combs - Staring at the Fire

SVERDLOVSK ANTHRAX LEAK, ON 2 APRIL 1979

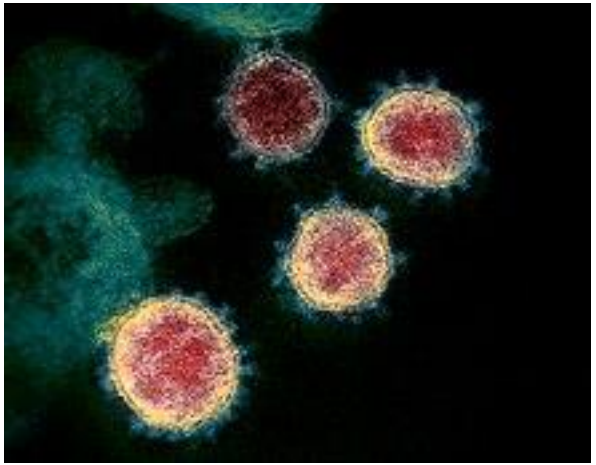
spores of *Bacillus anthracis* (the causative agent of anthrax) were accidentally released from a Soviet militaryresearch facility in the city of Sverdlovsk, Soviet Union (now Yekaterinburg, Russia). The ensuing outbreak of the disease resulted in the deaths of at least 68 people, although the exact number of victims remains unknown.



List of laboratory biosecurity incidents
https://en.wikipedia.org/wiki/List_of_laboratory_biosecurity_incidents

SARS-COV-2 DELTA LEAK, IN NOVEMBER 2021

In November 2021, a lab worker at a high-biosecurity facility in Taipei contracted COVID despite there being no other confirmed local cases at the time, raising suspicions of a lab leak. The sequence of the virus was then found to match a SARS-CoV-2 Delta variant contained in the lab, rather than the local strains of the virus previously in circulation in the community. This is deemed the first reported lab leak of the COVID-19 virus. None of the 110 contacts later identified as exposed to the worker tested positive for the virus.



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RISK ASSESSMENT IN BIOSAFETY OF BIOMEDICAL PRODUCT TECHNOLOGIES

1. Identifying Potential Biological Hazards:

Types of Hazards:

•Pathogens: Bacteria, viruses, fungi, and parasites that may pose a risk to human health.

•Toxins: Biological toxins produced by organisms that can cause harm.

•Genetically Modified Organisms (GMOs): Potential risks associated with altered organisms used in products.

Sources of Hazards:

- Raw materials and biological agents used in the development of biomedical products.
- Contamination during manufacturing or handling processes.
- Environmental factors that may contribute to biological risks.

2. Evaluating Likelihood and Severity of Adverse Effects:

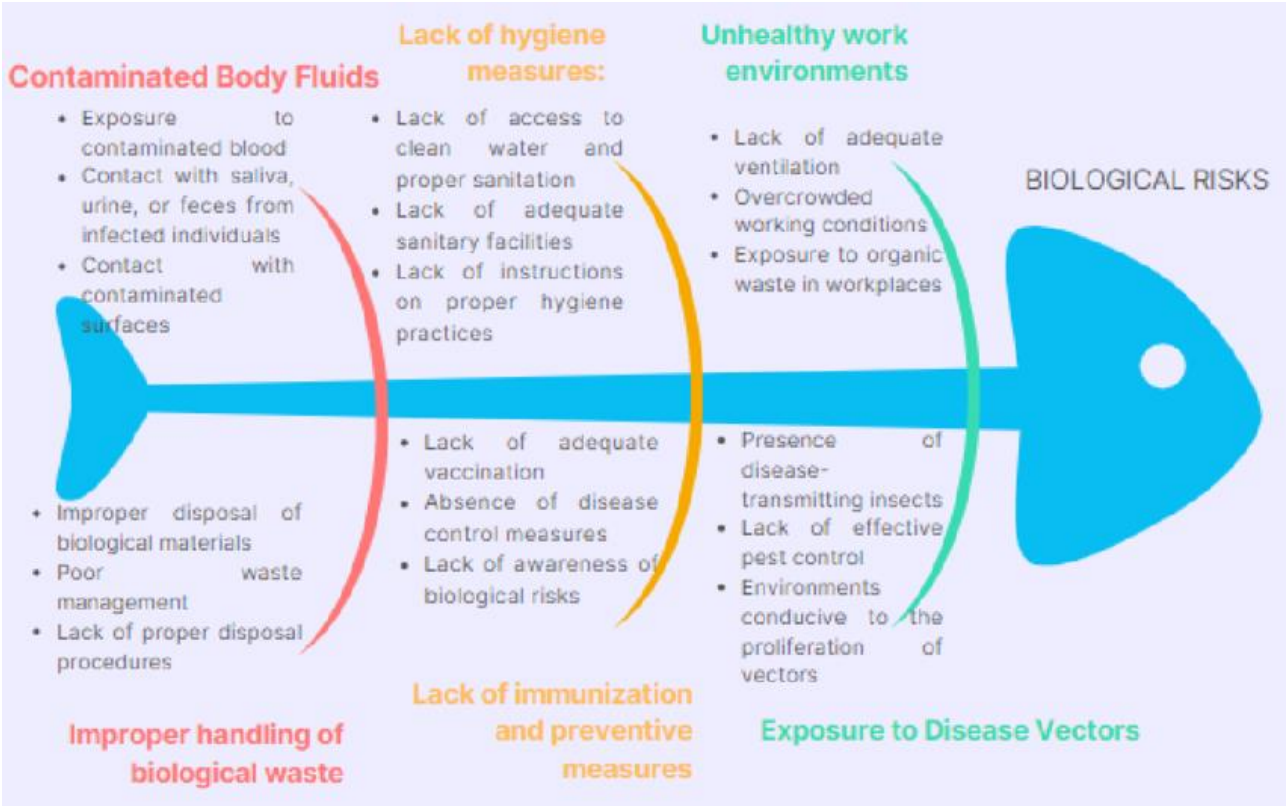
Likelihood Assessment:

- Exposure Pathways
- Frequency of Exposure

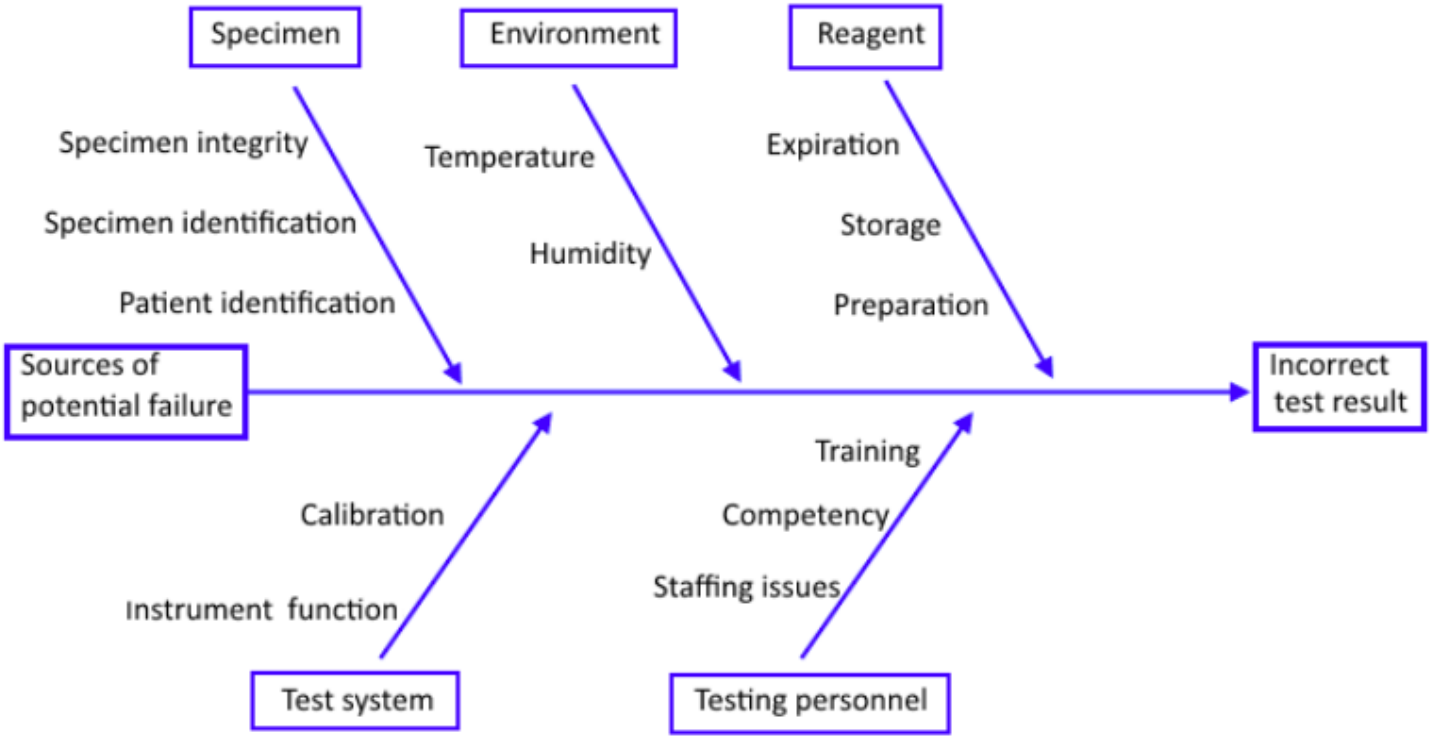
Severity Assessment:

- Health Impact
- Environmental Impact

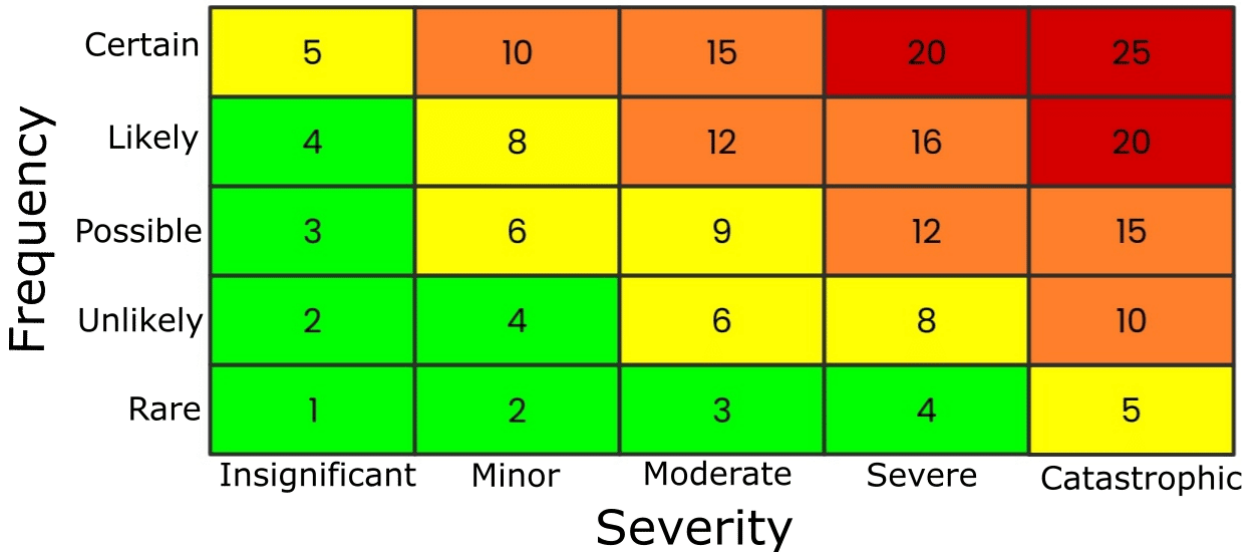
Risk Matrix: Utilizing a risk matrix to **categorize risks** based on their likelihood and severity, helping prioritize mitigation strategies.



Example of Ishikawa (fish-bone) Biological Risks Diagram



Another Example of Ishikawa Diagram



The Risk Matrix (5x5)


This is your
decision point.
Back country risks include death.

DISCUSSION QUESTION:

What do you think are the biggest biosafety risks in the field of biomedical products?

Are there specific situations or examples you can provide?

THE BIGGEST BIOSAFETY RISKS IN THE FIELD OF BIOMEDICAL PRODUCTS

1. **Contamination with pathogens**: During the production or testing of biomedical products, there can be instances of samples being contaminated with dangerous microorganisms, which can lead to serious consequences for patients.

2. **Improper waste management**: Improper disposal of biological waste can lead to environmental contamination and health risks.

3. ***Rejection of implants**: Implants that are not properly prepared can trigger an immune response, leading to serious complications.

4. **Insufficient safety testing**:The release of products that have not undergone proper safety testing can lead to severe side effects.

DEVELOPMENT AND MANUFACTURING + REGULATORY COMPLIANCE

1. Implementing Good Manufacturing Practices (GMP)

Quality Assurance:

- Robust quality management
- Regular audits and inspections

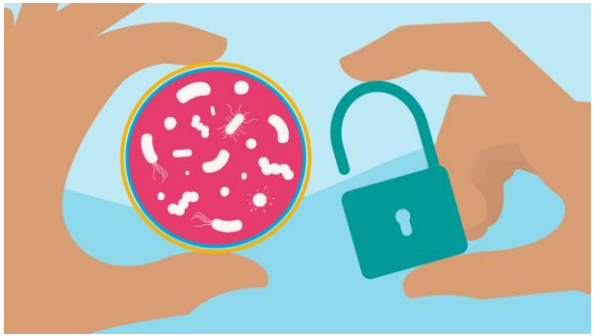
Standard Operating Procedures (SOPs):

- Developing and maintaining detailed SOPs for all manufacturing processes
- Trainings of personnel

Environmental Controls:

- Controlled environments (e.g., clean rooms)
- Waste management protocols

2. Ensuring Compliance with Biosafety Regulations and Standards



Regulatory Framework:

- •Guidelines of FDA, EMA, and WHO regarding the production of biomedical products
- •Keeping up-to-date with changes in regulations

Facility Design and Maintenance:

- •Designing production facilities
- •Regularly inspecting and maintaining equipment and facilities

Documentation and Reporting:

- •Records of all manufacturing activities
- •System for reporting adverse events or deviations from established protocols to regulatory authorities

TESTING AND EVALUATION

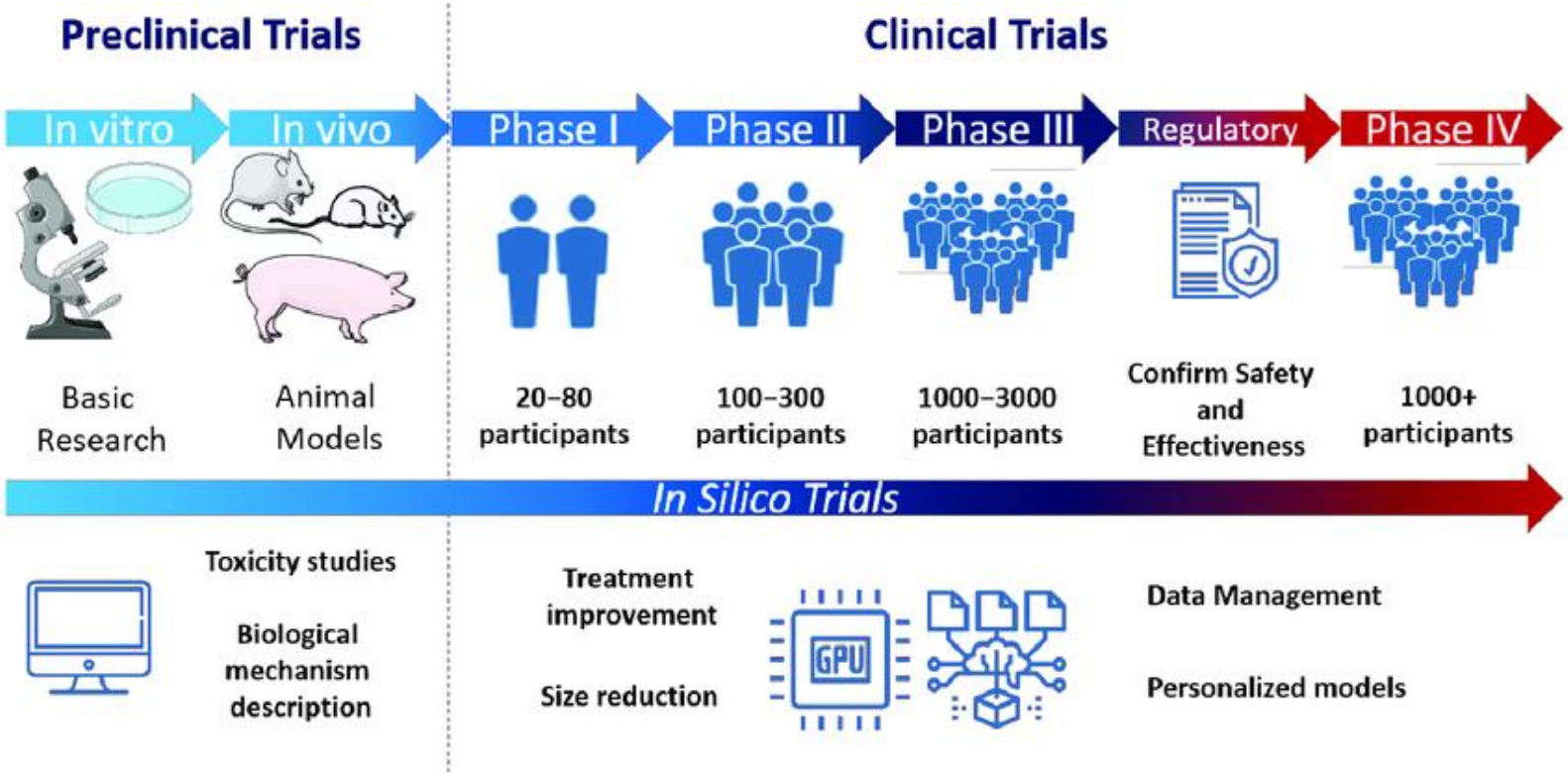
1. Conducting Preclinical and Clinical Trials

Preclinical Trials:

- Objective
- Study Design
- Data Collection

Clinical Trials:

- Phases
- Informed Consent
- Monitoring



Picture CC from: DOI:10.3390/biotech11030023

POST-MARKET SURVEILLANCE

1. Monitoring the safety of biomedical products after they are on the market

Monitoring the safety of biomedical products - ongoing evaluation and data collection methods

2. Implementing a robust system for reporting adverse events and addressing any safety concerns.

Implementing various data collection strategies, such as patient registries, electronic health records, and surveys to gather information on product performance and safety.

Establishing clear protocols for healthcare professionals and patients to report any adverse events or side effects associated with biomedical products.

3. Post-Market Studies

- Conducting additional studies, such as Phase IV trials, to further investigate safety issues or to assess long-term effects of biomedical products

Engaging with healthcare providers and patients to gather feedback and improve product safety profiles

EMERGENCY PREPAREDNESS

1. Developing Protocols for Managing Spills, Exposures, and Emergencies

Emergency Response Plans

Incident Reporting

2. Ensuring Access to Personal Protective Equipment (PPE) and Emergency Response Resources:

PPE Availability and Emergency Equipment Access

Training on PPE and Emergency Equipment Use

Biosafety level 1

Example of agent :

E.coli (non-pathogenic)

Safety Equipments (Primary)

Secondary Barriers (Facilities)

- Normal doors
- Water sink
- Cleanable furniture
- Physically linked building

Biosafety level 2

Example of agent :

Zika virus

Safety Equipments (Primary)

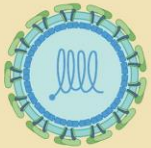
Secondary Barriers (Facilities)

- Self-closing doors
- Installed biosafety cabinet (II)
- Heat and chemical resistant bench
- Eye wash station
- Wondows are not recommended
- Cleanable furniture

Picture CC from: DOI:10.1016/j.jobb.2022.11.002

Biosafety level 3

Example of agent :



West Nile virus

Safety Equipments (Primary)

BSL-2 equipments that provide full protection

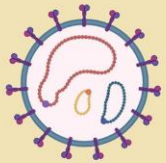
OR

Secondary Barriers (Facilities)

- Partially isolated laboratory
- Doubble pass doors
- Anteroom for clothing change
- Self-closing doors with locks
- Air ventilation system (ducted)
- Filters protecting vacuum lines
- Class III BSC
- Decontamination tools for wastes
- Cleanable walls and ceilings
- Sealed windows

Biosafety level 4

Example of agent :



Crimean-Congo virus

Safety Equipments (Primary)

Secondary Barriers (Facilities)

- Isolated laboratory
- Installed biosafety cabinet (III)
- Outer and inner clothing change areas seperated by shower room
- Unbreakable and sealed windows
- Chemical shower (suit decontamination)
- Emergency power source
- Communication systems (microphone)
- Non-recirculating ventilation system

Picture CC from: DOI:10.1016/j.jobb.2022.11.002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DISCUSSION QUESTION:

Which aspects of biosafety do you consider the most important in your (future) profession?

Are there specific protocols or standards that you believe are critical?

CASE STUDY TOPICS – BREAKOUT ROOMS

Room 1. Vaccine Development

Topic: How to mitigate biological risks during the testing of a new vaccine in a pandemic situation?

Discussion: Examine safety protocols, monitoring methods, and risk management during clinical trials.

Room 2. Infectious Threats

25 MIN

Topic: How to prevent contamination of biomedical materials in the laboratory?

Discussion: Explore best practices for sterilization, waste management, and the use of personal protective equipment.

Room 3. Medical Devices

Topic: How to ensure the safety and biocompatibility of a new type of implant?

Discussion: Analyze testing phases, regulatory requirements, and potential patient risks.

DEBREEFING

How New Technologies Can Improve Biosafety in Biomedical Technologies and Research?

1. Automation of Processes - robotic systems for automating sample collection and processing
2. Monitoring Systems - for tracking storage and processing conditions of biological materials
3. Data Analytics and AI - can identify potential risks and trends in real time, allowing for proactive management of biosafety concerns
4. Bioinformatics Tools – to enhance the analysis of biological data
5. Innovations in PPE design
6. Risk Assessment Software
7. Virtual Reality Training
8. Enhanced designs in biosafety cabinets
9. Implementing advanced HVAC systems to maintain optimal air quality and control environmental factors