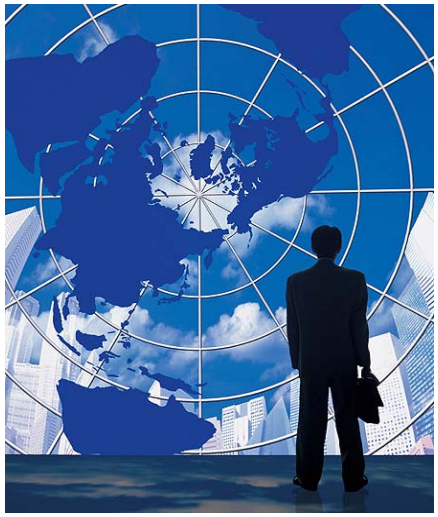

Biosafety and Biosecurity from a Scientist's perspective

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Overview

- **Past training**
- **Current Laboratory Biosafety**
- **What do we need as Biomedical researchers?**

Introduction

Biotechnology is one of Egypt's national research priorities

Because

Advances in life sciences and biotechnology bring enormous benefits to medicine, public health and Agriculture

But

The life science community should be engaged to set rules and regulations for the proper use of this kind of research

- **Biosafety: Protect laboratory personnel and the environment from accidental exposure to or release of potentially hazardous agents**

- **Biosecurity: Protect biological agents against theft by those who intend to cause deliberate exposure through malicious use**

Past training

1-DKFZ, Heidelberg, Germany
2-NIH, NCI, Frederick, MD, USA

Direction of Research

The use of genetically modified animals to understand the molecular mechanisms of cancer development, progression and in molecular targeted therapy..

Absolutely no use of infectious disease agents in this kind of research.

Experience

- **Recombinant DNA Technology: Cloning, PCR, Reverse Transcripti on, ….etc.**

- **Generation of Transgenic and Knockout mice (Not in Egypt)**

- **Cell Culture: mainly human tumorigenic cell lines and mouse cells**

- **Viruses: Used as vectors (vehicles to transfer foreign**
- **DNA into MOUSE cells) (Not in Egypt)**

  - **Retroviruses**

- **Bacteria: E. coli**
- **Animals: Mice, Rats, Toads**

- **Radioactive isotopes: ^{32}P, ^{33}P, ^{35}S (Not in Egypt)**

Current practices

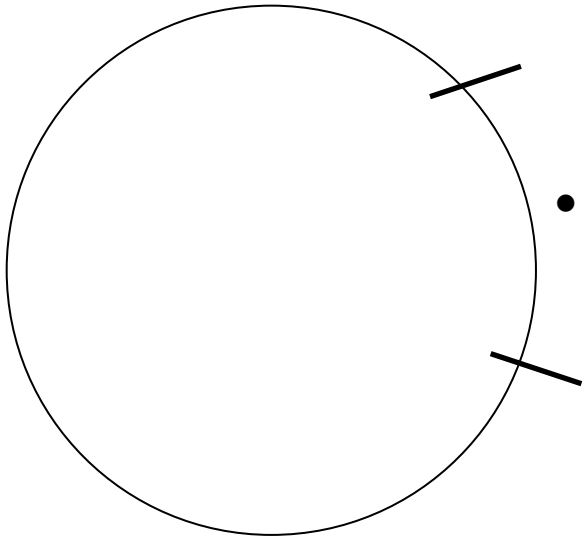
- **rDNA technology**
- **Cell culture (BSL-2)**

Control on: rDNA (Form)

- **Plasmid name:**
- **Requestor name:**
- **Restriction enzymes:**
- **Resistance:**

- **Reference Number:**
- **Date:**

- **Map:**



- **Multiple cloning site**

- **Picture of Digest**

- **Vector:**
- **Insert:**
- **Comments:**

- **Attach to this form the sequence of your rDNA**

- *Aquired through training at PK l ab, NCI-NIH, USA*

Good Laboratory Practices

- Never mouth pipette anything, use mechanical pipetting devices
- No eating, drinking, food storage or applying of cosmetics in the lab
- Wash your hands after handling chemicals, infectious materials or animals before leaving the lab.
- Wear laboratory coats while performing lab activities
- Feet and legs should be covered. Sandals and open-toed shoes should not be worn in labs
- Wear appropriate gloves while handling toxic or infectious materials and animals.
- Close lab doors. Restrict access to the lab
- Use a biological safety cabinet for handling infectious material and a fume hood for toxic and volatile materials.
- Minimize or contain all aerosol-producing activities, large volume work or concentrated cultures.
- Biological safety cabinets and chemical fume hoods should be located in l ow traffic areas. While working in a BSC, minimize activities that disrupt ai rflow in or around the cabinet.

Good Laboratory Practices

- Decontaminate all work surfaces daily as a minimum requirement and
- immediately after any spill of viable material.

- Place contaminated materials in covered, leak proof containers prior to removing them from lab for autoclaving or incineration.
- Decontaminate by autoclaving all biologically contaminated materials (glassware, animal cages, lab equipment..etc.) before washing, reuse, or disposal. Discard m aterial via the proper waste stream.

- Decontaminate all equipment before repair work is conducted.

- Be cautious when using sharps (needles, razors..etc.). Never recap a needle

- Pippetes and broken glassware should be placed in an appropriate container.

- Handle chemicals and radionucleotides following appropriate safety procedures
- Know the location of the nearest eye wash, safety shower and fire extinguisher, k now how to use them and flush eyewash weekly.

What we need

- National Legislation and Regulations for Laboratory and
- Transportation Biosecurity and Biosafety

- **Implementation of Standards or Guidelines**

Provide assistance to those who handle, store or transport "biological material" including pathogens so that they can comply with legislation while still meeting their biomedical and bioscience research and diagnostic duties!!!

Biosafety Risk Assessment

- **There MUST be a biological safety officer whose job is to:**

- **Become familiar with and overviews the proposed work activities**
  - **Procedures**
  - **Equipment**
  - **Personnel**
  - **Storage**
  - **Material Transfer and Transport**
  - **Proper Destruction of biological material**

- **Make a Risk analysis, which should answer three questions:**

- **What can go wrong?**
- **How likely is it to happen?**
- **What are the consequences?**

Biosafety Risk Assessment: Safety Risk Group Evaluation

- **What is known about the agent?**

- **Pathogenicity-ability to cause disease**
- **Virulence-degree of pathogenicity**
- **Host range-restricted or broad, human, animals, plants**
- **Communicability-are there reports of epidemics? Of laboratory**
- **Infections?**
- **Transmission-means (eg. Direct contact, vector borne) and**
- **Routes of transmission (eg. Ingestion, inhalation)**
- **Environmental stability: eg. Resistance to disinfection**

- **Additional Agent factors:**
- **Toxicity**
- **Is the agent associated with cancer (eg. HBV)**
- **Does the agent or by-products induce allergic reactions**

Biosafety Risk Assessment: Safety Risk Groups:

- **Risk Group 1:**
  - **No or low individual and community risk**
  - **Unlikely to cause human and animal disease**

  - **Examples:**
  - ***Bacillus subtilis:***
    - ubiquitous bacterium found in water, soil, air,
    - not considered pathogenic or toxogenic to humans, animals or plants)
  - ***E. coli K-12:***
    - E. coli is a normal inhabitant of colon in mammals
    - K-12 is a debilitated strain-does not normally colonize human intestine
    - History of safe commercial use

- *Adapted from Biosafety and Biosecurity workshop, cairo 2007*

Biosafety Risk Assessment: Safety Risk Groups:

- **Risk Group 2:**
  - **Moderate individual risk, low community risk**
  - **Can cause disease, but unlikely to be a serious hazard.**
  - **Lab exposures may cause serious infection, but effective Treatment and preventative measures are available and risk of spread of infection is limited.**

  - **Example:**
  - **Hepatitis B virus*:***
    - Pathogenicity: Asymptomatic and symptomatic infections
    - Long term fatality=2-3%
    - 95% of adult infections self-limiting
    - Host range: Humans (chimpanzee susceptible)
    - Vaccine available

- *Adapted from Biosafety and Biosecurity workshop, cairo 2007*

Biosafety Risk Assessment: Safety Risk Groups:

- **Risk Group 3:**
  - **High individual risk, low community risk.**
  - **Usually causes serious human or animal disease but does not ordinarily spread.**
  - **Effective treatment and preventative measures are available.**

  - **Example:**
  - ***Mycobacterium tuberculosis***
    - Proven hazard to lab workers (3x higher rate of infection)
    - Low aerosol infectious dose (ID_{50} less than 10 bacilli)
    - Host range: humans, cattle, primates and other (rodents)

- *Adapted from Biosafety and Biosecurity workshop, cairo 2007*

Biosafety Risk Assessment: Safety Risk Groups:

- **Risk Group 4:**
  - **High individual and community risk.**
  - **Usually causes serious human or animal disease and can be readily transmitted.**
  - **Effective treatment and preventative measures are NOT usually available.**

  - **Example:**
  - **Ebola virus**
    - Pathogenicity: sudden onset: 50-90% fatality
    - Host range: Humans, monkeys, chimpanzees, domestic Guinea pigs
    - BSL4 lab recommended even for clinical work.

- *Adapted from Biosafety and Biosecurity workshop, cairo 2007*

Biosafety levels:

- **Four Biosafety Levels provide increasing degree of protection**

- **Labs: BSL-1, 2, 3, 4**
- **Animal containment: ABSL-1, 2, 3, 4**
- **Plant containment: BSL-1P, 2P, 3P, 4P**

- **Control of Biohazard through:**

- Practices and Procedures (Good lab practices)
- Primary barriers (safety equipment)
    - BSC, lab equipment (pipetting device, waste containers,…), personal protective equipment.
- Secondary barriers (engineering and architectural control)
    - Building and room construction (floor plan)
    - HVAC issues-directional airflow, filteration
    - Waste treatment

- *Adapted from Biosafety and Biosecurity workshop, cairo 2007*

Thank you for your Attention