

Odessa National Medical University
Faculty: International
Department of philosophy and bioethics

Syllabus
FUNDAMENTALS OF BIOSAFETY

Volume	3 credits (90 h)
Semester, year of study	2nd semester, 1st year
Time/place	Time and place (number of the lecture hall, auditorium) of classes is determined according to the approved schedule.
Faculty members	Medyanova Elena; PhD; assistant professor.
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Working place	Assist. Prof. Medyanova E.V.: teachers ' office.
Tutoring/ guidance/consultations	<i>Offline</i> : according to the schedule of consultations. <i>Online</i> : by personal appointment (MS Teams, Zoom, Viber, Skype, etc.)

COMMUNICATION

Communication with students will be carried out remotely (tel., E-mail) and in person (at the teacher's workplace).

COURSE ANNOTATION

Subject of study of the discipline: conditions for the preservation of living organisms of their biological essence, biological qualities, system-forming ties and characteristics, by preventing, reducing and eliminating the negative impact of factors (biological, chemical, physical) on the biological structure and functions of the human body, biological objects of the natural environment (biosphere), farm animals and plants in the present and future generations.

Prerequisites course: the study of the course "Fundamentals of biosafety" is subject to knowledge of natural and socio-humanitarian disciplines of the first year, both compulsory and elective: "Biology with the basics of genetics", "Biological physics with physical methods", "Philosophy", etc.

Postrequisites of the course: the course "Fundamentals of biosafety" lays the foundation for the study of such disciplines as "Ethics and deontology in pharmacy", "Social pharmacy", "Biopharmacy", "Drug technology", etc.

The aim of the course is to form in students a holistic view of the biosafety of human life and the biosphere in general, to lay the foundations of a healthy lifestyle and prevention of dangerous situations in the professional activities of future pharmacists.

Course task:

- ♦ formation of knowledge, skills and competencies necessary for the preservation of human health and life in modern living conditions;
 - ♦ formation of knowledge, skills and competencies to protect against the dangers of man-made, anthropogenic, natural origin and create comfortable conditions for human life;
 - ♦ formation of knowledge on legal and organizational aspects of labor protection of pharmaceutical workers;
 - ♦ formation of knowledge about the moral side of human activity in medicine and biology;
 - ♦ formation of knowledge on the preservation of living organisms of their biological essence, biological qualities, prevention of large-scale loss of biological integrity;
 - ♦ formation of knowledge about legislative documents that protect the individual, society and humanity as a whole from the undesirable and detrimental consequences of the introduction of new medical and biological technologies; fostering a deep conviction in the need for strict observance of ethical and moral norms, rules and principles in their practical activities;
 - ♦ formation of the ability to evaluate the latest achievements of biology and medicine in terms of determining the degree of their danger to man and society today and in the future.

Expected results:

As a result of studying the discipline, students should *know*:

- ✓ basic principles of safety in ensuring human life;
- ✓ requirements of legislative and normative acts on life safety, labor protection of pharmaceutical workers;
- ✓ requirements for occupational safety of pharmaceutical personnel in modern conditions;
- ✓ historical stages of development of medical ethics, bioethics and nooethics;
- ✓ basic principles of biomedical ethics;
- ✓ international declarations on biosafety, medical ethics, bioethics;
- ✓ basics of state biosafety;
- ✓ bioethical problems of public health in various fields of medicine and pharmacy;
- ✓ bioethical and legal problems of clinical trials of drugs and medical technologies;
- ✓ principles of American and European models of bioethics, features of their implementation in medical and pharmaceutical practice in Ukraine.

Students must *understand*:

- theoretical and practical bases of safe human life;
- the relationship between health and exposure to harmful and dangerous factors;

- consequences of violations of valueological bases of formation of a healthy way of life and their influence on safety of human life;
- the need for legal regulation of the relationship "pharmacist - patient".

Students must be *able to*:

- analyze and evaluate situations dangerous to life, health and professional activity and independently make decisions on taking urgent measures;
- draw conclusions about the presence of harmful factors influencing pharmaceutical workers in the performance of their professional duties;
- anticipate the negative effects of dangerous factors on the human body;
- to determine individual psychological differences of personality by their manifestations in activity and communication;
- apply moral, ethical and professional norms in professional life;
- analyze pre-conflict and conflict situations and facilitate their resolution;
- demonstrate mastery of moral and ethical principles of attitude to a living person, his body as an object of anatomical and clinical research.

COURSE DESCRIPTION

Forms and methods of teaching

The course will be presented in the form of lectures (24 hours) and seminars (16 hours), organization of independent work of students (50 hours).

During the teaching of the discipline the following teaching methods will be used: lectures, conversations, explanations, visual, practical (imaginary experiment); inductive, deductive, analytical, synthetic; explanatory-illustrative and problematic presentation, "microphone", "brainstorming".

Consultations (collective or individual) are held according to the schedule of consultations.

The content of the discipline.

Topic 1. Biosafety system in Ukraine: subject, concepts, principles, directions of formation and functioning; biological danger, biological risk, biological terrorism. biological weapons.

Topic 2. Biological safety of work in laboratories.

Topic 3. Modern biotechnology, genetic engineering: historical conditions, methodological techniques. The role of heredity and variability in the evolution of wildlife. Genetically modified organisms: scientific and practical significance.

Topic 4. Human genetic engineering: benefits and risks.

Topic 5. Biological and medical risks of using genetically modified plants and food derived from them.

Topic 6. Ethical aspects and legal regulation of creation, expertise and use of genetically modified organisms.

Topic 7. History of origin, socio-cultural, philosophical, scientific and legislative principles of bioethics. Content and basic concepts of bioethics and nooethics. Bioethics as a modern medical ethics. International documents on bioethics and human rights. Bioethics and modern biomedical technologies.

Topic 8. Bioethics as a worldview. Global bioethics and nooethics: philosophical principles, values and principles. Environmental ethics as a component of global bioethics and nooethics. Theoretical and methodological substantiation of nature rights. Community of people and other living beings.

Topic 9. Ethical and legal aspects of the beginning and end of human life. Bioethical, psychological and spiritual problems of palliative care. The value of human life in the context of bioethics and christian ethics.

Topic 10. Values and principles of European bioethics. Introduction of the principles of bioethics in medical practice in Ukraine. Code of ethics of the Ukrainian doctor. The relationship of universal values, values of science, moral theories, principles of bioethics in solving moral dilemmas of practical medicine. Bioethical model of health.

Topic 11. Ethical and legal norms and requirements for conducting clinical and preclinical studies. The rights of participants in clinical trials. Ethical and legal aspects of working with experimental animals. Code of ethics of the scientist of Ukraine.

Topic 12. Bioethical expertise of scientific projects. Ethics committees: history of creation, methods of organization, role in ethical and legal regulation of clinical trials. Informed consent to participate in clinical trials as a realization of the principle of respect for the autonomy and dignity of the patient. Structure and content of the "Informed consent form".

Recommended literature

Handbook of global bioethics / ed. Henk A.M.J. ten Have, Bert Gordijn. – Dordrecht: Springer, 2013. – 1685 p.

Lewis M. Medical law, ethics and bioethics for the health professions / M. Lewis. – Pennsylvania: F.A. Davis Company, 2012. – 256 p.

Sateesh M.K. Bioethics and biosafety / M.K. Sateesh. – New Delhi: I K International Publishing House Pvt. Ltd, 2013. – 820 p.

ASSESSMENT

The grade in the discipline consists of the current performance (arithmetic mean of all student grades).

Current control. Assessment of the success of studying each topic of the discipline is carried out on a 4-point scale.

At the seminars there are used various types of objective control of student readiness: fixed speeches, compilation and presentation of abstracts, reports, essays, analysis and solution of situational cases, participation in discussions, as well as various tests, etc.

At the end of the course, the current performance is calculated as the average current score, i.e., the arithmetic mean of all grades obtained by the student on a traditional scale, rounded to 2 (two) decimal places, for example 4.75.

Assessment of independent work of students (ISW). Students' independent work, which is provided by the topic of the lesson along with the classroom work, is assessed during the current control of the topic at the seminar class. Understanding of topics that are left for independent work only is checked during the differentiated test. The score for the individual ISW is equated to the usual current score and is graded for the relevant topic.

COURSE POLICIES

Deadline and resit policy

- ◆ Absences are atoned with the permission from the dean's office if there are good reasons (for example, a doctor's note) according to the departmental schedule.
- ◆ The student has the right during the semester to resit the current unsatisfactory grades only in order to achieve an average score of 3.00.
- ◆ Current unsatisfactory grades should be 'reworked' by the student to his / her teacher.

Academic integrity

Adherence of students to academic integrity presupposes:

- ✓ independent performance of educational tasks, tasks of current and final control of learning outcomes (for persons with special educational needs this requirement is applied taking into account their individual needs and opportunities);
- ✓ references to sources of information in the case of the use of ideas, developments, statements, information;
- ✓ providing reliable information about the results of their own (scientific, creative) activities, used research methods and sources of information.

Inappropriate actions include use of prohibited auxiliary materials or technical means during checks (cheat sheets, notes, earphones, phones, smartphones, tablets, etc.).

Mobile devices may be used in the classroom only during online classes (in the case of distance learning) or as a source of educational information (with the permission from the teacher), etc.

Policies concerning attendance and tardiness

Attendance is a mandatory component of assessment. The absence is equated to academic debt and requires academic 'redemption'. It is forbidden to be late for classes and to be 'retarded'.

Behavior in the auditorium or lecture hall

- Students must adhere to moral standards, both in interaction with the teacher and in relation to their colleagues.
- To greet the teacher, students must stand up.
- No outside conversations (including on a mobile phone) or other noise that interferes with the lessons are allowed.

Walking in and out of the classroom during the lesson is allowed only with the permission of the teacher.