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FACULTY OF PHARMACY
STUDY PROGRAM 0916.1 PHARMACY
CHAIR OF PHARMACOGNOSY AND PHARMACEUTICAL BOTANY

APPROVED

at the meeting of the Commission for Quality Assurance and Evaluation of the Curriculum faculty of Pharmacy

Minutes No.2 of 21.12.2017

Chairman, PhD pharmacy, associate professor

UNCU Livia

(signature)

APPROVED

at the Council meeting of the Faculty of Pharmacy

Minutes No.2 of 22.12.2017

Dean of Faculty, PhD pharmacy, associate professor

CIOBANU Nicolae

(signature)

APPROVED

approved at the meeting of the chair of Pharmacognosy and pharmaceutical botany

Minutes No.10 of 10.11.2017

Head of chair, Dr. hab. biology, university professor

CALALB Tatiana

(signature)

SYLLABUS

DISCIPLINE GENETICALLY MODIFIED ORGANISMS

Integrated studies

Type of course: **Optional discipline**

Chisinau, 2017



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I. INTRODUCTION

- **General presentation of the discipline: place and role of the discipline in the formation of the specific competences of the professional / specialty training program**

The optional discipline Genetically modified organisms for third-year students will allow them to complete their knowledge on the involvement of modern genetic engineering techniques in developing modern sources of natural raw material in producing the new generation of food and medicines. Knowledge of the genetic transformation of living organisms in order to obtain organisms with new features used in food/drug production will contribute to the formation of a contemporary and correct vision and attitude of the actual pharmacist in the era of modern biotechnology; developing critical thinking in addressing issues related to the implementation and use of GMOs; application of knowledge in promoting healthy lifestyle and valorization of quality vegetable products in the field of phytopharmacy.

- **Mission of the curriculum (aim) in professional training**

To familiarize the future pharmacists-specialists with genetically modified organisms, state policies, fields of application (pharmacy and alimentation), human risks and biosecurity. The course will enable students to acquire knowledge about genetic transformation of living organisms; awareness of the benefits and impact of the GMOs on the environment, the traditional natural gene pool and public health; training abilities to use and enforce norms, normative acts and policies for the implementation and use of GMOs and biosecurity.

- **Languages of the course:** English, Romanian
- **Beneficiaries:** students of the IIIrd year, faculty of Pharmacy

II. MANAGEMENT OF THE DISCIPLINE

Code of discipline	S.06.A.058		
Name of the discipline	Genetically modified organisms		
Person(s) in charge of the discipline	doctor habilitate in biology science, univ. prof., Tatiana Calalb		
Year	III	Semestre/Semestres	V
Total number of hours, including:			30
Lectures	15	Practical/laboratory hours	
Seminars	15	Self-training	-
Form of assessment	colloquium	Number of credits	1



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III. TRAINING AIMS WITHIN THE DISCIPLINE

At the end of the discipline study the student will be able to:

- ***at the level of knowledge and understanding:***
 - general notions regarding the genetic transformation of living organisms;
 - the risks and benefits of GMOs;
 - the global framework on biological security;
 - the national regulatory and monitoring system for GMOs activities;
 - GMOs in the pharmaceutical industry;
 - GMO and human biosecurity.
- ***at the application level:***
 - the correct use of biotechnological terminology and genetic engineering in connection with genetically modified organisms;
 - knowledge of transgenic organisms in the pharmaceutical field;
 - regulatory strategies for GMOs testing;
 - knowledge of the impact of GMOs on public health;
 - norms, normative acts and policies for the implementation and use of GMOs;
 - the national legal framework for regulation and monitoring of GMOs activities.
- ***at the integration level:***
 - determining the position and importance of the discipline Genetically modified organisms in the disciplines provided by the study plan;
 - forming the right attitude towards the contemporary generation of drugs/food based on genetic engineers;
 - acquired knowledge will contribute to the formation of a conscious individual attitude and personal involvement in national policies on biological and public health;
 - GMO knowledge will serve as a benchmark for the subsequent acquisition of Pharmacognosy, Toxic plants, Phytotherapy, Biofarmacy, Pharmaceutical technology.

IV. PROVISIONAL TERMS AND CONDITIONS

Student of the IIIrd year requires the following:

- knowledge of the language of instruction;
- knowledge in biology at the lyceum level;
- knowledge from the courses: Pharmaceutical botany (Ist year), Molecular biology (Ist year), Ecology and medicinal plants (Ist year), Organic chemistry (IInd year);
- competences in modern information technologies (using the Internet, document processing, electronic tables and presentations, using graphics software);
- teamwork skills;
- analysis and synthesis skills, generalization and communication skills, discussion and presentation;
- qualities – tolerance, compassion, autonomy, collegiality.



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V. THEMES AND ESTIMATE ALLOCATION OF HOURS

Lectures, practical hours/ laboratory hours/seminars and self-training

No. d/o	THEME	Number of hours		
		Lectures	Practical hours	Self-training
1.	Introduction. History of GMOs “evolution”. General notions concerning genetic transformation. Necessity. Stages to obtain GMOs, genes of “interest”, GMOs selection and testing.	3	2	-
2.	Benefits and risks. Biosecurity, National and Global legal framework.	2	1	-
3.	Transgenic microorganisms. Transgenic techniques. Fields of application.	2	3	-
4.	Transgenic plants and their new properties. Techniques of obtaining. Transgenic cultivated plants. Impact on biodiversity, environment and human health.	2	2	-
5.	Transgenic animals and their new features. Techniques of animal transgenesis. Impact on biodiversity, environment and human health.	2	1	-
6.	Transgenic organisms (bacteria, algae, fungi, plants, animals) in the pharmaceutical, food, fodder, textile, tincture industries. Advantages and risks.	3	4	-
7.	GMOs global, national, policies and strategies. Balance on GMOs: the present and future of Genetically Modified Organisms. Consumer education, information and involvement of the population in decision-making. Own opinions, proposals.	1	2	-
Total		15	15	-

VI. REFERENCE OBJECTIVES OF CONTENT UNITS

Objectives	Content units
Theme 1. Generalities about genetic transformation	
<ul style="list-style-type: none"> To define the notion of genetically modified organisms. To know the terminology specific to genetic transformations. To understand the way and steps of obtaining the GMO. To know the strategies for identifying, isolating, cloning and transferring “interest genes”. To demonstrate that they can highlight the specificity of genetically modified organisms. 	Genetically modified organisms – organisms with new qualities and traits. Gene of interest. Methods and strategies for identifying, isolating, cloning and transferring “interest genes”. Test methods for transgenic organisms. Advantages and risks of GMOs.



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Objectives

Content units

- To be aware of the benefits and risks of transgenic organisms.

Theme 2. Legal framework and biosecurity

- To know the legal framework on GMOs and biological security.
- To demonstrate that they know the specificity of genetically modified organisms.
- To be aware of the risks, benefits and role of the human factor in GMOs policy.
- To integrate knowledge about the involvement of transgenic organisms in food and medicine production.

Global legal framework and biosecurity.
Legislation, national framework in the field of biological security.
Organisms and institutions responsible for biological security.
The role of the human factor.
Protection of producers and beneficiaries rights in the field of transgenic products or with transgenic content.

Theme 3. Transgenic organisms and their application

- To know the fields of application of transgenic organisms.
- To know transgenic microorganisms used in food, pharmaceutical and environmental field.
- To know the transgenic plants used in food and pharmaceutical field.
- To know the transgenic animals used in food and pharmaceutical field.
- To be able to integrate knowledge into the study of other pharmaceutical disciplines.

Fields of application of GMOs.
Transgenic microorganisms used in the production of drugs.
Transgenic plants as a source of raw material in food and medicine production.
Transgenic animals as a source of raw material in food and medicine production.

Theme 4. Genetically modified organisms and human factor

- To know the aspects of global and national GMOs policies.
- To be aware of the acceptance, challenge, and rejection of transgenic organisms.
- To integrate knowledge into later studies and everyday life.
- To form and promote a fair civic attitude towards GMOs policies.

GMOs and society. GMOs and human factor.
Pros and cons of GMOs in Europe and other regions of the world. Education of producers and beneficiaries. Active attitude in transgenesis policies.

VII. PROFESSIONAL (SPECIFIC (SC)) AND TRANSVERSAL (TC) COMPETENCES AND STUDY OUTCOMES

✓ Professional (specific) (SC) competences

- CP 1. Knowledge and understanding of the theoretical bases of genetic engineering in the production of GMOs and especially those involved in the pharmaceutical, food, feed, energetic industries.
- CP 2. To know the transgenic techniques in obtaining GMOs (bacteria, algae, fungi, plants, animals) as producers for obtaining the new generation of medicines and food. Evaluation of



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the benefits and risks of transgenic products in terms of the norms of the global and national legal framework in order to ensure the biosecurity.

- CP 3. Use and adaptation of knowledge gained from the field of transgenic organisms in everyday life and subsequent professional activity. Improving the pharmaceutical field and promoting correct attitude towards transgenic products by continuously updating knowledge in the field of applied genetic engineering.

✓ **Transversal competences (TC)**

- CT 1. Responsible implementation of tasks in compliance with the rules of professional ethics and application of ethical norms in national policies on the current generation of medicines and food based on genetically modified organisms (recombinogenesis and transgenesis).
- CT 2. Developing the trend of information and continuous perfection of practical knowledge and skills in the field of genetically modified organisms. The ability to design and present thematic projects.
- CT 3. Ability to work with respect and collegiality in the team. Developing the spirit of initiative in deepening and promoting knowledge about drugs and food, based on genetic engineering techniques.

✓ **Study outcomes**

- To know the techniques and stages of obtaining genetically modified organisms.
- To be able to distinguish the benefits and risks of growing and using GMOs.
- To know transgenic organisms (bacteria, algae, fungi, plants, animals) as producers in pharmaceutical, food, feed, energy industries.
- To be informed and competent to use the knowledge of GMOs to become a contemporary pharmacist specialist.
- To be competent to use critical and reliable scientific information obtained using the new information and communication technologies.

Note. Study outcomes (are deduced from the professional competencies and formative valences of the informational content of the discipline).

VIII. STUDENT'S SELF-TRAINING

No.	Expected product	Implementation strategies	Assessment criteria	Implementation terms
1.				
2.				
3.				

*Note: No hours were allocated for the student's self-training

IX. METHODOLOGICAL SUGGESTIONS FOR TEACHING-LEARNING-ASSESSMENT



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- ***Teaching and learning methods used***

Discipline Genetically modified organisms is taught in classical ways: lectures and seminars. Course hours are read by the course owner through the involvement of modern information technologies. At the seminars, the students will discuss the topics planned using different methodical-didactic methods: frontal / individual interactive discussion, disputes, mini-conferences, debates in teams with arguments, evidence, opinions, beliefs and oppositions on GMO activities, involvement of GMOs in the food, pharmaceuticals, cosmetics, conscientious attitude to existing policies and strategies, consumer education on human biosecurity and environment in relation to transgenic products. Presentation and discussion of thematically papers. All the activities will be targeted to raise awareness, knowledge of GMOs by students, which will be harnessed and promoted by them during their work in the field of national pharmacy and in strengthening the health of the national society.

- ***Applied teaching strategies / technologies (specific to the discipline)***

Front work, individually and in micro teams. Interactive discussion "Discussion Round Table"; debates "Case Study"; "Creative Controversy"; Virtual Practices.

- ***Methods of assessment (including the method of final mark calculation)***

Current: will be done through 2 assessments of the students' knowledge (1 evaluation – frontal and individual discussions, thematic debates, 1 evaluation – thematically report).

Final: colloquium with the qualification "attestate".

Final appreciation: The final appreciation will consist of an average score of 2 (0.5/0.5) assessments of the knowledge obtained with the qualification – attestate.

Method of mark rounding at different assessment stages

Intermediate marks scale (annual average, marks from the examination stages)	National Assessment System	ECTS Equivalent
1,00-3,00	2	F
3,01-4,99	4	FX
5,00	5	E
5,01-5,50	5,5	
5,51-6,0	6	
6,01-6,50	6,5	D
6,51-7,00	7	
7,01-7,50	7,5	C
7,51-8,00	8	
8,01-8,50	8,5	B



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8,51-8,00	9	
9,01-9,50	9,5	A
9,51-10,0	10	

The average annual mark and the marks of all stages of final examination (computer assisted, test, oral) - are expressed in numbers according to the mark scale (according to the table), and the final mark obtained is expressed in number with two decimals, which is transferred to student's record-book.

Absence on examination without good reason is recorded as "absent" and is equivalent to 0 (zero). The student has the right to have two re-examinations.

X. RECOMMENDED LITERATURE:

A. Compulsory:

1. Suport de curs/Course support information pe web-site catedrei.
2. Aspecte metodologice în testarea plantelor modificate genetic. Duca M., Lozan A., Port A., Glijin A., Lupașcu V. Tipografia centrală, Chișinău, 2008.
3. Biosafety Concerns in the Republic of Moldova: opportunities and challenges. By Dr. Angela Lozan, Ministry of Ecology and Natural Resources, UNEP-GEF Biosafety, Chișinău, 2008. 52 p.
4. First Biennial Update Report of the Republic of Moldova under the United Nations Framework Convention on Climate Change, Resp. V. Munteanu, Tipogr. "Bons Offices", Chișinău, 2016.

B. Additional

1. Cadrul Național pentru Securitatea Biologică. Elaborat în cadrul Proiectului UNEP/GEF nr. GE/2716-02-4520. Tipografia Centrală, Chișinău, 2004, 47 p.
2. Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects. National Research Council (US) Committee on Identifying and Assessing Unintended Effects of Genetically Engineered Foods on Human Health. Washington (DC): National Academies Press (US); 2004.
3. Watson R., Preedy V. Genetically Modified Organisms in Food: Production, Safety, Regulation and Public Health, 1st Edition, Caroline Johnson, 2016.
4. Impacts of GMOs on biodiversity and human health – Information Paper, IUCN, 2007.
5. Ediții curente/Current national and mondial publications on OMGs domain.