MINISTRY OF EDUCATION AND SCIENCE OF UKRAINE

SUMY NATIONAL AGRARIAN UNIVERSITY

Department of Management

«Affirm»

Head of the Department of

Management

_____A.M. Mykhailov

«_____» _____2019

CURRICULUM

Management of laboratory activity

Training field: Postgraduate students

091 "Biology"; 133 " Sectoral Engineering "; 201 "Agronomy"; 202 "Protection and Plant Quarantine"; 204 "Technology of production and processing of livestock products"; 211 "Veterinary Medicine"

Faculty: department of postgraduate and doctoral studies

2019 – 2020

Work program of the discipline «Management of laboratory activity».

Author: I.Lozynska, Head of Postgraduate Department, Professor at the Department of Management, D.Sci in Economics _____

Work program was considered at the Department of Management
Protocol from _____

Head of the Department of Management **_____ prof. A.M. Mykhailov**

Agreed:

Head of the Department of Graduate Studies _____ I.V. Lozynska

Methodist of the Educational Department _____ G.O. Baboshyna

Reiterated: date: _____

Approved by the Council of SNAU, June 12, 2019

1. Description of the educational discipline

<table>
<tr><th rowspan="2">Name</th><th rowspan="2">Knowledge area, field, educational qualification level</th><th colspan="2">Characteristics of the discipline</th></tr>
<tr><th>full-time study</th><th>part-time study</th></tr>
<tr><td rowspan="2">Number of credits – 2</td><td>Knowledge area:
Scientific</td><td colspan="2" rowspan="2">Variative</td></tr>
<tr><td rowspan="8">Specialty:

091 "Biology"; 133 " Sectoral Engineering "; 201 "Agronomy"; 202 "Protection and Plant Quarantine"; 204 "Technology of production and processing of livestock products"; 211 "Veterinary Medicine"</td></tr>
<tr><td>Modules – 2</td><td colspan="2">Year of preparation:</td></tr>
<tr><td>Content modules: 2</td><td>2019-2020</td><td>–</td></tr>
<tr><td rowspan="2">Individual scientific task:
absent</td><td colspan="2">Course</td></tr>
<tr><td>1</td><td>–</td></tr>
<tr><td colspan="2">Semester</td></tr>
<tr><td rowspan="2">Total hours – 24</td><td>-</td><td>+</td></tr>
<tr><td colspan="2">Lectures</td></tr>
<tr><td rowspan="10">Weekly hours for full-time study:
classroom – 2</td><td rowspan="10">Qualification level:
The third level</td><td>12 hours</td><td>–</td></tr>
<tr><td colspan="2">Practical, seminar</td></tr>
<tr><td>12 hours</td><td>–</td></tr>
<tr><td colspan="2">Laboratory</td></tr>
<tr><td>–</td><td>–</td></tr>
<tr><td colspan="2">Individual work</td></tr>
<tr><td>66 hours</td><td>–</td></tr>
<tr><td colspan="2">Individual tasks:
–</td></tr>
<tr><td colspan="2">Type of control:
exam</td></tr>
</table>

The ratio of the class hours number to the individual work hours number for full-time education is 24/36.

1. The purpose and objectives of the discipline

The purpose of the course is to master the algorithms of grading technologies and the efficiency of laboratory methods as a component of the diagnostic process.

The task of the discipline - mastering a set of standards for modern laboratory diagnostics; defining rules for sample preparation of biological material for modern and objective directions of laboratory research; implementation of modern laboratory testing procedures in accordance with international rules of good laboratory practice (GLP).

As a result of studying the discipline, the graduate student should know:

- The concept of quality management system in medical laboratories of Ukraine in accordance with the requirements of international standards and the Plan of measures for its implementation;
- DSTU EN ISO 15189: 2015 approved at the state level, which has set specific requirements for the quality and competence of medical laboratories;
- principles of good laboratory practice;
- how the state system of external evaluation of the quality of clinical laboratory investigations works by implementing Programs of interlaboratory comparisons of measurement results.

be able:

- to apply in practice the rules of international standards on good laboratory practice;
- apply the special skills of modern laboratory research defined by the Standard using modern equipment;
- Determine the tactics of complex laboratory research in accordance with the rules of good laboratory practice;
- Analyze the results of laboratory tests according to standard operating procedures.

3. The program of the discipline

Content module 1. REGULATORY, LEGAL, ETHICAL AND INTERNATIONAL STANDARDS OF MODERN LABORATORY RESEARCH

Topic 1. The rules of biomedical and legal ethics in laboratory research

Topic 2. International standards of good laboratory practice in conducting laboratory-instrumental research, principles of creation of laboratories with the use of modern equipment, the latest medical technologies and scientific developments

Topic 3. Creating standard operating procedures, laboratory test protocols, analysis rules, generalizations, and validation of current laboratory test results

Content module 2. ORGANIZATION OF AN EFFECTIVE LABORATORY MANAGEMENT SYSTEM: DOCUMENTATION REQUIREMENTS, PERSONNEL, EQUIPMENT, INTERNAL AUDITS

Topic 4. Building an effective laboratory management system.

Topic 5. Internal audits. Performing internal audits in accordance with ISO 19011: 2018

Topic 6. Assessment of risks and opportunities in laboratory activities.

4. The structure of the discipline

Title of module/topic	Number of hours											
	Full-time						Part-time					
	Total	Incl.					Total	Incl.				
		L	P	Lab	Ind.	I.w.		L	P	Lab	Ind.	I.w.
Content module 1. REGULATORY, LEGAL, ETHICAL AND INTERNATIONAL STANDARDS OF MODERN LABORATORY RESEARCH												
Topic 1. The rules of biomedical and legal ethics in laboratory research	16	2	2			12						
Topic 2. International standards of good laboratory practice in conducting laboratory-instrumental research, principles of creation of laboratories with the use of modern equipment, the latest medical technologies and scientific developments	16	2	2			12						
Topic 3. Creating standard operating procedures, laboratory test protocols, analysis rules, generalizations, and validation of current laboratory test results	16	2	2			12						
Together for Module 1	48	6	6			36						
Content module2. ORGANIZATION OF AN EFFECTIVE LABORATORY MANAGEMENT SYSTEM: DOCUMENTATION REQUIREMENTS, PERSONNEL, EQUIPMENT, INTERNAL AUDITS												
Topic 4. Building an effective laboratory management system.	14	2	2			10						
Topic 5. Internal audits. Performing internal audits in accordance with ISO 19011:	14	2	2			10						

2018												
Topic 6. Assessment of risks and opportunities in laboratory activities.	14	2	2			10						
Together for module 2	42	6	6			30						
Total	60	12	12			66						

5. Lectures
(full-time form)

No	Topic title	Number of hours
1	Topic 1. The rules of biomedical and legal ethics in laboratory research	2
2	Topic 2. International standards of good laboratory practice in conducting laboratory-instrumental research, principles of creation of laboratories with the use of modern equipment, the latest medical technologies and scientific developments	2
3	Topic 3. Creating standard operating procedures, laboratory test protocols, analysis rules, generalizations, and validation of current laboratory test results	2
4	Topic 4. Building an effective laboratory management system.	2
5	Topic 5. Internal audits. Performing internal audits in accordance with ISO 19011: 2018	2
6	Topic 6. Assessment of risks and opportunities in laboratory activities.	2
	Total	12

6. Practics
(full-time form)

No	Topic title	Number of hours
1	Topic 1. The rules of biomedical and legal ethics in laboratory research	2

2	Topic 2. International standards of good laboratory practice in conducting laboratory-instrumental research, principles of creation of laboratories with the use of modern equipment, the latest medical technologies and scientific developments	2
3	Topic 3. Creating standard operating procedures, laboratory test protocols, analysis rules, generalizations, and validation of current laboratory test results	2
4	Topic 4. Building an effective laboratory management system.	2
5	Topic 5. Internal audits. Performing internal audits in accordance with ISO 19011: 2018	2
6	Topic 6. Assessment of risks and opportunities in laboratory activities.	2
	Total	12

7. Individual work

(full-time form)

No	Topic title	Number of hours
1	Topic 1. The rules of biomedical and legal ethics in laboratory research	12
2	Topic 2. International standards of good laboratory practice in conducting laboratory-instrumental research, principles of creation of laboratories with the use of modern equipment, the latest medical technologies and scientific developments	12
3	Topic 3. Creating standard operating procedures, laboratory test protocols, analysis rules, generalizations, and validation of current laboratory test results	12
4	Topic 4. Building an effective laboratory management system.	10
5	Topic 5. Internal audits. Performing internal audits in accordance with ISO 19011: 2018	10
6	Topic 6. Assessment of risks and opportunities in laboratory activities.	10
	Total	66

8. Learning methods

1. Verbal methods: story, explanation, conversation, lecture, tables and graphs, supporting notes, etc.

2. Visual methods: demonstration, illustration, observation, etc.

3. Analytical, synthesis methods, inductive method.

4. Active teaching methods: brainstorming, debates, rolegames, trainings, use of problem situations, group research, self-assessment of knowledge, imitation training methods, use of educational and control tests, use of basic lecture notes.

5. Interactive learning technologies, use of multimedia technologies, case study.

9. Control methods

1. Rating control over the 100-point ECTS rating scale.

2. Conducting intermediate control during the semester (intermediate attestation)

3. Multicriteria assessment of students' current work:

– the level of knowledge demonstrated on practical classes;
– activity during the discussion;
–individual study;
– test results;
– written tasks, etc.

10. Points allocation

Current testing and individual work					**Module and individual work**	**Exam**	**Total**
Module 1 – 15		**Module 2 – 45**		**I/ W**			
T1	T2	T3 T4 T5	T6 T7		70	30	100
10	5	10 5 10	10 10	10	(60+10)		

Rating scale: national and ECTS

Total points	**ECTS**	**National rating**	
		For exam, practice	**Final test**
90 – 100	**A**	Very good	Passed
82-89	**B**	Good	
75-81	**C**		
69-74	**D**	Satisfactorily	
60-68	**E**		
35-59	**FX**	Unsatisfactory with the possibility of retesting	Not passed with the possibility of

			retesting
1-34	**F**	Unsatisfactory with the compulsory re-study of the discipline	Not passed with the compulsory restudy of the discipline

11. Recommended literature

1. Wareing S. How to Study Successfully.-Newport: University of Wales, Newport, 2004

2. Good Clinical Practice: standard Operating Procedures for clinical Researches / A. Kolman et al. – John Wiley Sons, 1998. – 177 p.

3. Henry's Clinical Diagnosis and Management by Laboratory Metods / A. Richard, M. D. McPerson, R. Matthew, M. D. Pincus. – Commended, Basic and Clinical Sciences, BMA Awards, 2006. – 1472 p.