MINISTRY OF EDUCATION AND SCIENCE OF UKRAINE

Sumy National Agrarian University

Chair epizootiology and parasitology

APPROVED
Head of Department
epizootiology and parasitology
"___" _____ 2020
_____ Kassich V.U.

WORKING PROGRAM TRAINING COURSE (SILABUS)

PP.04 Biotechnology veterinary immunological products

Specialty: *211 "Veterinary medicine"*

Educational program : *OPP* *"Veterinary Medicine"*

Faculty: *Veterinary Medicine*

2020 - 2021 academic year

Working program ***Biotechnology veterinary immunological products*** students 211 specialty "Veterinary Medicine"

Developers: d.v.n. Professor V.Y. Kassich ._____
(signature)

Art. Lecturer Y.V. Negreba _____
(signature)

Art. Lecturer V.I. Risovaniy _____
(signature)

Work Program endorsed by the Department of epizootiology and parasitology.

Minutes № 15 of "01" in June 2020

Head of the Department of
Parasitology and epizootiology _____ (Kassich VY)

Agreed:

Guarantor of the educational program _____ LG Ulko

Dean of the Faculty of Veterinary
Medicine_____ O.I. Nechiporenko

Methodist of the Department of Education Quality
licensing and accreditation _____

Registered in the electronic database : Date: 2020 r.

1. Description of discipline

<table>
<tr><td rowspan="2">Name of indicators</td><td rowspan="2">Industry knowledge and direction of training, education level</td><td colspan="2">Characteristics of discipline</td></tr>
<tr><td>full-time education</td><td>external form of education</td></tr>
<tr><td rowspan="2">Credits - 4</td><td>Branch of knowledge:
21 "Veterinary Medicine"</td><td colspan="2" rowspan="2">Regulatory</td></tr>
<tr><td rowspan="8">Specialty 211
"Veterinary Medicine</td></tr>
<tr><td>Modules - 2</td><td colspan="2">Year of training:</td></tr>
<tr><td>Content modules - 4</td><td>2020-2021</td><td></td></tr>
<tr><td rowspan="7">Total hours - 90</td><td colspan="2">Course</td></tr>
<tr><td>2</td><td></td></tr>
<tr><td colspan="2">Semester</td></tr>
<tr><td>4</td><td></td></tr>
<tr><td colspan="2">Lectures</td></tr>
<tr><td rowspan="8">A weekly hours for full-time:
classroom - 3 self-learning - 3</td><td rowspan="8">Education level:
master</td><td>14</td><td></td></tr>
<tr><td colspan="2">Practical, seminar</td></tr>
<tr><td>-</td><td></td></tr>
<tr><td colspan="2">Laboratory</td></tr>
<tr><td>30</td><td></td></tr>
<tr><td colspan="2">Independent work</td></tr>
<tr><td>46</td><td></td></tr>
<tr><td colspan="2">One problem:</td></tr>
<tr><td colspan="2">Final control - test</td></tr>
</table>

Note. The ratio of hours of classes to separate and individual work for full time is:
49% to 51%

2. The purpose and objectives of discipline

Goal: To teach future veterinarian navigate the modern range of immunological veterinary drugs, know the principles of action, the foundations of their production technology.

Task: learn the technologies and modern requirements, principles of production of immunological veterinary drugs to ensure the development and application of highly efficient remedies for animal disease control measures system in Ukraine.

Astudy discipline

Students should know:

Module 1:

- Methods and objectives biotechnology. Communication with other sciences.
- The history of biotechnology and its achievements.
- Safety at work infectious agents.
- The main groups of veterinary imunobiopreparativ principle of action and application.
- Selection and depositing infectious agents (production and control strains)
- The main types of culture media
- Equipment for the manufacture of biologics.

Module 2:

- Manufacturing techniques of viral, bacterial, fungal (live and inactivated) vaccine
- Manufacturing technology serum biologics
- Manufacturing technology diagnostics
- Manufacturing technology of probiotics and bio-stimulants
- The principles of GMP requirements for biopidpryyemstva

Students should be able to:

Module 1:

- Describe bopreparat.
- Determine the purpose of use of a biological principles and explain his actions.
- Prepare basic types of culture media that are used for the production of biologics.

Module 2:

- Organize the technological process of manufacturing of viral, bacterial, fungal (live and inactivated) vaccine, serum biopharmaceuticals, diagnostics, bio-stimulants and probiotics
- Ensure compliance biopidpryyemstva requirements of GMP.

Module 1. Introduction.

Content module 1. Introduction.

Topic 1: Introduction to Biotechnology veterinary immunological products. Biotechnology as a science. Subject and tasks of biotechnology. History of biotechnology and its achievements. Methods and biotechnology facilities. Communication with other sciences. The challenge of biotechnology in the current development of science and industry. Safety and personal prevention. Personal protection veterinarian. Immunological basis of a veterinary imunobiopreparativ. The penetration of pathogens into the body and nonspecific factors of non-immune defense system. Antigen-antibody reaction and its role in the immune response

Theme 2: Genetic engineering biotechnology of microorganisms for the production of biologics. The variability of organisms and its importance in biotechnology (mutation, modification, selection). By genetic engineering. Genetically engineered products used for biovyrobnytstva. Maintaining stability feno- and genotype-producers of biological objects.Create a collection of

microorganisms. What is required for deposit strains. Existing approaches to obtain the target gene. Modern methods of selection of cells expressing the target gene. Production of monoclonal antibodies.

Content module 2. The information on biologically active agents.

Theme 3: Classification of veterinary immunological products, the principle of action and application. The concept of immunological veterinary drugs. Classification VIP. Immunological basis of a veterinary vaccine preparations imunobiopreparativ. Serum preparations for health care treatments and diagnostics. Diagnostic antigens and allergens. Interferons, probiotics, enzymes, hormones and tissue stimulators.

Theme 4: Financial support of production and raw biologics. Stage biotechnological production. Types of growth media for culturing cells and miroorhanizmiv. Requirements for culture media. Classification of culture media. Types and composition of the culture medium. Methods for determining contamination of culture media and biologics extraneous viruses, bacteria, mycoplasma, fungi. Types of equipment biopidpryyemstv (bioreactors, apparatus for distillation and water treatment, filters, sensors, etc.). Marking biologics.

Module 2. The production process.

Content module 3. Technology for manufacturing biologics.

Theme 5: Manufacturing techniques of viral, bacterial, fungal (live and inactivated) vaccine. General information about the vaccine preparations. The main stages of manufacturing virus vaccines. Stages production of live bacterial and fungal vaccines. Production corpuscular bacterial vaccines. The principles of the production of inactivated vaccines. Production of subunit vaccines. Production of chemical or molecular vaccines.

Topic 6: Manufacturing technology serum biologics and diagnostics. Information serum. Selection of animal producers. Hiperimunizatsiya. Hrundimunizatsiya. Classification hiperimunyh sera. Production of hyperimmune serum. Steps to get hiperimunyh sera.Quality Control sыvorotochnыh drugs. Production of diagnostic sera. Structure serum shop. Biotechnology gamma globulin. Features production of diagnostic sera. Production of viral and bacterial antigenic diagnostics. Production of allergens. Manufacturing technology bacteriophages.

Theme 7: Manufacturing technology of probiotics and bio-stimulants. The mechanism of action of probiotics. Classification of probiotics. Principles receipt. Probiotics based on lactic acid bacteria. Production technology Bifidumbacterin. Production technology probiotic bacteria from the genus Bacillus. Classification of interferon. Principles receipt. Technology of production of interferon. The principles of obtaining tissue enzymatic, hormonal bio-stimulants, histolizativ.

Content module 4. Principles of production of biological products.

Topic 8: The problem of quality biotechnology products. The purpose of the operation GLP and GMP (Good Laboratory Practice; Good Manufacturing Practice). Basic principles of Good Manufacturing Practice (GMR) for the biotech industry. Characteristics of the standard ISO 9000. The documentation of the quality system. Requirements for raw materials. Requirements for packaging materials. Requirements for finished products. Vybrakovani, regenerated and returned materials. General requirements for quality control.

Subject 9: Principles of biopidpryyemstva. "Clean room". Methods of ensuring purity and control parameters. Organizational structure biopidpryyemstva. Clean room in the manufacture of immunological products. Sources micro contamination. Principles section zones with different classes of purity. Air flow. Adjusting the air pollution. Classification of air filters to European standards EN 779, EN 1822 and GOST R 51251 - 99. Control of temperature and humidity.Basic principles of Good Manufacturing Practice (GMP). Personnel requirements. Requirements for premises and equipment. Validation.Distribution. Types and structure documentation biotech company. The purpose of documentation. General requirements for documentation. Specification. Protocols. Production formulation, technical instructions on the packaging. Dossier series. Methods.

3. The structure of the discipline

Names of content modules and topics	Number of hours					
	All	including				
		l	n	lab	ind	SR
1	2	3	4	5	6	7
Module 1. Introduction.						
Content module 1. Introduction.						
Topic 1: Introduction to Biotechnology veterinary immunological products.	18	2		4		12
Theme 2: Genetic engineering, breeding and depositing infectious agents (production and control strains).	14	2		4		8
Together for the content modules 1	**32**	**4**		**8**		**20**
Content module 2. Details of biologically active preparations						
Theme 3: Classification of veterinary immunological products, the principle of action and application.	6	2		4		
Theme 4: Financial & Raw ensure the production of biological products.	4	-		4		
Together for the content modules 2	**10**	**2**		**8**		
Total hours per module 1	**42**	**6**		**16**		**20**
Module 2. The production process.						
Content module 3. Technology for manufacturing biologics						
Theme 5: Manufacturing techniques of viral, bacterial, fungal (live and inactivated) vaccine.	18	2		4		12
Topic 6. Manufacturing technology serum biologics and diagnostics.	4	2		2		
Theme 7. Manufacturing technology of probiotics and bio-stimulants.	4	2		2		
Total for 3 content modules	**26**	**6**		**8**		**12**
Content module 4. Principles biologics production						
Theme 8. The problem of quality biotechnology products.	10	2		2		6
Subject 9: Principles of biopidpryyemstva.	12			4		8
Total for 4 content modules	**22**	**2**		**6**		**14**
Total hours per module 2	**48**	**8**		**14**		**26**
The total number of hours	**90**	**14**		**30**		**46**

4. Themes and lectures plan

number p / p	The title and content modules and their elements	Number hours
	Module 1 .Vvedennya.	
1	**Subject: Introduction to Biotechnology veterinary immunological products.** ***Plan of the lecture:*** 1. Biotechnology as a science. 2. Subject and tasks of biotechnology. 3. History of biotechnology and its achievements. 4. Methods and biotechnology facilities. 5. Communication with other sciences. 6. The challenge of biotechnology in the current development of science and industry.	**2**
2	**Subject: Genetic engineering in biotechnology of microorganisms for the production of biologics.** ***Plan of the lecture:*** 1. The variability of organisms and its importance in biotechnology (mutation, modification, selection). 2. Genetically engineered 3. Genetically engineered products used for biovyrobnytstva. 4. Maintaining stability feno- and genotype-producers of biological objects.	**2**
3	**Subject: Classification of veterinary immunological products, the principle of action and application. Financial support of production and raw biologics.** ***Plan of the lecture:*** 1. The concept of immunological veterinary drugs. vaccine preparations 2. Serum preparations for health care treatments and diagnostics 3. Diagnostic antigens and allergens 4. Interferons, probiotics, enzymes, hormones and tissue stimulators. 5. Stage biotechnological production 6. Types of growth media for culturing cells and miroorhanizmiv. 7. Types of equipment biopidpryyemstv (bioreactors, apparatus for distillation and water treatment, filters, sensors, etc.)	**2**
	2. The module manufacturing process.	
4	**Subject: Manufacturing techniques of viral, bacterial, fungal (live and inactivated) vaccine** ***Plan of the lecture:*** 1. The main stages of manufacturing virus vaccines 2. Stages production of live bacterial and fungal vaccines 3. Production corpuscular bacterial vaccines 4. Principles of production inactivated vaccines 5. Production of subunit vaccines 6. Production of chemical or molecular vaccines 7.	**2**
5	**Subject: Manufacturing technology serum biologics and diagnostics** ***Plan of the lecture:*** 1. Selection of animal producers 2. Hiperimunizatsiya	**2**

	3. Production of hyperimmune serum 4. Biotechnology gamma globulin 5. Features production of diagnostic sera 6. Production of viral and bacterial antigenic diagnostics 7. Production of allergens 8. Manufacturing technology bacteriophages	
6	**Subject: Manufacturing technology of probiotics and bio-stimulants** ***Plan of the lecture:*** 1. Probiotics based on lactic acid bacteria 2. Production technology Bifidumbacterin 3. Technology of production of probiotic bacteria from the genus Bacillus 4. Technology of production of interferon. The principles of obtaining tissue enzymatic, hormonal bio-stimulants, histolizativ.	**2**
7	***Subject: The problem of quality biotechnology products. Principles of biopidpryyemstva. "Clean room". Methods of ensuring purity and control of parameters*** ***Plan of the lecture:*** 1. The purpose of the operation GLP and GMP (Good Laboratory Practice; Good Manufacturing Practice) 2. Basic principles of Good Manufacturing Practice (GMR) for the biotech industry. 3. Of standards ISO 9000 4. Organizational structure biopidpryyemstva 5. Clean room in the manufacture of immunological products. Sources micro contamination 6. Principles section zones with different classes of purity 7. Air flow. Adjusting the air pollution. Classification of air filters to European standards EN 779, EN 1822 and GOST R 51251 - 99 temperature and humidity control	2
Together		**14**

5. Topics laboratory classes

number / p	topic	Amount hours
	Module 1: Introduction	
1	Introduction to personal prevention measures when working with mikroorhanism, the environment and the finished product biovyrobnytstva. Determination of microbial pollution in clean rooms and public areas.	2
2	Storage and maintenance of major biotech facilities. Methods of genetic engineering and hennoinzhenerni products used for biovyrobnytstva. Immunological basis of a veterinary imunobiopreparativ.	2
3	Classification of veterinary immunological products	2
4	The production strains and cultivation conditions of production strains - superprodu cents. Deposition of infectious agents (production and control strains).	2
5	Sterelizatsiyi methods in biotechnology. Filtration of medicinal products which may not be in the final prosterelizovani original packaging.	2
6	Getting immunological products. Principles of design, performance and use of	2

	vaccine, diagnostic and health care VIP.	
7	Control parameters increase production strains super-producers during cultivation.	2
8	Types of equipment biopidpryyemstv, types of culture media for culturing microorganisms and principles of cooking.	2
Module 2. The production process.		
9	Classification vaccine preparations. Methods for separating the biomass from the culture fluid.	2
10	Manufacturing techniques of viral, bacterial, fungal (live and inactivated, subunit, recombinant) vaccine	2
11	Production of inactivated vaccines using adjuvants.	2
12	Technology training and hiperimunizatsiyi animal producers to manufacture biologics serum (hyperimmune serum lacto-hlobulniv gamma globulin).	2
13	Production diagnostics (diagnostic serum viral and bacterial antigenic diagnostics, allergens and bacteriophages).	2
14	Manufacturing technology based probiotics lakto-, bifidbakteriy and bacteria of the genus Bacillus.	2
15	Technology of production of interferon, tissue bio-stimulants and other drugs	2
Together:		**30**

6. Independent work

number / p	topic	K-ist hours
1	**Topic 1: Introduction to Biotechnology veterinary immunological products.** Immunological basis of a veterinary imunobiopreparativ. The penetration of pathogens into the body and nonspecific factors of non-immune defense system. Antigen-antibody reaction and its role in the immune response	**12**
2	**Topic 2: Genetic engineering biotechnology of microorganisms for the production of biologics.** Existing approaches to obtain the target gene. Modern methods of selection of cells expressing the target gene. Production of monoclonal antibodies.	**8**
3	**Topic 4: Financial & Raw ensure the production of biological products.** The method of determining contamination of culture media and biologics extraneous viruses, bacteria, mycoplasma, fungi. Marking biologics	**12**
4	**Topic 8: The problem of quality biotechnology products** The basic principles of good manufacturing practice in the process. Requirements for raw materials. Requirements for packaging materials. Requirements for finished products. Vybrakovani, regenerated and returned materials. General requirements for quality control	**6**
5	**Topic 9: Principles of biopidpryyemstva. "Clean room". Methods of ensuring purity and control of parameters** Validation. Distribution. Types and structure documentation biotech company. The purpose of documentation. General requirements for documentation. Specification. Protocols. Production formulation, technical instructions on the packaging. Dossier series. Procedures	**8**
Together		**46**

8. Teaching methods

When used verbal teaching, practical and visual methods, using methods of induction, deduction, analysis and synthesis.

Lectures involve the use of explanatory demonstration of the method in which the lecturer verbally describes and explains the program material and clearly reinforces his perception schemes, photo and video illustrations.

For laboratory practical classes enjoy performances by the students problem tasks solving which are under the direction of teacher actively learn new skills.

Partly retrieval method involves students in finding ways, methods and means of solving cognitive tasks. The teacher directs the course of a search of mental activity of students using the system logically motivated questions; encourages and welcomes the cognitive activity of students in solving educational problems; analyzes the successes and mistakes difficulties.

Interactive learning technologies - the use of multimedia technology, viewing video on the topic during lectures and workshops, co-students.

9. Methods of control

In the study of Biotechnology VIP progress testing methods are:

- Assessing the level of knowledge demonstrated in the oral responses and activity when discussing issues submitted to classes;
- Assessing the level of skills in rapid control a sequence of operations when performing manipulations;
- the results of the written assignments in the workbook;
- perform analytical and computational tasks;
- By Computer test results;
- written answers to tests on topics of self-employment;

10. Distribution of points receiving students (test)

Routine testing and independent work									**CPC**	**However, for modules and CPC**	**Certification**	**Sum**
Module 1 - 30				**Module 2 - 40**								
Content module 1		**Content module 2**		**Content module 3**			**Content module 4**					
T1	T2	T3	T4	T5	T6	T7	T8	T9				
7	8	7	8	8	8	8	8	8	15	85 (70 + 15)	15	100

Grading scale: national and ECTS

Total points for all the educational activities	**Assessment ECTS**	**Evaluation of national scale**	
		for examination, course project (work), practice	**for scoring**
90 - 100	**AND**	perfectly	Accepted
82-89	**IN**	okay	
75-81	**WITH**		
69-74	**D**	satisfactorily	
60-68	**IS**		
35-59	**FX**	unsatisfactorily with possibility of re-drafting	not reckoned with the possibility of re-drafting

0-34	**F**	unsatisfactorily with the mandatory repeated study of discipline	not reckoned with the obligatory re-learning courses

11. Suggested Reading

Basic

1. V. Gerasimenko, MO Gerasimenko, MI Tsvilihovskyy and in.Biotehnolohiya: Tutorial By: Firm "INKOS." 2006. -647 p.
2. Becker ME, Lyepynsh GK, Raynulys E.P biotechnology M .: "Agropromizdat." 2001.235s.
3. Y.M.Hrachevoy, L.A.Yvanovoy biotechnology biologically aktyvnыh substances: Textbook. posobye. IZ-in NPO "Эlevar." 2006. - 453 p.
4. N.S.Ehorova, VD Samuylova. Biotechnology: Textbook. posobye for Universities. Problems and prospects in the M .: High society. school. - 2007. - 159 p.
5. V. Sheveluha Selskohozyaystvennaya biotechnology. Uchebnoe posobye M .: "Higher School" .2003. 321 p.

Support

1. V. Smirnov, Selnikova OP Dumanskii VD, Moses GV, O. Hrynevych Immunological products. - K: Morion, 2001. - 192 p.
2. V. Gerasimenko Biotechnological Dictionary - K., 1991
3. KF Foster, DA J. Weis. Environmental of Biotechnology, 1990. - Trans. ed .: United Kingdom, 1987. - 384 p.
4. Radchuk ND / Veterynarnaya Microbiology and Immunology Agropromizdat, 2001. - 383 p.
5. D.U. Dzhyrsha Ymmunolohycheskaya engineering M .: Medicine, 1982. - 416 p.