Annex 2
To the Procedure for development and periodic review of educational programs

The syllabus of the discipline «Quality system in pharmacy»

1. General information	
The name of the faculty	**pharmaceutical**
Educational program (branch, specialty, level of higher education, form of education)	22 Healthcare, 226 Pharmacy, industrial pharmacy, second (master's) level of higher education, full-time
Academic year	2023-2024 y.
Name of discipline, code *(e-mail address on the website of Danylo Halytsky LNMU)*	OK 26.3 «Quality system in pharmacy» Kaf_organizationpharm@meduniv.lviv.ua
Department *(name, address, phone, e-mail)*	Department of Organization and Economics of Pharmacy, Lviv, Pekarska str., 69 (032) 2768639Kaf_organizationpharm@meduniv.lviv.ua
Head of the department *(contact e-mail)*	Head of the the Department: Doctor of Pharmaceutical Sciences Professor Hromovyk B.P. hromovyk@gmail.com
Year of study *(year in which the study of the discipline)*	5
Semester *(semester in which the study of the discipline is implemented)*	9
Type of course / module *(obligatory / optional)*	obligatory
Teachers *(names, surnames, scientific degrees and titles of teachers who teach the discipline, contact e-mail)*	Dorykevych Kateryna, PhD of Pharmaceutical Sciences, Associate Professor, kpushak@gmail.com
Erasmus yes / no *(availability of the discipline for students within the Erasmus + program)*	
Person responsible for the syllabus *(person to be commented on the syllabus, contact e-mail)*	Hromovyk B.P., Doctor of Pharmaceutical Sciences, Professor hromovyk@gmail.com
Number of ECTS credits	3
Number of hours	Total: 90, incl. lectures - 10 hours, practical classes - 30 hours, Independent student`s work - 50 hours)
Language of teaching	Ukrainian, English
Information about consultations	According to the schedule of the department
Address, telephone and regulations of the clinical base, office ... *(if necessary)*	-
2. Short annotation to the course	

The discipline "Pharmaceutical Quality System" is the final in a set of pharmaceutical management and economic disciplines that form masters of pharmacy. It enables the formation of applicants for higher pharmaceutical education a sufficient amount of theoretical knowledge and practical skills to plan and implement quality management of processes that affect the quality of pharmaceutical products at all stages of its life cycle: from development, research, registration and production to wholesale and retail implementation.

3. The purpose and objectives of the course

The purpose of teaching the discipline "Pharmaceutical Quality System" is to acquire higher pharmaceutical education students the ability to think systemically and integrated practical skills in planning and implementing work to control, ensure and manage the quality of processes affecting the quality of pharmaceutical products at all stages of its life cycle: development, research, registration and production for wholesale and retail sales

The main task is the formation of system knowledge and practical skills in relation to quality management work carried out during the life cycle of the drug, the development of pharmaceutical quality systems and the preparation and conduct of their internal audits (self-inspections).

4. Prerequisites of the course

Interdisciplinary links in the study of the discipline "Pharmaceutical Quality System" are based on general knowledge of such disciplines as "Hygiene in Pharmacy and Ecology", "Information Technology in Pharmacy", "Computer Modeling in Pharmacy", "Pharmaceutical Law and Legislation "," Pharmacognosy "," Organization and economics of pharmacy "," Pharmaceutical and medical commodity science "," Pharmaceutical management and marketing "," Occupational safety and health in the industry "," Drug technology "," Pharmaceutical chemistry "," Standardization medicines ".

5. Program learning outcomes

List of learning outcomes

Learning outcome code *(K – Knowledge, S – skills, C – competence, AD – ??)*	The content of the learning outcome	Reference to the competency matrix code (*PLO – practical learning outcomes, GC – general competence, SC – special competence)*
K-1	Know the methods of implementing knowledge in solving practical problems	GC 2, PLO 2, PLO 4, PLO 7
K-2	Know the current trends in the industry and analyze them	GC 4, PLO 2
K-3	Know the features of the modern professional environment and professional activity	GC 5, PLO 7
K-4	Know the structure and features of professional activity	GC 6, PLO 7
K-5	Know the mechanisms of adaptation and algorithms for action in a new situation	GC 7, PLO 7
K-6	Know modern information and communication technologies	GC 9, PLO 9
K-7	Know the methods of assessing the quality of work performed	GC 11, PLO 11
K-8	Know the regulatory and legal framework of Ukraine, a set of good pharmaceutical practices that regulate the requirements for professional activity	SC 12, PLO 24
K-9	Know the principles of organizing a quality management system of pharmaceutical organizations, quality audit and risk management for the quality of pharmaceutical products	SC 18, PLO 30
K-10	Know the principles of organization and implementation of quality control and standardization of medicines	SC 19, PLO 30, PLO 31,
S-1	Be able to use professional knowledge to solve practical	GC 2, PLO 2, PLO 12

	situations	
S-2	Be able to analyze professional information, make informed decisions, acquire modern knowledge	GC 4, PLO 4, PLO 12
S-3	Be able to show initiative; to constantly search for new opportunities outside the available resources, to engage in self-development and self-realization	GC 5, PLO 7
S-4	Be able to carry out professional activities that require updating and integration of knowledge	GC 6, PLO 7
S-5	Be able to adapt to the new and act according to specific situations	GC 7, PLO 7
S-6	Be able to apply modern information and communication technologies in practice	GC 9, PLO 9
S-7	Be able to ensure the quality of work performed	GC 11, PLO 11, PLO 30
S-8	Be able to apply knowledge of regulations, legislation of Ukraine and recommendations of good pharmaceutical practices in practice	SC 12, PLO 24
S-9	Be able to apply the knowledge of current Standards for quality management of pharmaceutical products	SC 18, PLO 7, PLO 24
S-10	Be able to apply knowledge of the requirements of the current State Pharmacopoeia of Ukraine and good practices in pharmacy	SC 19, PLO 31
C-1	Identify, pose and solve problems, make informed decisions	GC 2, GC 4, GC 11, PLO 2, PLO 7, PLO 10
C-2	Use the qualities of a leader to establish links with various subjects of professional activity	GC 2, GC 4, GC 5, GC 11, PLO 6, PLO 7, PLO 10
C-3	To form a communication strategy in the context of a new professional situation	GC 6, GC 7, PLO 7, PLO 10, PLO 11, PLO 30
C-4	Use information and communication technologies in professional activities	GC 9, PLO 4, PLO 9, PLO 12
C-5	To form conclusions and professionally apply normative-legal, legislative acts of Ukraine and recommendations of good pharmaceutical practices	SC 12, SC 18, SC 19, PLO 7, PLO 24, PLO 31
AB-1	Be responsible for the identified initiatives, timeliness of decisions and quality of work performed	GC 2, GC 5, GC 11, SC 18, SC 19, PLO 2, PLO 6, PLO 11
AB-2	Be responsible for the timely acquisition of modern knowledge and professional development with a high level of autonomy	GC 4, GC 6, PLO 2, PLO 6
AB-3	Be responsible for the chosen mechanism of adaptation and action in the new situation	GC 7, PLO 2, PLO 6, PLO 7, PLO 10, PLO 31
AB-4	Be responsible for the choice of information or communication technologies	GC 9, PLO 2, PLO 4, PLO 6, PLO 9, PLO 12
AB-5	Be responsible for the quality and timely use of regulations in professional activities	SC 12, PLO 2, PLO 6, PLO 24, PLO 30, PLO 31
6. Format and scope of the course		
Course format *(specify full-time or part-time)*	Full-time education	

Kind of occupations	Number of hours	Number of groups
Lectures (L)	**10**	5
Practical classes (PC)	**30**	5
Seminars (S)	**-**	
Independent student`s work (ISW)	**50**	5

7. Topics and content of the course

Occu-pations type code	Topic	Learning content	Learning outcome code	Teacher
L-1	The evolution of the world development of science in quality management and its role in pharmacy	A systematic approach to the problem of product quality management. Models of quality management systems: model A. Feigenbaum, model J. Ettinger and J. Sittig, model D. Juran. Theories of M. Tugan-Baranovsky, A. Maslow and D. Mac-Gregor. The sequence of development of methods and approaches to quality management in the world: quality control and testing; quality control (QC); quality assurance (QA) systems; quality management (QM); total quality management (TQM). Industrial logic of general quality management. Japanese Material Requirements Planning System (MRP). Western moment of re-order planning (ROP). Just-In-Time (JIT) and Just-In-Case (JIC) systems. The concept of quality management system of organizations - subjects of the pharmaceutical market (pharmaceutical quality systems). Integrated quality management system for medical care (KSUYALO). Life cycle of drugs. Implementation of the principles of quality assurance at the stages of the life cycle of medicines.	K-1, K-2, K-3, K-4, C-1, Ав-2	Hromovyk B.P., Yarko N.B.
PC-1			K-1, K-2, K-3, K-4, S-1, S-3, S-4, C-1, AB-2	
ISW-1			K-1, K-2, K-3, K-4, C-2, AB-2 S-1, S-3, S-4, C-1, AB-2	
PC-2	Regulatory framework for quality management of medicines in the world and in Ukraine	Quality system in international standards ISO 9000 series and industry guidelines ICH Q10 "Pharmaceutical quality system". Stages of building a pharmaceutical quality system.	K-5, K-6, K-8 S-2, S-4, S-5, S-6, S-8, S-9, S-10, C-4, C-5,	Hromovyk B.P., Yarko N.B.

		The concept of good pharmaceutical practices (GxP) and their role in quality assurance at all stages of the life cycle of medicines. Integrated management systems of organizations - subjects of the pharmaceutical market. Standards ISO 14001, ISO 22000 HACCP, ISO 134	AB-5	
ISW-2			K-5, K-6, K-8 S-2, S-4, S-5, S-6, S-8, S-9, S-10, C-4, C-5, AB-5	
L-2	State system for quality assurance of medicines. Certification and licensing of the pharmaceutical market of Ukraine	The structure of the state system for regulating the circulation of medicines. Registration of medicines as a mechanism for admission of drugs to use. Procedure for state registration (re-registration) of medicines in Ukraine. Differences in the procedure for registration of drugs in Ukraine and the EU. Regulatory framework for pharmacovigilance. The structure of pharmacovigilance in Ukraine. Certification and licensing as components of the licensing system for business activities in pharmacy. The role of the State Pharmacopoeia of Ukraine in the system of standardization and quality control of medicines	K-4, K-6, K-8, K-9, K-10, C-4, C-5, AB-4, AB-5	Hromovyk B.P., Yarko N.B.
PC-3			K-4, K-6, K-8, K-9, K-10 S-1, S-2, S-6, S-8, S-9, S-10, C-4, C-5, AB-4, AB-5	
ISW-3			K-4, K-6, K-8, K-9, K-10, S-1, S-2, S-6, S-8, S-9, S-10, C-4, C-5, AB-4, AB-5	
PC-4	Statistical methods of quality control	The essence of statistical methods of quality control. The procedure for collecting information. Statistical series and its characteristics. Seven quality control tools: checklist, histogram, scattering diagram, stratification method, Pareto diagram, causal diagram of Ishikawa, Schuhart control chart). Principles of their construction and application	K-1, K-5, 3-6, K-7 S-1, S-2, S-3, C-3, C-4, C-5, AB-2, AB-4	Hromovyk B.P., Yarko N.B.
ISW-4			K-1, K-5, K-6, K-7 S-1, S-2, S-3, C-3, C-4, C-5, AB-2, AB-4	
PC-5	Regulation and documentation of pharmaceutical quality system processes	Development of Guidelines for quality, documented procedures for the implementation of pharmaceutical quality system processes and standard operating procedures (SOP). The role of records (protocols) of the pharmaceutical quality system in data registration. Checking the compliance of the document	K-7, K-8, K-9, K-10 S-1, S-3, S-6, S-8, S-9, S-10, C-1, C-2, C-4, C-5, AB1-AB-5	Hromovyk B.P., Yarko N.B.
ISW-5			K-7, K-8, K-9, K-10	

		management system of the pharmaceutical quality system	S-1, S-3, S-6, S-8, S-9, S-10, C-1, C-2, C-4, C-5, AB1-AB-5	
L-3	Risk assessment for the quality of the drug at the stages of its life cycle	Risk classification. Risk identification. Goals and objectives of risk management. Basic principles of risk management for quality. Stages of the risk management process. Characteristics of the main methods and tools of risk analysis for the quality of pharmaceutical products	K-1, K-4, K-5, K-7, K-8, K-9, K-10, C-1, C-2, C-3, C-4, AB-2	Hromovyk B.P., Yarko N.B.
PC-6			K-1, K-4, K-5, K-7, K-8, K-9, K-10,S-1, S-2, S-3, S-4, S-5, S-7, S-9, C-2, C-3, C-4, AB-1-AB-5	
ISW-6			K-1, K-4, K-5, K-7, K-8, K-9, K-10, C-1, S-2, S-3, S-4, S-5, S-7, S-9, C-2, C-3, C-4, AB-1-AB-5	
L-4	Organization of activity on validation of production processes and qualification of equipment and auxiliary systems in the organizations - subjects of the pharmaceutical market	Basics of qualification and validation. Types of validation and qualification. Validation of analytical methods. Validation of cleaning. Validation of computerized systems	K-1, K-2, K-3, K-7, K-9, K-10, C-1, C-2, C-3, C-4, AB-2	Hromovyk B.P., Yarko N.B.
PC-7			K-1, K-2, K-3, K-7, K-9, K-10, S-1, S-2, S-3, S-4, S-5, S-6, S-7, S-9, C-1-C-5, AB-1-AB-5	
ISW-7			K-1, K-2, K-3, K-7, K-9, K-10, S-1, S-2, S-3, S-4, S-5, S-6, S-7, S-9, C-1-C-5, AB-1-AB-5	
L-5	Internal audits (self-	Basic components of modern	K-1, K-2,	Hromovyk

	inspections) of pharmaceutical quality systems	models of quality management systems. The importance of audits in modern management systems. Classification of quality audits. Specifics of internal audits of quality management systems. Approaches to audit process management and program. Organization, documentary support, application of audit methods. Psychological and ethical aspects of audit. Corrective and preventive actions (SARA)	K-5, K-7, K-9, K-10, C-1, C-2, C-3, C-4, AB-2	B.P., Yarko N.B.
PC-8			K-1, K-2, K-5, K-7, K-9, K-10, S-1, S-2, S-3, S-4, S-5, S-6, S-7, S-9, C-1-C-5 AB-1-AB-5	
ISW-8			K-1, K-2, K-5, K-7, K-9, K-10, S-1, S-2, S-3, S-4, S-5, S-6, S-7, S-9, C-1-C-5, AB-1-AB-5	

8. Верифікація результатів навчання

Поточний контроль

Learning outcome code	Code type of classes	Method of verifying learning outcomes	Enrollment criteria
K-1	L-1, L-3, L-4, L-5, PC-1, PC-6, PC-7, PC-8, ISW-1, ISW-4, ISW-6, ISW-7, ISW-8	Observation of educational and cognitive activities of students in the classroom, oral examination, written control of knowledge through written testing using a set of standardized tasks to establish the input and output level of knowledge, structured control of practical skills; control of practical work.	Assessment of current learning activities is standardized and includes control of theoretical and practical training on a traditional 4-point scale. Grades on a traditional scale are converted into points.
K-2	L-1, L-4, L-5, PC-1, PC-7, PC-8, ISW-1, ISW-7, ISW-8		
K-3	L-1, L-4, PC-1, PC-7, ISW-1, ISW-7		
K-4	L-1, L-2, L-3, PC-1, PC-3, PC-6, ISW-1, ISW-3, ISW-6		
K-5	L-3, L-5, PC-2, PC-4, PC-6, PC-8, ISW-2, ISW-4, ISW-6, ISW-8		
K-6	L-2, PC-2, PC-3, PC-7, ISW-2, ISW-3, ISW-7		
K-7	L-3, L-4, L-7, PC-4, PC-5, PC-6, PC-7, PC-8, ISW-4, ISW-6, ISW-7, ISW-8		
K-8	L-3, PC-2, PC-3, PC-5, PC-6, ISW-2, ISW-3, ISW-5, ISW-6		
K-9	L-2, L-3, L-4, L-5, PC-3, PC-5, PC-6, PC-7, PC-8, ISW-3, ISW-5, ISW-6, ISW-7, ISW-8		
K-10	L-2, L-3, L-4, L-5, PC-3, PC-5, PC-6, PC-7, PC-8, ISW-3, ISW-5, ISW-6, ISW-7, ISW-8		
S-1	PC-1, PC-3, PC-4, PC-5, PC-6, PC-7, PC-8 ISW-1, ISW-3, ISW-4, ISW-5, ISW-6, ISW-7, ISW-8	Observation of educational and cognitive activities of students in the classroom, oral	Assessment of current learning activities is standardized and includes control of
S-2	PC-2, PC-3, PC-4, PC-7, PC-8		

	ISW-2, CPCP-3, ISW-4, ISW-7, ISW-8	examination, written control of knowledge through written testing using a set of standardized tasks to establish the input and output level of knowledge, structured control of practical skills; control of practical work.	theoretical and practical training on a traditional 4-point scale. Grades on a traditional scale are converted into points.
S-3	PC-1, PC-4, PC-5, PC-6, PC-7, PC-8 ISW-1, ISW-4, ISW-5, ISW-6, ISW-7, ISW-8		
S-4	PC-1, PC-4, PC-6, PC-7, PC-8 ISW-1, ISW-4, ISW-6, ISW-7, ISW-8		
S-5	PC-2, PC-6, PC-7, PC-8 ISW-2, ISW-6, ISW-7, ISW-8		
S-6	PC-2, PC-3, PC-5, PC-7, PC-8 ISW-2, ISW-3, ISW-5, ISW-7, ISW-8		
S-7	PC-6, PC-7, PC-8 ISW-6, ISW-7, ISW-8		
S-8	PC-2, PC-3, PC-5 ISW-2, ISW-3, ISW-5		
S-9	PC-2, PC-3, PC-5, PC-6, PC-7, PC-8 ISW-2, ISW-3, ISW-5, ISW-6, ISW-7, ISW-8		
S-10	PC-2, PC-3, PC-5, ISW-2, ISW-3, ISW-5		
C-1	L-1, L-3, L-4, L-5, PC-1, PC-5, PC-7, PC-8 ISW-1, ISW-5, ISW-7, ISW-8	Observation of educational and cognitive activities of students in the classroom, oral examination, written control of knowledge through written testing using a set of standardized tasks to establish the input and output level of knowledge, structured control of practical skills; control of practical work.	Assessment of current learning activities is standardized and includes control of theoretical and practical training on a traditional 4-point scale. Grades on a traditional scale are converted into points.
C-2	L-3, L-4, L-5, PC-5, PC-6, PC-7, PC-8, ISW-5, ISW-6, ISW-7, ISW-8		
C-3	L-3, L-5, PC-4, PC-6, PC-7, PC-8 ISW-4, ISW-6, ISW-7, ISW-8		
C-4	L-2, L-3, L-4, L-5, PC-2, PC-4, PC-6, PC-7, PC-8 ISW-2, ISW-4, ISW-6, ISW-7, ISW-8		
C-5	L-2, L-3, L-4, L-5, PC-2, PC-4, PC-6, PC-7, PC-8 ISW-2, ISW-4, ISW-6, ISW-7, ISW-8		
AB-1	PC-5, PC-6, PC-7, PC-8, ISW-5, ISW-6, ISW-7, ISW-8	Observation of educational and cognitive activities of students in the classroom, oral examination, written control of knowledge through written testing using a set of standardized tasks to establish the input and output level of knowledge, structured control of practical skills; control of practical work.	Assessment of current learning activities is standardized and includes control of theoretical and practical training on a traditional 4-point scale. Grades on a traditional scale are converted into points.
AB-2	L-1, L-4, L-5, PC-1, PC-4, PC-5, PC-6, PC-7, PC-8, ISW-1, ISW-4, ISW-5, ISW-6, ISW-7, ISW-8		
AB-3	PC-5, PC-6, PC-7, PC-8, ISW-5, ISW-6, ISW-7, ISW-8		
AB-4	L-2, PC-3, PC-4, PC-5, PC-6, PC-7, ISW-3, ISW-4, ISW-5, ISW-6, ISW-7, ISW-8		
AB-5	L-2, PC-2, PC-3, PC-5, PC-6, PC-7, ISW-2, ISW-3, ISW-5, ISW-6, ISW-7, ISW-8		
Final control			
General evaluation system	Participation in the work during the semester on a 200-point scale		
Rating scales	traditional 4-point scale, multi-point (200-point) scale, ECTS rating scale		

Conditions of admission to the final control	Students who have attended all classes provided by the curriculum, performed all types of work provided by the program and received grades sufficient to convert to a minimum number of points (not less than 120 points for current performance) are allowed to the final control.	
Test	It consists in assessing the student's mastery of educational material solely on the basis of the results of his performance of certain types of work in practical classes and during independent work. The semester test is held at the last lesson of the discipline. The test in the discipline is set according to the results of the current control and is expressed on a two-point scale: "credited" or "not credited".	*The maximum number of points is 200.* *The minimum number of points is 120*

9. Course policy

Every higher education applicant should get acquainted and follow:
- Code of Academic Ethics of Danylo Halytskyi Lviv National Medical University (http://nauka.meduniv.lviv.ua/wp-content/uploads/2020/04/kodeks-akademichnoyi-etiki.pdf) and Guidelines to support the principles of academic integrity (https://new.meduniv.lviv.ua/uploads/repository/else/quality_dept/07.Академічна_доброчесність/01.Методичні_рекомендації.pdf);
- Statute (https://new.meduniv.lviv.ua/uploads/repository/dept/law_dept/01.Статут/statut_2018.pdf) and the Rules of internal labor regulations (https://new.meduniv.lviv.ua/uploads/repository/dept/human_resources_dept/02.Правила%20внутрішнього%20трудового%20розпорядку/01.Правила%20внутрішнього%20трудового%20розпорядку.pdf) of the University;
- Strategies and procedures for ensuring the quality of education (https://new.meduniv.lviv.ua/uploads/repository/else/quality_dept/01.Стратегія%2C%20політика_та%20_процедури_забезпечення_якості_освіти/01.Стратегія_та_процедури_забезпечення_якості_освіти.pdf), Regulations on the organization of the educational process (https://new.meduniv.lviv.ua/uploads/repository/dept/nv_dept/09.Документи_з_організації_освітнього_процесу/01.Положення_про_огранізацію_освітнього_процесу_ЛНМУ.pdf) and on the criteria, rules and procedure for evaluating the results of educational activities (https://new.meduniv.lviv.ua/uploads/repository/dept/nv_dept/09.Документи_з_організації_освітнього_процесу/02.Критерії_і_правила_оцінювання.pdf).

To successfully master the course, the applicant must:
- to take an active part in the educational process, in particular to properly study the educational material on each topic;
- not to miss lectures and practical classes without a good reason, and in case of illness to provide information;
- not to be late for lectures and practical classes;
- timely work off missed classes;
- prepare for practical classes and maintain feedback during them;
- timely and accurately perform tasks for VTS;
- turn off your mobile phone during lectures and practical classes;
- take part in control measures (current control, VTS control, final control), during which hints and write-offs are not allowed.

Any copying or reproduction of the results of someone else's work, unless the work has a group format, the use of materials downloaded from the Internet qualifies as a violation of the rules and regulations of academic integrity and involves bringing the perpetrator to justice under applicable regulations.

Failure to comply with and / or non-compliance with the course policy may result in a grade of "unsatisfactory".

10. Literature

Required

1. Lecture material.
2. State Pharmacopoeia of Ukraine: in 3 volumes / SE "Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines". - 2nd type. - Kharkiv: SE "Ukrainian Scientific Pharmacopoeial Center for Drug Quality", 2015.
3. Medicines. Process validation: ST-N MOZU 42-3.5: 2016 - [Effective from 2016-07-29]. - K.: MHU, 2016. - 28 c. - (Instruction). - [E-resource]. - Access mode: http://old.moz.gov.ua/docfiles/dn_20160729_0802dod.pdf.
4. Medicines. Preclinical safety studies as a basis for human clinical trials and drug registration (ICH M3 (R2)): CT-H 42-6.0: 2014 - [Effective from 2014-09-19]. - K.: MHU, 2014. - 56 c. - (Instruction). - [E-resource]. - Access mode: https://dec.gov.ua//wp-content/uploads/attitude/n1.pdf
5. Medicines. Bioequivalence study: ST-N MOZU 42-7.2: 2018 - [Valid from 2018-11-02]. - K.: МОЗ України, 2014. - 62 c. - (Instruction). - [E-resource]. - Access mode: https://dec.gov.ua//wp-content/uploads/attitude/1.pdf
6. Medicines. Good manufacturing practice: ST-N MOZU 42-4.0: 2016 - [Effective from 2016-07-01]. - K.: MHU, 2016. - 332 c. - (Instruction). - [E-resource]. - Access mode: http://aipm.org.ua/wp-content/uploads/2016/08/GMP_42-4.0_2016.pdf
7. Medicines. Good distribution practice: ST-N MOZU 42-5.0: 2014 - [Effective from 2014-08-22]. - K.: МОЗ України, 2014. - 44 c. - (Instruction). - [E-resource]. - Access mode: http://bsc-gmp.com/uploads/files/news/60/gdp-anastanovaa-2014.pdf
8. Medicines. Good practice of promotion: ST-N MOH 42-1.2: 2013 - [Effective from 2013-10-09]. - Kyiv: Ministry of Health of Ukraine, 2013. - 20 p. - (Instruction). - [E-resource]. - Access mode: https://zakon.rada.gov.ua/rada/show/v0870282-13/ed20131118
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10. Medicines. Good pharmacovigilance practices: ST-N MOZU 42-8.5: 2015 - [Effective from 2015-05-21]. - Kyiv: Ministry of Health of Ukraine, 2015. - 120 p. - (Instruction). - [E-resource]. - Access mode: https://dec.gov.ua/materials/nastanovi/
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11. Equipment, logistics and software of the discipline / course

Working curriculum for the discipline.
Multimedia support of lectures.
Abstracts of lectures on the discipline.
Methodical recommendations for practical classes of higher education students.
Methodical materials that provide independent work for graduates.
Test and control tasks for practical classes.
Questions and tasks for the final control.
Methodical recommendations for the teacher.
MISA training platform.
The online system of continuing pharmaceutical education AdFarm S.A.
Computer class for 16 workstations connected to the local network of the university with direct access to the Internet.

12. Additional information

Responsible for the educational process at the department - Associate Professor I.Ya. Horodetska. There is a student scientific circle at the department. Practical classes are held at: st. Pekarska, 75, building of the Training and Production Pharmacy.
*Department website::*https://new.meduniv.lviv.ua/kafedry/kafedra-organizatsiyi-i-ekonomiky-farmatsiyi/

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Yarko N.B.., PhD of Pharmacy Sciences, Associate Professor _____

Head of the department:

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