THE SYLLABUS OF THE EDUCATIONAL COMPONENT
GOOD PHARMACEUTICAL PRACTICES

for higher education applicants 5 year full-time forms of education
educational programme "Pharmacy"
speciality "226 Pharmacy, industrial pharmacy"
area of knowledge "22 Healthcare"
Master level of higher education

TEACHERS

			Information about the teacher
Olena LITVINOVA	**professor of department of management, marketing and quality assurance in pharmacy, Doctor of Pharmacy, professor**	**litvinova@nuph.edu.ua**	**https://mmqaph.nuph.edu.ua/litvinova-olena-vyacheslavna/ /**

1. Name of the higher education institution and structural unit: National University of Pharmacy, Department of management, marketing and quality assurance in pharmacy.
2. Department address: Valentynivska st., 4, Kharkiv, Ukraine, 61168.
3. Department website: https://mmqaph.nuph.edu.ua/
4. Consultations: take place according to the online schedule *(*https://mmqaph.nuph.edu.ua/grafiki-potochnih-konsultacij/*)*.
5. Abstract of the educational component: the discipline is elective in the master's program in 226 Pharmacy, industrial pharmacy. The subject of educational component is the study of general principles of good practice in pharmacy, the requirements of which are used to ensure the quality of drugs during the stages of their life cycle, from development to implementation (good laboratory practice GLP, good clinical practice GCP, good manufacturing practice GMP), good distribution practice (GDP), good pharmaceutical practice (GPP), etc.).
6. Purpose of teaching the educational component: is to prepare applicants for higher education in specialty "Pharmacy, industrial pharmacy" for the pharmaceutical sector of health care, who have sufficient theoretical knowledge and practical skills to plan and implement work to control, ensure and manage the quality of processes affecting quality of pharmaceutical products at all stages of its life cycle: from development, research, registration and production to wholesale and retail sales.
7. Competencies in accordance with the educational programme:
Soft- skills / General competencies (GC):
GC 2. Ability to apply knowledge in practical situations and make informed decisions.
GC 6. Knowledge and understanding of the subject area and understanding of professional activity.
Hard-skills / Professional (speciality) competencies (PC):
PC 7. Ability to ensure proper storage of medicines and other products of the pharmacy assortment in accordance with their physical and chemical properties and the rules of Good Storage Practice (GSP) in health care facilities.
PC 12. Ability to use knowledge of the regulatory and legislative acts of Ukraine and recommendations for good pharmaceutical practices in professional activity.
PC 18. Ability to develop and implement the quality management system of pharmaceutical enterprises in accordance with the requirements of current standards and to perform quality audits and risk management for the quality of pharmaceutical products.
8. Programme learning outcomes (PLO):

PLO 24. Plan and implement professional activities on the basis of normative legal acts of Ukraine and recommendations of good pharmaceutical practices

PLO 30. Ensure quality control of medicinal products and document its results. To carry out quality risk management at all stages of the life cycle of medicinal products

9. The status of the educational component: elective.

10. Prerequisites of the educational component: "Industrial Technology of Drugs", "Organization and Economics of Pharmacy", "Pharmaceutical Marketing and Management", "Pharmaceutical Law and Legislation", "Medical and Pharmaceutical Commodity Research" and a number of others.

11. The scope of the educational component: 3 ECTS credits.

Full time study: 35 hours of classroom classes, including 7 hours of lectures, 28 hours of practical classes, 55 hours of independent work.

12. Organisation of the teaching process:

Teaching methods:

The following methods are used:

- *explanatory (information and reproductive) method:* lecture-based learning – lectures, video materials;
- *reproductive method:* traditional practical classes;
- *problem-based learning:* brainstorming;
- *partially-search method:* project-based learning;
- *research method:* research-based learning – participation in research work, preparation of abstracts of reports at the conference, scientific articles.

The content of the educational component:

Content module 1. *The quality assurance system of medicines – the structure, functions of regulatory agencies, regulatory framework. The concept of quality management system of enterprises – subjects of the pharmaceutical market (pharmaceutical quality systems)*

Topic 1. Introduction to the course "Good pharmaceutical practices". Chronology of world development of science on quality assurance and management. The concept of good pharmaceutical practices (GXP) and their role in quality assurance at all stages of the life cycle of medicines. Regulatory framework for ensuring and quality control of medicines in the European Union.

Topic 2. Activities of regulatory organizations in the field of medicines circulation: their functions and sphere of work. Analysis of the main elements of the state quality assurance system of medicines. The role of the International Pharmacopoeia. Certification and licensing of pharmaceutical market players.

Topic 3. The concept of quality management system of enterprises - subjects of the pharmaceutical market (pharmaceutical quality systems). Review of the requirements of ISO 9001 standard, universal and industry guidance ICH Q10 Pharmaceutical Quality System. Stages of construction of PQS.

Topic 4. The concept of integrated management systems of enterprises – subjects of the pharmaceutical market. Overview of the requirements of ISO 14001, ISO standards 22000 HACCP, ISO 13485.

Content module 2. *Applied aspects of formation, implementation, analysis and development of pharmaceutical quality systems*

Topic 5. Regulation and documentation processes PQS. Development of quality manual, documented implementation PQS processes and standard operating procedure.

Topic 6. Analysis and risk assessment for quality in pharmaceutical development, production and distribution of medicines. Methods for the determination analysis and risk assessment for drug quality.

Topic 7. The activities of the validation of manufacturing processes and qualification of equipment and auxiliary systems in enterprises, the subject of the pharmaceutical market.

Topic 8. Internal audits (self-inspections) of pharmaceutical quality systems: organization, documentary support, audit techniques, psychological and ethical aspects. Corrective and preventive actions (CAPA).

Organisation of individual work:

Individual work involves studying 2 and 4 topics of the educational component that are not included in classroom learning, and performing tasks on these topics in order to consolidate the theoretical material.

13. Types and forms of control:

Types and forms of control:

Current control:

Knowledge control in each lesson (on each topic): oral questioning, passing test tasks, solving situational tasks.

Control of content modules: passing test tasks, solving situational tasks.

Conditions for admission to the control of content modules: for admission to the control of content module 2, you must have a minimum number of points for the topics (classes) of content module 1, for the control of content module 1.

Semester control:

The form of semester control: semester credit test.

Conditions for admission to the semester control:

The current rating is more than 60 points, the academic detention of missed practical classes, the fulfilment of all types of work and requirements provided for in the working programme of the educational component.

14. The assessment system for the educational component:

Assessment of the acquisition of topics of the educational component during classes:

The number of the topic (lesson) of the educational component	***The maximum number of points by topic (lesson)***	***Distribution of the maximum number of points per topic (lesson) by type of work***	***Types of work for which the applicant receives points***
Content module 1			
Topic 1.	10	2	*oral answer*
		2	*solving situational problems*
		2	*solving situational problems*
		2	*solving situational problems*
		2	*testing*
Topic 2.	8	2	*oral answer*
		2	*solving situational problems*
		2	*solving situational problems*
		2	*testing*
Topic 3.	6	2	*oral answer*
		2	*solving situational problems*
		2	*testing*
Topic 4.	6	2	*solving problems for individual work*
		2	*solving problems for individual work*
		2	*solving problems for individual work*
Total points for content module 1:		32	
Content module 2			
Topic 5.	7	2	*solving problems for individual work*
		2	*solving problems for individual work*

		3	*solving problems for individual work*
Topic 6.	7	2	*oral answer*
		5	*solving situational problems*
Topic 7.	7	2	*oral answer*
		5	*solving situational problems*
Topic 8.	7	2	*oral answer*
		5	*solving situational problems*
Total points for content module 2:		28	
Total points per module:		60	

The study of the educational component by higher education applicants is possible through non-formal education. Instead of performing types of work on the topic of the educational component, the following types of work of a higher education applicant can be credited:

– taking training courses or distance courses on the use of modern educational technologies on Coursera, Prometheus and other platforms (if there is a corresponding document on their completion, providing a copy to the teacher);

– participation in master classes, forums, conferences, seminars, webinars on the topic of the educational component (with the preparation of essays, abstracts, informational messages, etc.; it is confirmed by the program of the event, or abstracts of reports, or the corresponding certificate);

– participation in research and applied research on the topic of the educational component (in the development of questionnaire forms, conducting experimental research, processing research results, preparing a report, presenting results, etc.; it is confirmed by the demonstration of relevant materials).

The assessment of applicants by type of work during classes:

Types of work for which the applicant receives points	***The maximum number of points***
testing	*10*
oral answer	*15*
solving situational problems	*20*
individual work	*15*
Total points:	*60*

The assessment during the content module control:

Types of work for which the applicant receives points	***Distribution of the maximum number of points for the content module control by type of work***	***The maximum number of points for the content module control***
Content module 1		
testing	10	*20*
answers to theoretical questions	10	
Content module 2		
testing	10	*20*
answers to theoretical questions	10	
Total points for control of the content modules:		*40*

Assessment of individual work of a higher education applicant:

during the current control: 6 points: – solving problems for individual work, testing (Topic 4), 7 points – solving problems for individual work (Topic 5).

during the control of content module 1: cards for content module 1 include theoretical questions and test tasks on the topic 4.
during the control of content module 2: cards for content module 2 include calculation tasks on the topic 5.

The assessment scale of semester credit test:

When studying the educational component, several assessment scales are used: 100-point scale, and undifferentiated assessment (pass/fail), two-point scale (for semester credit test) and ECTS rating scale. Results are converted from one scale to another according to the table.

15. Educational component policies:

Academic Integrity Policy. It is based on the principles of academic integrity given in the Regulation "On measures to prevent cases of academic plagiarism in the NUPh". Cheating when assessing the success of a higher education applicant during control activities in practical (seminar, laboratory) classes, monitoring of content modules and semester examinations is prohibited (including using mobile devices). Abstracts must have correct text links to the literature used. Identification of signs of academic dishonesty in the written work of a higher education applicant is the basis for its disregard by the teacher.
Class attendance policy. A higher education applicant is required to attend academic studies (Regulation "On the organisation of the educational process of the NUPh") according to the class schedule (https://nuph.edu.ua/rozklad-zanyat/), adhere to ethical standards of behaviour.
Policy on deadlines, academic detention, improving the rating, and eliminating academic debt. Academic detention of missed classes by a higher education applicant is carried out in accordance with the "Regulations on academic detention of missed classes by applicants and the procedure for eliminating the academic difference in the curriculum in the NUPh" in accordance with the schedule for academic detention of missed classes set at the Department. Improving the rating and eliminating academic debt on the educational component is carried out by higher education applicants according to the procedure given in the Regulation "On the procedure for assessing the learning outcomes of higher education applicants in the NUPh". Higher education applicants are required to comply with all deadlines set by the Department for performing types of written works on the educational component. Works that are submitted in violation of deadlines without valid reasons are rated at a lower rating – up to 20% of the maximum number of points for this type of work.
Policy on challenging the assessment on the educational component (appeals). Higher education applicants have the right to appeal the assessment on the educational component obtained during control activities. The appeal is carried out in accordance with the "Regulations on appealing the results of semester control of knowledge of higher education applicants in the NUPh".
Policy on the recognition of learning outcomes obtained through non-formal and/or informal education by higher education applicants. Higher education applicants have the right to recognise the results of training acquired in non-formal and informal education in accordance with the Regulation "On the procedure for recognising learning outcomes obtained through non-formal and/or informal education by applicants for higher education in the NUPh".
Within the framework of academic freedom of the teacher, instead of performing types of work on the topic of the educational component, it is possible to credit a non-formal education of a higher education applicant.

16. Information and methodological support of the educational component:

Required reading	1. Good Pharmaceutical Practices: method. recommend. for practical studies for foreign students of the specialty Pharmacy / O. V. Tkachenko, E.V. Litvinova, S. M. Kovalenko - Kharkiv: NUPh, 2021. - 48 p. 2. Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances URL: http://data.europa.eu/eli/dir/2004/10/oj 3. Guideline on good pharmacovigilance practices: Module I – Pharmacovigilance systems and their quality systems

	https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-i-pharmacovigilance-systems-and-their-quality-systems_en.pdf 4. EMA/CHMP/CVMP/QWP/749073/2016 Guideline on process validation for finished products — information and data to be provided in regulatory submissions. URL : https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-process-validation-finished-products-information-data-be-provided-regulatory-submissions_en.pdf 5. EMA/CHMP/ICH/135/1995 Committee for Human Medicinal Products *ICH: E 6 (R2):* Guideline for good clinical practice - Step 5. December 2016. URL: https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-6-r2-guideline-good-clinical-practice-step-5_en.pdf 6. EMA/CHMP/ICH/167068/2004 - ICH. - Committee for Human Medicinal Products ICH guideline Q8 (R2) on pharmaceutical development. Step 5, June 2017 URL: https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use_en-11.pdf 7. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guideline Q9 (R1) on quality risk management - Step 5 - Revision 1. URL : https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use-ich-guideline-q9-r1-quality-risk-management-step-5-revision-1_en.pdf 8. ICH guideline Q10 on pharmaceutical quality system Step 5 URL : https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-guideline-q10-pharmaceutical-quality-system-step-5_en.pdf 9. EudraLex. – The Rules Governing Medicinal Products in the European Union. – Volume 4. EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use. URL: https://ec.europa.eu/health/documents/eudralex/vol-4_en 10. EudraLex. – The Rules Governing Medicinal Products in the European Union. – Volume 4. – Other documents related to GMP. – Guidelines of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01) (OJ C 95, 21.3.2015, p. 1 URL: http://academy.gmp-compliance.org/guidemgr/files/GDP%20for%20APIs.pdf 11. International Pharmacopoeia. 2022. URL : https://apps.who.int/phint/en/p/docf/. 12. ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes. URL : https://www.iso.org/standard/59752.html 13. ISO 14001:2015 Environmental management systems — Requirements with guidance for use. URL : https://www.iso.org/standard/60857.html 14. ISO 19011:2018 Guidelines for auditing management systems. URL : https://www.iso.org/obp/ui/#iso:std:70017:en 15. ISO 22000:2018 Food safety management systems — Requirements for any organization in the food chain. URL : https://www.iso.org/obp/ui/#iso:std:iso:22000:ed-2:v1:en 16. ISO 9001:2015 Quality management systems — Requirements. URL : https://www.iso.org/standard/62085.html 17. ICH guideline M4 (R4) on common technical document (CTD) for the registration of pharmaceuticals for human use - organisation of CTD https://www.ema.europa.eu/system/files/documents/scientific-guideline/m4_step_5_ctd_for_the_registration_of_pharmaceuticals_for_human_use_-_organisation_of_ctd-en.pdf
Additional literature for	1. Chen, Hsinjung, Shinlun Liu, Yijyuan Chen, Chinshuh Chen, Huiting Yang, and Yuhshuen Chen. Food Safety Management Systems Based on ISO 22000:2018

in-depth study of the educational component	Methodology of Hazard Analysis Compared to ISO 22000:2005. *Accreditation and Quality Assurance*. 2020. V. 25. N 1. P. 23–37. https://doi.org/10.1007/s00769-019-01409-4. 2. CPMP/QWP/EWP/1401/98 Rev.1/Corr** "Guideline on the Investigation of Bioequivalence" URL: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-investigation-bioequivalence-rev1_en.pdf 3. EMA/CHMP/ICH/493213/2018 «ICH M9 guideline on biopharmaceutics classification system-based biowaivers» https://www.ema.europa.eu/en/documents/scientific-guideline/ich-m9-biopharmaceutics-classification-system-based-biowaivers-step-5_en.pdf 4. Ferrón-Vílchez, Vera. Does Symbolism Benefit Environmental and Business Performance in the Adoption of ISO 14001? *Journal of Environmental Management*. 2016. V. 183, N. Pt 3. P. 882–94. https://doi.org/10.1016/j.jenvman.2016.09.047. 5. Good Manufacturing Practice for Manufacturers of Food Supplements. URL : https://foodsupplementseurope.org/wp-content/themes/fse-theme/documents/publications-and-guidelines/good-manufacturing-practice-for-manufacturers-of-food-supplements.pdf 6. Ikram, Muhammad, Amin Mahmoudi, Syed Zulfiqar Ali Shah, and Muhammad Mohsin. Forecasting Number of ISO 14001 Certifications of Selected Countries: Application of Even GM (1,1), DGM, and NDGM Models. *Environmental Science and Pollution Research International*. 2017. V. 26, N. 12. P. 12505–21. https://doi.org/10.1007/s11356-019-04534-2. 7. Linders, Peter W.J. *Setting Standards* : ISO 13485: Challenges in Achieving High-Level Structure Compliance. *Biomedical Instrumentation & Technology*. 2020. V. 54. N 1. P. 68–70. https://doi.org/10.2345/0899-8205-54.1.68. 8. Neves, Fábio de Oliveira, Eduardo G. Salgado, and Luiz A. Beijo. Analysis of the Environmental Management System Based on ISO 14001 on the American Continent. *Journal of Environmental Management*. 2017. V. 199. P.251–62. https://doi.org/10.1016/j.jenvman.2017.05.049. *9.* Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System Guidance for Industry// U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER). - August 2017.
Up-to-date electronic information resources (journals, websites, etc.) for in-depth study of the educational component	1. World Health Organization – WHO. URL : https://www.who.int/home 2. The International Council for Harmonisation – ICH. URL : https://www.ich.org/ 3. Pharmaceutical Inspection Co-operation Scheme - PIC/S. URL : https://picscheme.org/ 4. The European Directorate for the Quality of Medicines & HealthCare – EDQM. URL : https://www.edqm.eu/ 5. European Medicines Agency – EMA. URL : https://www.ema.europa.eu/en 6. EudraGMDP. URL : http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do 7. Food and Drug Administration – FDA. URL : https://www.fda.gov/ *8.* United Kingdom's Medicines and Healthcare Products Regulatory Agency – MHRA. URL : https://www.gov.uk
Moodle distance learning system	*https://pharmel.kharkiv.edu/moodle/course/view.php?id=4307*

17. Material and technical support and software of the educational component:

Technical equipment**:** computer, video camera, multimedia projector, screen.

Software: Microsoft Word, Excel, Power Point, Acrobat rider, Google Workspace for Education Standard, ZOOM, MOODLE.