SYLLABUS OF THE EDUCATIONAL COMPONENT
GOOD PHARMACEUTICAL PRACTICES
(the name of the educational component)
for applicants for higher education of 5 year of study, full time
of education (2023-2024 year of study)
of educational program «Pharmacy»
(Educational Program Name)
in specialty «226 Pharmacy, industrial pharmacy»
(Code and Specialty Name)
field of knowledge «22 Healthcare»
(Code and Knowledge Field Name)
training for Master
(Higher Educational Level Name)

TEACHERS

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1. The name of higher education establishment and department: the National University of Pharmacy, Department of Management and Quality Assurance in Pharmacy.
2. Address of the department: Kharkiv, O. Nevskogo str., 18.
3. Web site of the department: https://quality.nuph.edu.ua/
4. Information about teachers:
Tkachenko Olena Valentinivna
Candidate of Pharmaceutical Sciences, associate professor, associate professor of department of management, economy and quality assurance in pharmacy of the National University of Pharmacy. Academic experience – 3 years, scientific-pedagogical experience – 12 years. She gives lectures, conducts practical classes in the disciplines "Good Pharmaceutical Practices". Research interests: creation of organizational and methodological bases for training quality management specialists for the pharmaceutical sphere of healthcare; development and scientific substantiation of methodological approaches to the formation, implementation and continuous improvement of pharmaceutical quality systems in accordance with the requirements of ISO 9000 series standards and GxP guidelines for pharmaceutical companies and cosmetic companies, etc.
Litvinova Olena Vyacheslavna
Doctor of Pharmacy, PhD in Biology, senior research assistant, professor, professor of department of management, economy and quality assurance in pharmacy of the National University of Pharmacy. Academic experience – more than 20 years, scientific-pedagogical experience – 15 years. She gives lectures: "Strategic management of the organization" (masters); "Intellectual business" (masters); "Methodology and logic of scientific research" (masters); "Good pharmaceutical practices" (masters). Research interests: intellectual resources, innovation, patent protection, pharmacology.

5. Consultations: take place according to the online schedule.

6. Brief summary of the educational component: the discipline is elective in the master's program in 226 Pharmacy, industrial pharmacy. The subjects of study in the discipline "Good Pharmaceutical Practices" are quality management systems in pharmacy, approaches to its operation, and regulation of pharmaceutical companies.

7. The purpose statement of studying 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.

8. Competences in accordance with the educational program:

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 competencies of the specialty (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.

9. The program 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

10. Status of the educational component: selective.

11. 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.

12. The volume 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.

13. Organization of training:

The format of teaching the educational component

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.

History of the development of the science of quality assurance and management. Life cycle of drugs. Implementation of the principles of quality assurance at the stages of the life cycle.

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

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 medicinal

products in the European Union. Regulatory framework for pharmacovigilance. Licensing as a component of the permitting system in the field of economic activity. Stages of confirmation of compliance of conditions of production of medicines with GMP requirements. The role of the International Pharmacopoeia in the system of standardization and quality control of medicines.

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.

Analysis of GMP requirements for pharmaceutical quality system. Analysis of the main provisions of the ICH Q10 guidelines. Analysis of the main requirements of the ISO 9001: 2015 standard. Determining the main stages of designing quality management systems for pharmaceutical companies.

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

The concept of integrated management systems, environmental management, food safety systems, quality management systems for medical devices.

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

Regulation and documentation of PQS processes, document management. Development of Quality Guidelines, documented procedures for the implementation of PQS processes and standard operating procedures (SOP). The role of PQS records (protocols) in data registration. Checking the compliance of the document of pharmaceutical quality systems.

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

Risk classification. Risk identification. Aims 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.

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.

Basics of qualification and validation. Types of validation and qualification. Validation of analytical methods. Validation of cleaning.

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

Basic components of modern 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. Basic principles of effective audit.

Semester module supervision

14. Forms and types of academic achievements supervision:

Forms and types of academic achievements supervision

Progress supervision: oral survey, writing test tasks, solving situational problems, etc.
Supervision of content modules: preparation of test tasks, solution of situational problems, etc.
Semester credit: writing test tasks, solving situational problems, etc.
Semester control form: semester credit.
Conditions for admission to the supervision of content modules: for admission to the supervision of content module, it is necessary to have a minimum number of points for the topics 1-8.
Conditions for admission to semester supervision: a current rating of more than 60 points, absence of missed practical classes, fulfillment of all requirements stipulated in the work program of the educational component.

15. Evaluation system of the educational component:

Evaluation system of the educational component: *the results of the semester supervision in the form of a semester credit are evaluated on a 100-point, non-differentiated scale ("passed", "failed") and on the ECTS*

scale.

Points from the educational component are calculated according to this ratio:

Types of evaluation	Maximum number of points (% of the number of points per module - for content modules)
Module 1	
Content module 1: The quality assurance system of medicines *- evaluation of topics (1-4) (work in classes 1-4): work in classes (oral survey, writing test tasks, solving situational (calculation) problems);* *- supervision of content module 1 (writing test tasks, solving situational (calculation) tasks)*	*52 (52 %)*
Content module 2: Applied aspects of formation, implementation, analysis and development of pharmaceutical quality systems - evaluation of topics (5-8) (work in classes 5-8): work in classes (oral survey, writing test tasks, solving situational (calculation) problems); - supervision of content module 1 (writing test tasks, solving situational (calculation) tasks)	*48 (48 %)*
Semester Supervision of Module 1	100

The individual work of applicants for higher education is evaluated during the progress supervision and during the content module supervision

16. Academic policies of the educational component:

Academic Integrity Policy. It is based on the principles of academic integrity stated in the POL "On measures to prevent cases of academic plagiarism at the National University of Pharmacy" (https://nuph.edu.ua/akademichna-dobrochesnist/). Cheating during the evaluation of an applicant for higher education during supervision activities in practical (seminar, laboratory) classes, supervision of content modules and the semester exam is prohibited (including the use of mobile devices). Abstracts must have correct text references to the used literature. The detection of signs of academic dishonesty in the student's written work is a reason for the teacher not to credit it.

Class attendance policy. An applicant for higher education is obliged to attend classes (POL "On the organization of the educational process of the National University of Pharmacy ") according to the schedule (https://nuph.edu.ua/rozklad-zanyat/), to observe ethical norms of behavior.

Policy regarding deadlines, working out, rating increase, liquidation of academic debts. The completion of missed classes by an applicant for higher education is carried out in accordance with the POL "Regulations on the completion of missed classes by applicants and the procedure for eliminating academic differences in the curricula of the National University of Pharmacy" in accordance with the schedule for working out missed classes established by the department. Increasing the rating and liquidating academic debts from the educational component is carried out by the applicants in accordance with the procedure specified in the POL "On the procedure for evaluating the results of training of applicants for higher education at the National University of Pharmacy ". Applicants of higher education are obliged to comply with all deadlines set by the department for the completion of written works from the educational component. Works that are submitted late without valid reasons are assessed at a lower grade - up to 20% of the maximum number of points for this type of work.

Policy on appeals of evaluation of the educational component (appeals). Applicants for higher education have the right to contest (appeal) the evaluation of the educational component obtained during control measures. The appeal is carried out in accordance with the POL "Regulations on appealing the results of the final

supervision of knowledge by applicants of higher education at the National University of Pharmacy" (https://nuph.edu.ua/wp-content/uploads/2016/12/pol- a2.2-38-050_polozhennja-pro-oskarzhennja-rezultativ-pidsumkovogo-kontrolju-znan-zdobuvachami-vishhoi- osviti-u-nfau-red.01-2021.pdf).

Policy on the recognition of learning outcomes obtained through non-formal and/or informal education by higher education applicants. Recognition of learning outcomes obtained through non-formal and/or informal education by higher education applicants is carried out in accordance with the Regulations "On the procedure for recognition of learning outcomes obtained through non-formal and/or informal education by higher education applicants at National University of Pharmacy" (https://nuph.edu.ua/wp-content/uploads/2020/11/pol-a2.3-32-208_polozhennja-pro- porjadok-viznannja-rezultativ-navchannja-otrimanih-shljahom-neformalnoi-ta-informalnoi-osviti-red.02- 2022.pdf). To evaluate the results of non-formal and/or informal learning of a higher education applicant, the attestation commission determines the scope and methods of demonstrating and measuring these learning outcomes, taking into account their content and possible specifics. The methods for demonstrating and measuring the results of the applicant's non-formal and/or informal learning may differ from the methods used for students in the relevant study programme, but they must ensure the substantive validity of the assessment. The Attestation Commission decides on the recognition of the results of non-formal and/or informal learning of the applicant if the assessment confirms that these results correspond to the learning outcomes provided for by the relevant educational programme.

17. Information and educational and methodical support of the discipline:

The main reading suggestions	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 harmonization 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 (codified version) URL: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:050:0044:0059:EN:PDF 3. EMA/541760/2011 «Guideline on good pharmacovigilance practices (GVP). Module I – Pharmacovigilance systems and their quality systems» («Настанова з належних практик фармаконагляду (ННПФ). Модуль I - Фармаконагляд та його система якості») 4. EMA/CHMP/600958/2010/Corr.* "Appendix IV of the Guideline on the Investigation on Bioequivalence (CPMP/EWP/QWP/1401/98 Rev.1): Presentation of Biopharmaceutical and Bioanalytical Data in Module 2.7.1" URL: https://www.ema.europa.eu/en/documents/scientific-guideline/appendix-iv-guideline-investigation-bioequivalence-cpmp/ewp/qwp/1401/98-rev1-presentation-biopharmaceutical-bioanalytical-data-module-271_en.pdf 5. EMA/CHMP/CVMP/QWP/BWP/70278/2012-Rev 1 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 6. 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

7. 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
8. EMA/INS/GMP/79766/2011 Quality Risk Management (ICH Q9). URL : https://www.inspiredpharma.com/wp-content/uploads/2012/03/ich-9.pdf
9. EMA/INS/GMP/79818/2011 Pharmaceutical Quality System (ICH Q10). URL : https://www.inspiredpharma.com/wp-content/uploads/2012/03/ich-10.pdf
10. 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
11. 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
12. International Pharmacopoeia. 2019. URL : https://apps.who.int/phint/en/p/docf/.
13. ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes. URL : https://www.iso.org/standard/59752.html
14. ISO 14001:2015 Environmental management systems — Requirements with guidance for use. URL : https://www.iso.org/standard/60857.html
15. ISO 19011:2018 Guidelines for auditing management systems. URL : https://www.iso.org/obp/ui/#iso:std:70017:en
16. 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
17. ISO 9001:2015 Quality management systems — Requirements. URL : https://www.iso.org/standard/62085.html
18. Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services from the WHO technical report series, No. 961, 45th report of the WHO Expert Committee on specifications for pharmaceutical preparations © World Health Organization 2011 URL: https://www.who.int/medicines/areas/quality_safety/quality_assurance/FIPWHOGuidelinesGoodPharmacyPracticeTRS961Annex8.pdf
19. The Rules Governing Medicinal Products in the European Union. Notice to Applicants - V. 2B. - Common Technical Document. - May 2008. - European Commission. Enterprise and Industry Directorate-General URL: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/b/update_200805/ctd_05-2008_en.pdf
20. The Rules Governing Medicinal Products in the European Union. Notice to Applicants - V. 2B. - Common Technical Document. - May 2008. - European Commission. Enterprise and Industry Directorate-General URL : https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/b/update_200805/ctd_05-2008_en.pdf
21. World Health Organization. (2011). Marketing authorization of pharmaceutical products with special reference to multisource (generic) products : a manual for National Medicines Regulatory Authorities (NMRAs), 2nd ed. World Health Organization. https://apps.who.int/iris/handle/10665/44576

Supplementary reading suggestions for in-depth study of the educational component	1. Chen, Hsinjung, Shinlun Liu, Yijyuan Chen, Chinshuh Chen, Huiting Yang, and Yuhshuen Chen. Food Safety Management Systems Based on ISO 22000:2018 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
Current electronic information resources (magazines, websites) for in-depth study of the educational component	1. Кафедра управління, економіки та забезпечення якості у фармації НФаУ: http://yep.nuph.edu.ua/uk/ 2. Бібліотека НФаУ: e-mail library@nuph.edu.ua 3. Центр дистанційних технологій навчання НФаУ [Електронний ресурс]. - Режим доступу: http://www.pharmel.kharkiv.edu 4. World Health Organization – WHO. URL : https://www.who.int/home 5. The International Council for Harmonisation – ICH. URL : https://www.ich.org/ 6. Pharmaceutical Inspection Co-operation Scheme - PIC/S. URL : https://picscheme.org/ 7. The European Directorate for the Quality of Medicines & HealthCare – EDQM. URL : https://www.edqm.eu/ 8. European Medicines Agency – EMA. URL : https://www.ema.europa.eu/en 9. EudraGMDP. URL : http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do 10. Food and Drug Administration – FDA. URL : https://www.fda.gov/

	11. 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=2726

18. Technical support and software of the educational component: a personal computer/laptop/tablet/smartphone with Internet access and an installed Zoom device, Microsoft Office, Moodle virtual learning environment, and multimedia screen.