NATIONAL PIROGOV MEMORIAL MEDICAL UNIVERSITY, VINNYTSIA

COURSE SYLLABUS

Academic discipline for Master's degree training:
QUALITY SYSTEMS IN THE PHARMACY

Specialty	226 Pharmacy, Industrial Pharmacy
Educational Programme	**EPP "Pharmacy" (2023)**
Higher Education Level	Second (Master's)
Academic Year	2026-2027
Status of the Discipline	Mandatory
Language of Instruction	Ukrainian / English
Total Workload	(3,0 of ECTS credits)
Year of Study / Semester	V / 9
Developer	O. Kohut, Associate Professor, Candidate of Pharmaceutical Sciences
Instructor(s), Guest Lecturers	O. Kohut, Associate Professor, Candidate of Pharmaceutical Sciences; O. Blahun, Sup. teacher
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1. DESCRIPTION OF THE ACADEMIC DISCIPLINE

ABSTRACT

Brief course overview and relevance. The academic discipline "Quality Systems in Pharmacy" belongs to the cycle of professional training courses for specialists in the field of study 226 "Pharmacy, Industrial Pharmacy," specialization 226.01 "Pharmacy."

The subject matter of this course encompasses the theoretical foundations, legislative requirements, and practical tools for establishing, implementing, and maintaining a Pharmaceutical Quality System (PQS) throughout the entire life cycle of medicinal products.

Within the overall framework of pharmacist training, "Quality Systems in Pharmacy" serves as a core specialized discipline. Its objective is to examine the organization of quality control systems for pharmaceutical products and services, as well as the provisions of legislative and regulatory acts governing the circulation and control of medicinal products and quality standards. Together with other pharmaceutical disciplines, "Quality Systems in Pharmacy" plays a vital role in shaping the professional perspective of pharmaceutical specialists regarding product quality. It focuses on ensuring the safety, efficacy, and suitability of medicines—as well as related pharmaceutical services (such as proper storage, distribution, and patient counseling)—to meet consumer needs. Furthermore, the course develops practical skills related to the processes required to establish a Pharmaceutical Quality System (PQS).

Prerequisites for the Educational Component.

This discipline requires the following curriculum subjects as prerequisites: Organization and Economics of Pharmacy, Drug Technology, Pharmaceutical and Medical Commodity Science, and Pharmaceutical Law and Legislation.

Pharmaceutical Management and Marketing focuses on equipping future specialists with the knowledge and skills required to conduct business activities within a market environment, as well as managing pharmaceutical enterprises with various forms of ownership and business structures.

Pharmaceutical Law and Legislation covers the legislative and regulatory acts of Ukraine that govern pharmaceutical activities, including management, accounting, and tax record-keeping, while also developing the skills to interpret and apply these regulations.

Drug Technology is a discipline that examines the theoretical foundations and production processes involved in transforming medicinal substances into finished pharmaceutical products (medicines) by formulating them into specific dosage forms, based on established physical, chemical, mechanical, and other scientific principles.

Organization and Economics of Pharmacy is a discipline that studies the organizational and economic processes within pharmaceutical establishments.

The program focuses on the organization of quality control systems for pharmaceutical goods and services. It is designed to provide knowledge regarding the organization of quality control within business operations—encompassing the production, wholesale, and retail distribution of medicinal products—and to develop skills in assessing key quality indicators for pharmacy operations in compliance with current legislation.

PURPOSE AND OBJECTIVES

The objective of the course "Quality Systems in Pharmacy" is to equip higher education students with systematic knowledge and practical skills regarding the organization, assurance, and management of the quality of medicinal products throughout their entire life cycle. The primary tasks of the course include: studying the life cycle of medicinal products—encompassing stages from pharmaceutical development, preclinical and clinical trials, and state registration to manufacturing, distribution, storage, and retail sale; mastering the concepts of Good Practices (quality standards) and the documentation of quality-related processes; examining the legislative and regulatory framework governing pharmaceutical enterprises in Ukraine and the EU, the mandates of regulatory authorities within quality systems, and methods of control and oversight; and exploring sanitary and anti-epidemic measures in pharmaceutical facilities, quality control within the relationship between providers and consumers of pharmaceutical goods and services, the analysis of quality systems in the context of procurement, and the requirements for pharmaceutical personnel and their qualifications.

Competencies

General Competencies (GC):

GC 02. Ability for abstract thinking, analysis, and synthesis.

GC 03. Knowledge and understanding of the subject area and professional activity.

GC 04. Ability to adapt and act in new situations; ability to take initiative.

GC 05. Ability to communicate in the state language (both orally and in writing) and in a foreign language (primarily English) at a level sufficient for effective professional activity.

GC 06. Skills in using information and communication technologies.

GC 07. Ability to select communication strategies; ability to work in a team and collaborate with experts from other fields of knowledge or economic sectors.

- *integrated:* the ability to solve tasks and to comprehend and address practical problems of a research and/or innovative nature in the field of pharmacy.
- *general:*

GC 02. Ability to think abstractly, analyse and synthesise.

GC 03. Knowledge and understanding of the subject area and understanding of professional practice.

GC 04. Ability to adapt and act in new situations. Ability to show initiative.

GC 06. Skills in the use of information and communication technologies.

GC 07. Ability to select communication strategies; ability to work in a team and with experts from other fields of knowledge or types of economic activity.

GC 08. Ability to assess and ensure the quality of work performed.

GC 09. Ability to conduct research at the appropriate level.

- *specialised (professional, subject-specific) competences (PC):*

PC 04. The ability to apply knowledge of the regulatory and legislative acts of Ukraine, as well as recommendations for Good Pharmaceutical Practices, within professional activities.

PC 05. The ability to demonstrate and apply communication skills, along with the fundamental principles of pharmaceutical ethics and deontology—grounded in moral obligations, values, ethical standards of professional conduct, and responsibility—in accordance with the Code of Ethics for Pharmaceutical Professionals of Ukraine and WHO guidelines.

PC 06. The ability to communicate one's own knowledge, conclusions, and reasoning in the field of pharmacy clearly and unambiguously to both professionals and non-professionals, including learners; [and] to determine prices for medicinal products and medical devices in compliance with the current legislation of Ukraine.

PC 16. The ability to develop and implement a quality management system for pharmaceutical enterprises in accordance with the requirements of current standards, and to conduct quality audits and manage risks related to the quality of pharmaceutical products.

PC 22. The ability to organize and carry out quality control of medicinal products in compliance with the requirements of the current State Pharmacopoeia of Ukraine and Good Pharmaceutical Practices; to determine sampling methods for medicinal products and perform their standardization according to current requirements; and to prevent the distribution of falsified medicinal products..

Post-requisites *(How will this be useful in your future studies and professional career?)*

"Quality Systems in Pharmacy" is a specialized pharmaceutical discipline that examines the legislative requirements and practical tools for establishing, implementing, and maintaining a Pharmaceutical Quality System (PQS) throughout the entire lifecycle of medicinal products, as well as Quality Risk Management (QRM).

The objective of studying "Quality Systems in Pharmacy" is to acquire the knowledge and practical skills necessary to understand the organization of quality control systems for pharmaceutical products and services, the provisions of legislative and regulatory acts governing the circulation and control of medicinal products, and quality standards.

This discipline serves as a foundation for the study of other subjects, including "Drug Technology" (covering both extemporaneous and industrial drug manufacturing), "Pharmaceutical and Medical Commodity Science," the elective course "State Regulation and Control in Pharmacy," and practical training in the Organization and Economics of Pharmacy (OEP).

The educational process involves integrating the curriculum with the aforementioned disciplines, fostering the ability to apply acquired knowledge both during further studies and in professional practice.

2. LEARNING OUTCOMES

PLO 01. Apply specialized knowledge and skills from general and professional disciplines in professional practice.

PLO 02. Critically analyze scientific and applied issues within the field of pharmacy.

PLO 03. Evaluate and ensure the quality and effectiveness of activities within the field of pharmacy.

PLO 04. Adhere to sanitary-hygienic standards and safety requirements when performing professional duties.

PLO 05. Plan and execute professional activities in accordance with the regulatory and legal acts of Ukraine and the guidelines for Good Pharmaceutical Practices.

PLO 06. Engage in professional communication in the state language; utilize oral communication skills in a foreign language to analyze specialized texts and translate information sources from foreign languages.

PLO 08. Develop and make effective decisions to address complex pharmaceutical challenges—both independently and through collaborative discussion; define objectives for one’s own work and that of the team, taking into account societal and operational interests, the overall strategy, and existing constraints; and determine the optimal paths to achieve these objectives.

PLO 15. Formulate and substantiate information—based on one’s own knowledge, professional experience, and key development trends in global pharmacy and related fields—and communicate it clearly and specifically to both professionals and non-professionals, including higher education students.

PLO 26. Ensure and carry out quality control of medicinal products of natural and synthetic origin and document the results; prepare quality certificates and certificates of analysis in accordance with the requirements of the current edition of the State Pharmacopoeia of Ukraine, quality control methods (QCM), manufacturing instructions, etc.; and implement measures to prevent the distribution of substandard, falsified, and unregistered medicinal products.

3. FORMS OF ORGANISATION OF THE EDUCATIONAL PROCESS AND THEIR SCOPE

Type of Learning Activity	Hours
Full-time form of study	
Lectures:	**18**
Practical Classes:	**32**
Independent Study (IS):	**50**
Total	**90**
Part-time form of study	
Lectures:	**4**
Practical Classes:	**12**
Independent Study (IS):	**74**
Total	**90**

4. THEMATIC PLAN

№	Topic Titles
1	Fundamentals of the national quality system in pharmaceutical enterprises.
2	Requirements for conducting economic activities in the production of medicines.
3	Requirements for conducting economic activities in the wholesale trade of medicines.
4	Requirements for conducting economic activities in the retail trade of medicines
5	Basic principles of state supervision (control) in pharmacy.
6	Final lesson
7	State mechanisms for controlling sanitary and anti-epidemic measures in pharmaceutical enterprises. Definition, regulation and documentation of processes of quality systems of pharmaceutical organizations (FSO).
8	Quality system between consumers of pharmaceutical goods and services and performers.
9	Market quality system in procurement and economic competition of pharmaceutical enterprises. Methods of identifying and assessing risks to product quality.
10	State regulation of the quality of compliance with tax legislation in pharmaceutical enterprises.
11	Inspection of pharmaceutical enterprises by internal affairs bodies. Internal audits (self-inspections) of pharmaceutical quality systems.
12	State policy on quality control of medicines, medical equipment and medical devices. Market surveillance.
13	Requirements for pharmaceutical personnel and their qualifications. Regulatory and legal framework for ensuring and controlling the quality of medicines in Ukraine and the European Union.
14	Responsibility in pharmacy. Validation in the production of medicines.
15	Final lesson.
16	Differential credit.

5. FORMS AND METHODS OF ASSESSMENT OF LEARNING OUTCOMES

Ongoing Assessment during Practical Classes	Methods: oral and/or written assessment and testing, computer-based assessment and testing, completion of situational tasks.
Final Assessment of the Academic Discipline – Pass/Fail Assessment	It is conducted during the final practical class and is determined on the basis of the student's ongoing academic performance in accordance with the Regulations on the Organisation of the Educational Process at National Pirogov Memorial Medical University, Vinnytsia**:** General Information / Key Documents https://www.vnmu.edu.ua/downloads/other/polog_organiz_ocv_proc(2026).pdf)
*Final Assessment of the Academic Discipline –	It is conducted during the final practical class and is assessed in accordance with the Regulations on the Organisation of the Educational Process at National Pirogov Memorial Medical

differentiated assessment	University, Vinnytsia:General Information / Key Documents https://www.vnmu.edu.ua/downloads/other/polog_organiz_ocv_proc(2026).pdf)
Assessment Tools for Learning Achievement	Theoretical questions, tests, clinically oriented situational tasks, practical assignments, demonstration of practical skills.

6. ASSESSMENT CRITERIA

Assessment of students' knowledge is carried out in accordance with the current Regulations on the Organisation of the Educational Process at National Pirogov Memorial Medical University, Vinnytsia**.** (https://www.vnmu.edu.ua/downloads/other/polog_organiz_ocv_proc(2026).pdf)

Type of Assessment	Assessment Criteria / Scale
Ongoing Assessment	According to the traditional grading scale: 5 – "Excellent", 4 – "Good", 3 – "Satisfactory", 2 – "Unsatisfactory"
Interim Assessments	According to the traditional grading scale
Final Grade of the Academic Discipline	The sum of points for the examination test (12–20 points) and oral assessment (38–60 points). Examination grade: 71–80 points – "Excellent"; 61–70 points – "Good"; 50–60 points – "Satisfactory"; fewer than 50 points – "Unsatisfactory" / Failed.
Overall Assessment for the Academic Discipline	Ongoing academic performance – 72–120 points (conversion of the average traditional grade for practical classes to the 120-point scale): 60% of the final grade for the academic discipline. Final Assessment – 50–80 points: 40% of the final grade for the academic discipline. Individual Assignments– 1–12 points. Total: 122–200 points.

GRADING SCALE: NATIONAL AND ECTS

Total Score for All Learning Activities	ECTS Grade	National Grade: Examination, Course Project (Paper), Practical Training	National Grade: Pass
180–200	**A**	Excellent	Passed
170–179.99	**B**	Good	Passed
160–169.99	**C**	Good	Passed
141–159.99	**D**	Satisfactory	Passed
122–140.99	**E**	Satisfactory	Passed
60–121.99	**FX**	Unsatisfactory, with the possibility of retaking	Failed, with the possibility of retaking
0–59.99	**F**	Unsatisfactory, with mandatory repetition of the discipline	Failed, with mandatory repetition of the discipline

Criteria for Assessing Students' Knowledge

Assessment of Oral/Written Responses during Ongoing Assessment

The grade "Excellent" is awarded when a student demonstrates comprehensive knowledge of the topic, illustrating responses with a variety of relevant examples; provides complete, accurate, and clear answers without prompting or leading questions; presents the material without errors or inaccuracies; confidently solves problems and completes practical tasks of varying levels of complexity; and independently generates innovative ideas.

The grade "Good" is awarded when a student demonstrates good knowledge and understanding of the topic and provides correct, coherent, and well-structured answers, although they may not be fully comprehensive. The student answers additional questions correctly and without significant errors; successfully solves problems and completes practical tasks, experiencing difficulties only with the most complex assignments.

The grade "Satisfactory" is awarded when a student demonstrates knowledge of the overall content of the topic and a satisfactory level of understanding. With the help of guiding questions, the student is able to solve modified (simplified) problems; solves problems and completes practical

tasks, although experiencing difficulties even with relatively simple assignments; is unable to formulate a coherent and systematic response independently but provides correct answers to direct questions.

The grade "Unsatisfactory" is awarded when a student's knowledge and skills do not meet the requirements for the grade "Satisfactory".

The assessment criteria for all other types of students' academic work are based on the requirements of the Regulations on the Organisation of the Educational Process at National Pirogov Memorial Medical University, Vinnytsya,

(https://www.vnmu.edu.ua/downloads/other/polog_organiz_ocv_proc(2026).pdf) and are specified in the programme of the academic discipline.

Assessment of Students' Independent Study

Students' independent study undertaken as part of a topic alongside contact hours is assessed as part of the ongoing assessment of that topic during the relevant practical class.

The maximum number of points a student may receive upon completion of the discipline is 200 points. The minimum passing score is 122 points.

7. METHODOLOGICAL SUPPORT

Teaching and learning materials (lecture notes or extended lecture outlines), thematic plans for lectures, practical classes and independent study, assignments for ongoing assessment, methodological guidelines, and teaching manuals.

8. ACADEMIC DISCIPLINE POLICIES

The completion of learning activities and all academic work within the discipline must comply with the requirements of the Regulations on the Organisation of the Educational Process at National Pirogov Memorial Medical University, Vinnytsya**;** (https://www.vnmu.edu.ua/downloads/other/polog_organiz_ocv_proc(2026).pdf), the Regulations on the Organisation of the Educational Process for Higher Education Students Pursuing the Degree of Doctor of Philosophy at National Pirogov Memorial Medical University, Vinnytsya (https://www.vnmu.edu.ua/downloads/other/pologPhD_org.pdf),; the Law of Ukraine "On Education" (Article 42**)**; the Law of Ukraine "On Academic Integrity**"**; and the Code of Academic Integrity of National Pirogov Memorial Medical University, Vinnytsya (https://www.vnmu.edu.ua/downloads/other/kodex_akad_dobr_edit%202026.pdf)

Students are entitled to high-quality educational services and a safe learning environment under martial law, emergency situations and states of emergency; access to up-to-date scientific and educational information; and qualified academic guidance and support in studying the discipline and acquiring practical skills.

The Department's policy on the provision of educational services is student-centred and is based on the regulatory documents of the Ministry of Education and Science of Ukraine and the Ministry of Health of Ukraine, the University Statute, the procedures governing the provision of educational services, including in emergency situations, as stipulated by the principal regulations and administrative directives governing the organisation of the educational process at National Pirogov Memorial Medical University, Vinnytsya, as well as on the principles of academic integrity.

Academic Integrity. When studying the discipline and completing all types of learning assignments and/or research activities, students must comply with the Law of Ukraine "On Education" (Article 42)**,** th**e** Law of Ukraine "On Academic Integrity"**,** and the Code of Academic Integrity of National Pirogov Memorial Medical University, Vinnytsya (University website → General Information → Key Documents → Code of Academic Integrity). In the event of a violation of academic integrity principles, appropriate measures shall be taken in accordance with the applicable regulatory documents.

Compliance with VNMU Internal Regulations and Safety Requirements during Practical Classes. At the first practical class, the instructor provides a safety briefing on appropriate conduct on the Department premises, informs students of the location of the shelter and the evacuation route to the shelter in accordance with the approved evacuation plan, explains the rules of conduct while proceeding to and remaining in the shelter, and provides instructions on all actions stipulated by the

Emergency Response Plan (pursuant to Order No. 505 dated 30 August 2023). In the event of an air raid alert or any other emergency warning signal, the instructor suspends the class. The instructor and students proceed together to the shelter and remain there until the warning signal is cancelled. Once the alert has been lifted, the instructor and students either resume the class in the Department's classrooms or students independently complete the remaining learning material, which is subsequently assessed at the next class.

Requirements for Preparation for Practical Classes

Students are required to participate actively in the educational process: attend classes and come adequately prepared; complete the test tasks related to the current topic in their workbooks and fill in the required diagrams and tables; actively participate in discussions of the class topic; complete all assignments specified in the programme; search for additional information relevant to the topic and present it to their peers.

Students are expected to arrive at classes on time. Late arrival is not permitted in accordance with the Internal Regulations for Students of VNMU**.** A student who arrives more than 10 minutes late is not admitted to the class and is required to make up the missed class in accordance with the established procedure.

Students are expected to be polite, courteous, and respectful in their interactions with teaching staff, other University employees, fellow students, and other persons studying at VNMU. Students must maintain a quiet and orderly environment and demonstrate appropriate conduct on the Department premises.

In its activities, the Department adheres to the principles of mutual respect and tolerance. Students are expected to uphold the same principles.

Students must comply with safety regulations while on the Department premises.

When working in teaching and research laboratories, students must comply with the applicable safety regulations (published on the website of the Pharmacy Department). When completing practical assignments, students must keep their workstations clean and orderly and leave them tidy upon completion of the practical work.

Use of Mobile Phones and Other Electronic Devices. The use of mobile phones and other electronic devices during classes is not permitted, except for emergency calls or when such devices are used to present supplementary materials relevant to the topic of the class.

Absence from Classes. Missed classes must be made up in accordance with the procedure established by the current Regulations on the Organization of the Educational Process at National Pirogov Memorial Medical University, Vinnytsya https://www.vnmu.edu.ua/downloads/other/polog_organiz_ocv_proc(2026).pdf), at the times specified in the make-up schedule published on the website of the Pharmacy Department (VNMU website), either with the instructor on duty or with the student's regular instructor. Making up a missed class involves completing the assignments related to the topic of the missed class in accordance with the specific requirements of the discipline.

Mastery of lecture topics is assessed during practical classes, seminars (including the assessment of practical skills), and final assessment, in accordance with the Regulations on the Organisation of the Educational Process at National Pirogov Memorial Medical University, Vinnytsya (https://www.vnmu.edu.ua/downloads/other/polog_organiz_ocv_proc(2026).pdf)

Admission to Final Assessment. The procedure for admission to final assessment in the discipline is set out in the current Regulations on the Organisation of the Educational Process at National Pirogov Memorial Medical University, Vinnytsya (https://www.vnmu.edu.ua/downloads/other/polog_organiz_ocv_proc(2026).pdf).

Students are admitted to final assessment provided that they have no outstanding academic requirements**:** the average grade for ongoing assessment must be at least 3.0 (72 points on the 120-point scale); all final sessions for the content modules must have been completed with a passing grade **(**"3" or higher); and all missed practical classes must have been made up with a passing grade **(**"3" or higher**).** Otherwise, the student must improve their average grade by making up unsatisfactory grades and must make up all missed classes.

Additional Points for Individual Assignments. Students may receive additional points in the discipline for the successful completion of individual assignments, the content of which is published on the Department's website as part of the teaching and learning materials for the discipline. The number of points awarded is determined based on the results of the individual assignment in accordance with the current Regulations on the Organisation of the Educational Process at National Pirogov Memorial Medical University, Vinnytsya**.** (https://www.vnmu.edu.ua/downloads/other/polog_organiz_ocv_proc(2026).pdf).

Resolution of Conflict Situations

In the event of misunderstandings or concerns regarding the quality of educational services, assessment of academic performance, or other conflict situations involving an instructor, students should first raise their concerns directly with the instructor. If the issue remains unresolved, the student has the right to submit an appeal to the Head of the Department in accordance with the Regulations on the Consideration of Appeals from Higher Education Students at National Pirogov Memorial Medical University, Vinnytsya (VNMU website → General Information → Key Documents).

Students also have the right to contact the student self-government bodies, the administration of the Faculty (Institute), or the University administration, either directly or through the designated feedback channels ("trust boxes"), links and addresses for which are available on the official VNMU website.

The Department recognises that a student-centred approach entails students' responsibility for the conscious and active acquisition of knowledge and for proper compliance with the rules and requirements established by applicable legislation and VNMU regulatory documents. The Department reserves the right to inform the relevant University bodies of any violations committed by students.

Policy on Blended Learning

The organisation of blended learning is governed by the Regulations on the Introduction of Elements of Distance Learning at National Pirogov Memorial Medical University, Vinnytsya (VNMU website → General Information → Key Documents). The main online learning platforms used for classes are Microsoft Teams and Google Meet.

The procedures for conducting practical classes, lectures, make-up classes, and consultations in the distance learning format are published on the Department's webpage (VNMU website → Pharmacy Department → For Students/Postgraduate Students → Mode of Study → Year of Study → Teaching and Learning Materials**).**

Communication with the Instructor. Students may contact the instructor via Microsoft Teams chat, messaging applications (Viber, Telegram, WhatsApp), or email**,** as determined by the instructor, during working hours.

9. LEARNING RESOURCES

Teaching and learning materials for the discipline are available on the Department's website. The materials can be accessed via: VNMU website → [Pharmacy Department] → For Students/Postgraduate Students.

LITERATURE

Core Literature for Quality Systems in the Pharmacy:

1. Quality Systems in Pharmacy. Section "Quality Systems in Pharmacy": a study guide for pharmaceutical faculties, specialty 226 "Pharmacy, Industrial Pharmacy" / compiled by N. O. Tkachenko, V. O. Demchenko, N. M. Chervonenko, T. P. Zarichna; edited by N. O. Tkachenko. – Zaporizhzhia: ZDMFU, 2025. – 162 p.

2. Law of Ukraine dated July 28, 2022, No. 2469-IX "On Medicinal Products." Version as of June 5, 2025; basis: 4454-IX. URL: **https://zakon.rada.gov.ua/laws/show/2469-20#Text**

3. Law of Ukraine "On Remuneration of Labor," No. 2888-IX. Version as of April 1, 2023; basis: 2888-IX. URL: **https://zakon.rada.gov.ua/laws/show/2888-20#n326**

4. Law of Ukraine dated July 16, 2025, No. 4536-IX "On Amendments to the Tax Code of Ukraine and Other Legislative Acts." URL: **https://zakon.rada.gov.ua/laws/show/4536-20#Text**
5. LAW OF UKRAINE dated February 12, 2025, No. 4239-IX "On Amendments to Certain Laws of Ukraine Regarding Specifics of State Registration of Medicinal Products That May Be Procured by an Entity Authorized to Conduct Procurement in the Healthcare Sector, and Regarding the Regulation of Certain Issues Related to the Sale of Medicinal Products." URL: https://zakon.rada.gov.ua/laws/show/4239-20#Text
6. Resolution of the Cabinet of Ministers of Ukraine No. 929 "On Approval of Licensing Conditions for the Conduct of Business Activities Related to the Manufacturing of Medicinal Products, Wholesale and Retail Trade in Medicinal Products, and Importation of Medicinal Products." Version as of June 1, 2026; legal basis: 377-2026-p. URL: **https://zakon.rada.gov.ua/laws/show/929-2016-%D0%BF)#Text**
7. Resolution of the Cabinet of Ministers of Ukraine dated December 26, 2025, No. 976 “On Amendments to the Licensing Conditions for Conducting Business Activities Related to the Manufacturing of Medicinal Products, Wholesale and Retail Trade in Medicinal Products, and the Import of Medicinal Products (Excluding Active Pharmaceutical Ingredients).” URL: https://zakon.rada.gov.ua/laws/show/1802-2025-%D0%BF#Text
8. Resolution of the Cabinet of Ministers of Ukraine dated June 4, 2026, No. 739 “Certain Issues Regarding the Establishment of the Ukrainian Pharmaceutical Agency.” URL: https://ips.ligazakon.net/document/view/KP260739?ed=2026_06_04
9. Resolution of the Cabinet of Ministers of Ukraine dated April 19, 2020, No. 426 “On Reference Pricing for Certain Medicinal Products Procured Using Budget Funds.” URL: https://zakon.rada.gov.ua/laws/show/426-2019-п#Text
10. Resolution of the Cabinet of Ministers of Ukraine dated August 13, 2025, No. 996. "On Amendments to the Licensing Conditions for Conducting Business Activities Related to the Cultivation of Plants (Excluding Cannabis for Industrial Purposes, as Defined by the Law of Ukraine 'On Narcotic Drugs, Psychotropic Substances, and Precursors')." URL: https://zakon.rada.gov.ua/laws/show/996-2025-%D0%BF#Text
11. Resolution of the Cabinet of Ministers of Ukraine No. 902 "On Approval of the Procedure for Exercising State Quality Control over Medicinal Products Imported into Ukraine." Version as of June 1, 2026; basis: 377-2026-p. URL: https://zakon.rada.gov.ua/laws/show/902-2005-%D0%BF#Text
11. Resolution of the Cabinet of Ministers of Ukraine No. 1052 "On Approval of the Regulation on the State Emergency Service of Ukraine." Current version: as of September 5, 2025; basis: 1090-2025-p.
- URL: https://zakon.rada.gov.ua/laws/show/1052-2015-%D0%BF#Text
12. Resolution of the Cabinet of Ministers of Ukraine dated July 14, 2021, No. 725 "On Approval of the Regulation on the System of Continuous Professional Development for Healthcare Professionals." URL: https://zakon.rada.gov.ua/laws/show/725-2021-%D0%BF#Text
13. Resolution of the Cabinet of Ministers of Ukraine dated September 26, 2024, No. 1121 "Certain Issues Regarding the Safety and Verification of Medicinal Products..." ...medicines.” URL: https://zakon.rada.gov.ua/laws/show/1121-2024-%D0%BF#Text
14. Resolution of the Cabinet of Ministers of Ukraine dated May 27, 2026, No. 687 “On Certain Issues Regarding the National List of Essential Medicines.” URL: https://zakon.rada.gov.ua/laws/show/687-2026-%D0%BF#Text
15. Organization and Economics of Pharmacy. Part 1. Organization of Pharmaceutical Provision for the Population: National Textbook for Students of Higher Educational Institutions / A.S. Nemchenko, V.M. Nazarkina, H.L. Panfilova, et al.; edited by A.S. Nemchenko. – Kharkiv: NUPh: Zoloti Storinky, 2017. – 327 p.

Supplementary Literature for Quality Systems in the Pharmacy:

1. Order of the Ministry of Health of Ukraine No. 677 (current version as of March 3, 2026; legal basis: z0288-26) "On Approval of the Procedure for Quality Control of Medicinal Products during Wholesale and Retail Trade." URL: https://zakon.rada.gov.ua/laws/show/z1515-14#Text
2. Order of the Ministry of Health of Ukraine dated May 14, 2026, No. 618 "On Amendments to Certain Regulatory Legal Acts of the Ministry of Health of Ukraine Regarding Specific Issues of Postgraduate Education in the Healthcare Sector." URL: https://zakon.rada.gov.ua/laws/show/z0783-26#Text
3. Order of the Ministry of Health of Ukraine dated June 16, 2026, No. 815 "On Amendments to the Criteria for Determining Enterprises, Institutions, and Organizations of Importance to the National Economy in the Healthcare Sector." URL: https://zakon.rada.gov.ua/laws/show/z0894-26#Text
4. Order of the Ministry of Health of Ukraine dated May 29, 2026, No. 706 "On Approval of Amendments to the Rules for the Production (Preparation) and Quality Control of Medicinal Products in Pharmacies." URL: https://zakon.rada.gov.ua/laws/show/z1006-26#Text
5. Order of the Ministry of Health of Ukraine dated May 14, 2026. "On Approval of the List of Medical and Pharmaceutical Specialties for Which Mandatory Training of Citizens of Ukraine Is Conducted under the Reserve Officer Training Program." URL: https://zakon.rada.gov.ua/laws/show/z0777-26#Text
6. Order of the Ministry of Health of Ukraine dated April 24, 2026, No. 544 "On Approval of the List of Non-Prescription Medicinal Products Prohibited from Being Advertised." URL: https://zakon.rada.gov.ua/laws/show/z0650-26#Text
7. Order of the Ministry of Health of Ukraine dated March 16, 2026, No. 330 “On Approval of the List of Medicinal Products Permitted for Use in Ukraine That Are Dispensed Without a Prescription.” URL: https://zakon.rada.gov.ua/laws/show/z0423-26#Text
8. Order of the Ministry of Health of Ukraine dated January 15, 2024, No. 73 “On Approval of the Procedure for the Destruction and Disposal of Humanitarian Aid Goods (Items) by Legal Entities Authorized by the Ministry of Health of Ukraine to Receive Medicinal Products, Medical Devices, Consumables, Medical Equipment, Personal Protective Equipment, and Other Goods Necessary for the Proper Provision of the Healthcare Sector Under Martial Law.” URL: https://zakon.rada.gov.ua/laws/show/z0190-24#Text
9. Order of the Ministry of Health of Ukraine dated July 10, 2025, No. 1099 “On Approval of State Sanitary Norms and Rules ‘Sanitary and Anti-Epidemic Requirements for Pharmacy Establishments.’” URL: https://zakon.rada.gov.ua/laws/show/z1233-25#Text
10. Order of the Ministry of Health of Ukraine dated October 28, 2025, No. 1633 “On Approval of Amendments to the Directory of Qualification Characteristics of Employee Professions. Issue 78 ‘Healthcare.’” URL: https://zakon.rada.gov.ua/rada/show/v0307282-25#Text
11. Order of the Ministry of Health of Ukraine dated June 6, 2022, No. 958 “On Approval of Amendments to the Directory of Qualification Characteristics of Employee Professions.” Issue 78 "Healthcare". URL: https://zakon.rada.gov.ua/rada/show/v0958282-22#Text
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13. Order of the Ministry of Health of Ukraine dated August 26, 2024, No. 584 "On Approval of Amendments to the Requirements for Facilities and Premises Intended for Activities Involving the Handling of Narcotic Drugs, Psychotropic Substances, and Precursors, and for the Storage of Such Substances Seized from Illicit Circulation". URL: https://zakon.rada.gov.ua/laws/show/z1355-24#Text

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15. Resolution of the Cabinet of Ministers of Ukraine dated July 14, 2025, No. 895 "On Amendments to the Licensing Conditions for Conducting Business Activities Related to the Manufacturing of Medicinal Products, Wholesale and Retail Trade in Medicinal Products, and the Import of Medicinal Products..." ...products (excluding active pharmaceutical ingredients)" Access mode: https://zakon.rada.gov.ua/laws/show/895-2025-%D0%BF#Text
16. Standards and Guidelines for Quality Assurance in the European Higher Education Area (ESG). URL: https://ihed.org.ua/wp-content/uploads/2018/10/04_2016_ESG_2015.pdf 17. ST-N MoH Ukraine 42-3.0:2011 Medicinal Products. Pharmaceutical Development (ICH Q8). URL: https://compendium.com.ua/uk/clinical-guidelines-uk/standartizatsiya-farmatsevtichnoyi-produktsiyi-tom-1/st-n-mozu-42-3-0-2011/
18. ST-N MoH Ukraine 42-4.0:2020 Medicinal Products. Good Manufacturing Practice. URL: https://compendium.com.ua/uk/clinical-guidelines-uk/standartizatsiya-farmatsevtichnoyi-produktsiyi-tom-3/st-n-mozu-42-4-0-2020/
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22. ST-N MOHU 42-5.1:2011 Medicinal Products. Good Storage Practice. URL : https://compendium.com.ua/uk/clinical-guidelines-uk/standartizatsiya- farmatsevtichnoyi-produktsiyi-tom-1/st-n-mozu-42-5-1-2011/
23. ST-N MOHU 42-8.7:2018 Medicinal Products. Good Pharmacovigilance Practices. URL : https://compendium.com.ua/uk/clinical-guidelines-uk/standartizatsiya- farmatsevtichnoyi-produktsiyi-tom-3/st-n-mozu-42-8-7-2018/

ELECTRONIC RESOURCES

1. University website: National Pirogov Memorial Medical University, Vinnytsya
2. Department website: VNMU Departments — Pharmacy Department
3. University Library website: VNMU Library
4. National Scientific Medical Library of Ukraine: National Scientific Medical Library of Ukraine
5. World Health Organization: World Health Organization (WHO)
6. Ministry of Health of Ukraine: Ministry of Health of Ukraine
7. Public Health Center of the Ministry of Health of Ukraine: Public Health Center of Ukraine
8. English-language database of medical and biomedical literature: PubMed
9. English-language online resource for physicians and other healthcare professionals: Medscape
10. State Expert Center of the Ministry of Health of Ukraine: State Expert Center of the Ministry of Health of Ukraine
11. State Service of Ukraine on Medicines and Drugs Control: https://www.dls.gov.ua/
12. Ukrainian Pharmaceutical Quality Institute: Home page
13. Verkhovna Rada of Ukraine: Legislation of Ukraine

The course syllabus for the academic discipline **"Quality Systems in the Pharmacy"** was discussed and approved at the meeting of the Department of Pharmacy (Protocol No. 1, dated "26" August 2026).

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