

MINISTRY OF HEALTH OF UKRAINE

ODESA NATIONAL MEDICAL UNIVERSITY

Department of General and Clinical Pharmacology and Pharmacognosy

APPROVE

Vice-Rector for Scientific and Pedagogical Work

Eduard BURYACHKIVSKY

01 September 2024 року

**WORK PROGRAM OF THE DISCIPLINE
"QUALITY SYSTEM IN PHARMACY"**

Level of higher education: second (master's)

Field of knowledge: 22 "Healthcare"

Specialty: 226 "Pharmacy, industrial pharmacy"

Specialization: 226.01 "Pharmacy"

Educational and professional program: Pharmacy, industrial pharmacy

2024

The work program is based on the educational and professional program "Pharmacy, Industrial Pharmacy" for the training of specialists of the second (master's) level of higher education in the specialty 226 "Pharmacy, Industrial Pharmacy" of the field of knowledge "Health Care", approved by the Academic Council of ONMedU (protocol No. 10 dated June 27, 2024).

Developers:

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The work program was approved at the meeting of the Department of General and Clinical Pharmacology and Pharmacognosy

Minutes No. 1 dated "29". august 2024

Head of the Department



Yaroslav ROZHKOVSKEYI

Agreed with the guarantor of the OPP



Liana UNGURIAN

Approved by the subject-specific cyclical methodological commission on pharmaceutical disciplines of ONMedU

Minutes No. 1 dated "30". august 2024

Chairman of the commission



Nataliya FIZOR

Reviewed and approved at the meeting of the department _____

(name of the department)

Minutes No. _____ dated "____". _____ 20__

Head of the Department _____

(signature) (Name SURNAME)

Reviewed and approved at the meeting of the department _____

(name of the department)

Minutes No. _____ dated "____". _____ 20__

Head of the department _____

(signature) (First name SURNAME)

1. DESCRIPTION OF THE ACADEMIC DISCIPLINE

Name of Indicators	Field of Study, Specialty, Specialization, Level of Higher Education	Course Characteristics	
Total amount: ECTS Credits: 3 Hours – 90	Field of Study: 22 “Healthcare” Specialty: 226.01 “Pharmacy” Level of Higher Education: Second (Master’s)	<i>Full-time study</i> <i>Compulsory course</i>	
		<i>Year of study:</i>	5
		<i>Semester:</i>	X
		<i>Lectures (hours):</i>	20 hours
		<i>Seminars (hours):</i>	0 hours
		<i>Practical classes:</i>	40 hours
		<i>Laboratory classes (hours):</i>	0 hours
		<i>Self-study (hours):</i>	30 hours
	<i>Final assessment: pass/fail</i>	<i>pass/fail</i>	

1. PURPOSE AND OBJECTIVES OF THE ACADEMIC DISCIPLINE, COMPETENCIES, AND LEARNING OUTCOMES

Purpose: To develop in higher education students theoretical knowledge and practical skills regarding the application of general principles and key methods for the development, implementation, maintenance, and continuous improvement of Quality Management Systems (QMS) in pharmaceutical enterprises/organizations in accordance with international standards, Good Practice guidelines (GxP), and other industry regulations.

Objectives: To form students’ awareness of the regulatory and legal framework for the quality management of medicinal products, as well as to develop systematic knowledge and practical skills related to the design of quality systems in pharmacy, quality management activities throughout the lifecycle of medicinal products, preparation of corrective and preventive action (CAPA) plans to eliminate causes of non-conformities and optimize QMS processes, and preparation and conduct of QMS audits.

The study of the discipline is aimed at developing the following competencies:

The ability to solve research and/or innovation-oriented problems in the field of pharmacy and to critically analyze and address practical issues in professional pharmaceutical practice using principles, theories, and methods of fundamental, chemical, technological, biomedical, and socio-economic sciences; to integrate knowledge and solve complex problems, formulate judgments under conditions of incomplete or limited information; to clearly and unambiguously communicate one’s knowledge, conclusions, and their justification to both professional and non-professional audiences. The ability to continue learning with a high degree of autonomy.

General Competencies (GC):

- GC01. Ability for abstract thinking, analysis, and synthesis; ability to learn and be up-to-date.
- GC02. Knowledge and understanding of the subject area and professional activity.
- GC03. Ability to communicate in the state language both orally and in writing.
- GC04. Ability to communicate in a foreign language (primarily English) at a level sufficient for effective professional activity.
- GC05. Ability to evaluate and ensure the quality of performed work.
- GC07. Ability to exercise one’s rights and responsibilities as a member of society; awareness of the values of a civil (free democratic) society, sustainable development, the rule of law, and human and civil rights and freedoms in Ukraine.

GC09. Ability to use information and communication technologies.

GC10. Ability to make decisions and act in accordance with the principle of zero tolerance for corruption and any other forms of misconduct.

Professional Competencies (PC):

PC02. Ability to collect, interpret, and apply data necessary for professional activity, research, and implementation of innovative projects in pharmacy.

PC04. Ability to clearly and unambiguously communicate knowledge, conclusions, and arguments in the field of pharmacy to specialists and non-specialists, including students.

PC12. Ability to ensure proper storage of medicinal products of natural and synthetic origin and other pharmacy goods in accordance with their physicochemical properties and Good Storage Practice (GSP) requirements in healthcare institutions.

PC13. Ability to organize pharmacy activities to supply the population and healthcare institutions with medicinal products and other pharmacy goods, implement appropriate reporting and accounting systems, conduct commodity analysis, and perform administrative documentation in compliance with pharmaceutical legislation.

PC14. Ability to analyze and forecast key economic indicators of pharmacy institutions, calculate major taxes and fees, and set prices for medicinal products and other pharmacy goods in accordance with current legislation of Ukraine.

PC16. Ability to organize and carry out production activities in pharmacies related to the compounding of medicinal products in various dosage forms based on prescriptions and healthcare institution requirements, including justification of technology and selection of excipients in accordance with Good Pharmacy Practice (GPP).

PC17. Ability to perform pharmaceutical development and participate in the production of medicinal products of natural and synthetic origin at pharmaceutical enterprises in accordance with Good Manufacturing Practice (GMP).

PC19. Ability to organize and conduct quality control of medicinal products of natural and synthetic origin in accordance with the current edition of the State Pharmacopoeia of Ukraine, quality control methods, technological instructions, etc.; and to prevent the distribution of substandard, falsified, and unregistered medicinal products.

Program Learning Outcomes (PLO):

PLO01. To possess and apply specialized conceptual knowledge in pharmacy and related fields, taking into account modern scientific achievements.

PLO02. To critically analyze scientific and applied problems in pharmacy.

PLO04. To communicate fluently in the state and English languages, both orally and in writing, for discussing professional issues, presenting research results, and innovative projects.

PLO05. To evaluate and ensure the quality and effectiveness of activities in pharmacy.

PLO07. To collect necessary information on the development and production of medicinal products using professional literature, patents, databases, and other sources; to systematize, analyze, and evaluate it, including through statistical analysis.

PLO09. To formulate, argue, and clearly communicate information based on personal knowledge and professional experience, as well as global trends in pharmacy and related fields, to specialists and non-specialists, including students.

PLO15. To predict and determine the impact of environmental factors on the quality and consumer characteristics of medicinal products of natural and synthetic origin and other pharmacy goods, and to organize their storage in accordance with physicochemical properties and Good Storage Practice (GSP).

PLO21. To ensure competitive positioning and effective development of pharmaceutical organizations, including consideration of marketing research and market processes at national and international levels.

PLO22. To ensure and carry out quality control of medicinal products of natural and synthetic origin and document its results; to prepare certificates of quality and certificates of analysis in accordance with the current edition of the State Pharmacopoeia of Ukraine, quality control methods, technological instructions, etc.; and to implement measures to prevent the distribution of substandard, falsified, and unregistered medicinal products.

As a result of studying the academic discipline, higher education applicants must:

Know:

- methods of implementing knowledge in solving practical issues;
- the regulatory and legislative framework of Ukraine, which regulates the requirements for professional activity;
- modern trends in the development of the industry and analyze the features of the modern professional environment and professional activity;
- modern information and communication technologies;
- principles of organizing the quality management system in pharmacy;
- the structure and functions of regulatory bodies of Ukraine in the field of quality management of medicines;
- statistical methods in quality management of production processes in pharmacy;
- principles of regulating and documenting pharmaceutical quality system processes;
- methods of managing risks for the quality of medicines;
- principles of organizing activities for the validation of production processes and qualification of equipment and auxiliary systems in organizations - entities of the pharmaceutical market;
- principles of conducting QMS audits.

Be able to:

- use professional knowledge in solving practical issues;
- analyze professional information, make informed decisions, acquire modern knowledge;
- show initiative, constantly search for new opportunities beyond the available resources, engage in self-development and self-realization;
- carry out professional activities that require updating and integration of knowledge;
- apply modern information and communication technologies in practical activities;
- develop, implement, maintain up-to-date and improve the QMS of pharmaceutical enterprises/organizations;
- apply statistical methods in quality management of production processes in pharmacy;
- document the processes of the pharmaceutical quality system;
- apply risk management methods for the quality of medicines;
- implement activities to validate production processes and qualify equipment and auxiliary systems in organizations - entities of the pharmaceutical market;
- conduct QMS audits.

3. CONTENT OF THE COURSE

Content module 1. Regulatory and legal basis of quality management systems of pharmaceutical enterprises/organizations

Topic 1. Evolution of the world development of quality management science and its role in pharmacy.

Basic terms of quality management. Stages of development of quality management in the world. F. Taylor's concept. W. Shewhart's concept. The concept of total quality control (TQC). The concept of quality management throughout the company (CWQC). The concept of total quality

management (TQM). The concept of E. Deming. The concept of J. Juran. The concept of Ettinger - Sittig. The concept of G. Tagutti. The concept of F. Crosby.

Topic 2. Regulatory and legal basis for quality management of medicines.

ISO 9000 series standards. ISO 10000 series standards. ISO 13485 standard. ISO 14000 series standards. ISO 19011 standard. ISO 22000 standard. ISO 26000 standard. SA 8000 standard. UN Global Compact. ISO 27000 series standards. ISO 31000 series standards. ISO 37001 standard. OHSAS 18001 standard. ISO 45001 standard. The concept of good pharmaceutical practices (GxP) and their role in ensuring quality at all stages of the life cycle of medicines. ICH Q8. Good laboratory practice. Good clinical practice. Good regulatory practice. Good manufacturing practice. Good storage practice. Good distribution practice. Good pharmacy practice. Good pharmacovigilance practices. ICH Q9. ICH Q10. Integrated quality management systems of pharmaceutical organizations. State Pharmacopoeia of Ukraine.

Topic 3. Regulatory bodies of Ukraine in the field of quality management of medicines.

Structure of the state system of regulation of circulation of medicines in Ukraine. Ministry of Health of Ukraine. State Expert Center of the Ministry of Health of Ukraine. Directorate of Pharmaceutical Supply of the Ministry of Health of Ukraine. State Service of Ukraine for Medicines and Drug Control. Certification and licensing as components of the quality system in pharmacy.

Topic 4. Statistical methods of quality control.

The essence of statistical methods of quality control. Checklist. Pareto diagram. Cause-and-effect diagram of Ishikawa. Histogram. Scatter diagram. Control map. Stratification.

Topic 5. Regulation and documentation of processes of the pharmaceutical quality system.

The essence of documenting the quality management system at a pharmaceutical enterprise. Quality manual. Process implementation methods. Third-level quality management system documents. Fourth-level quality management system documents. "Inter-process" documents. Formation of a document management procedure.

Topic 6. Assessing risks to the quality of medicinal products at all stages of their life cycle.

Quality risk management process. Failure mode and effects analysis (FMEA). Failure mode, effects and criticality analysis (FMECA). Fault tree analysis (FTA). Hazard analysis and critical control points (HACCP). Hazard analysis and operability analysis (HAZOP). Preliminary hazard analysis (PHA). Risk ranking and filtering.

Topic 7. Organization of activities for the validation of production processes and qualification of equipment and auxiliary systems in organizations - entities of the pharmaceutical market. Validation: definition of the concept, objects, types. Validation staffing.

Validation documentation. Validation of analytical methods. Validation of purification. Qualification: definition of the concept, objects. User Requirements Specification (URS). Design Qualification (DQ). Factory Acceptance Test (FAT) / Site Acceptance Test (SAT). Installation Qualification (IQ). Operational Qualification (OQ). Performance Qualification (PQ).

Topic 8. Pharmaceutical Quality System Audits.

Concept of Audit. Classification of Audits. Audit Criteria. Audit Evidence. Principles of Auditing. Sequence of Work for Audit Program Management. Sequence of Work for Auditing. Audit Methods. Follow-up of Audit Results.

4. STRUCTURE OF THE ACADEMIC DISCIPLINE

Назви теми	Number of hours of full-time study			
	Total	including		
		lectures	practical	SIT
Topic 1. Evolution of the world development of quality management science and its role in pharmacy.	8	2	4	2
Topic 2. Regulatory and legal basis for quality management of medicines.	14	4	6	4
Topic 3. Regulatory bodies of Ukraine in the field of quality management of medicines.	12	2	6	4
Topic 4. Statistical methods of quality control.	10	2	4	4
Topic 5. Regulation and documentation of processes of the pharmaceutical quality system.	12	4	4	4
Topic 6. Assessing risks to the quality of medicinal products at all stages of their life cycle.	12	2	6	4
Topic 7. Organization of activities for the validation of production processes and qualification of equipment and auxiliary systems in organizations - entities of the pharmaceutical market. Validation: definition of the concept, objects, types. Validation staffing.	12	2	6	4
Topic 8. Pharmaceutical Quality System Audits.	10	2	4	4
Total: hours	90	20	40	30

5. TOPICS OF LECTURES / SEMINARS / PRACTICAL / LABORATORY CLASSES

5.1. Full-time form of education

5.1.1. Thematic plan of lectures

№	Topic name	Number of hours
1	Topic 1. Evolution of the global development of quality management science and its role in pharmacy	2
2	Topic 2. Regulatory and legal framework for quality management of medicines	4

3	Topic 3. Regulatory bodies of Ukraine in the field of quality management of medicines	2
4	Topic 4. Statistical methods of quality control	2
5	Topic 5. Regulation and documentation of pharmaceutical quality system processes	4
6	Topic 6. Risk assessment for the quality of medicines at all stages of their life cycle	2
7	Topic 7. Organization of activities for the validation of production processes and qualification of equipment and auxiliary systems in organizations - entities of the pharmaceutical market.	2
8	Topic 8. Audits of pharmaceutical quality systems.	2
	Together	20

5.1.2. Seminar topics

Seminars are not provided.

5.1.3. Topics of practical classes

№	Topic name	Number of hours
1	2	3
1	Topic 1. Evolution of the global development of quality management science and its role in pharmacy	4
2	Topic 2. Regulatory and legal framework for quality management of medicines	6
3	Topic 3. Regulatory bodies of Ukraine in the field of quality management of medicines	6
4	Topic 4. Statistical methods of quality control	4
5	Topic 5. Regulation and documentation of pharmaceutical quality system processes	4
6	Topic 6. Risk assessment for the quality of medicines at all stages of their life cycle	6
7	Topic 7. Organization of activities for the validation of production processes and qualification of equipment and auxiliary systems in organizations - entities of the pharmaceutical market	6
8	Topic 8. Audits of pharmaceutical quality systems	4
	Together	40

5.1.14. Topics of laboratory classes

Laboratory classes are not provided.

6. INDEPENDENT WORK OF A HIGHER EDUCATION STUDENT

6.1. Full-time form of education

№	Topic name	Number of hours
1	Topic 1. Evolution of the global development of quality management science and its role in pharmacy	2
2	Topic 2. Regulatory and legal framework for quality management of medicines	4
3	Topic 3. Regulatory bodies of Ukraine in the field of quality management of medicines	4
4	Topic 4. Statistical methods of quality control	4
5	Topic 5. Regulation and documentation of processes of the pharmaceutical quality system	4
6	Topic 6. Risk assessment for the quality of medicines at all stages of their life cycle	4
7	Topic 7. Organization of activities for the validation of production processes and qualification of equipment and auxiliary systems in organizations - entities of the pharmaceutical market	4
8	Topic 8. Audits of pharmaceutical quality systems	4
	<i>Together</i>	30

7. FORMS AND METHODS OF TEACHING

Forms of teaching:

The discipline is taught in the form of practical classes; organization of independent work of the applicant.

Teaching methods:

Lectures: story, explanation, conversation.

Practical classes: conversation, solving situational problems, preparation and presentations of reports, performing tasks on the computer.

Independent work: independent work with a textbook, independent work with a computer.

8. FORMS OF CONTROL AND CRITERIA FOR ASSESSING LEARNING RESULTS

Forms of current control: oral interview, testing, assessment of theoretical skills, solving situational problems, assessment of activity in the lesson.

Forms of final control: credit.

Criteria for assessing the learning results of higher education applicants during current control

Rating	Evaluation criteria
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Perfectly «5»	The applicant is fluent in the material, actively participates in the discussion and solution of a situational clinical problem, confidently demonstrates practical skills during the examination of the patient and the interpretation of clinical, laboratory and instrumental research data, expresses his opinion on the topic of the lesson, and demonstrates clinical thinking.
Good «4»	The applicant has a good command of the material, participates in the discussion and solution of a situational clinical problem, demonstrates practical skills during the examination of the patient and the interpretation of clinical, laboratory and instrumental research data with some errors, expresses his opinion on the topic of the lesson, and demonstrates clinical thinking.
Satisfactorily «3»	The applicant does not have sufficient knowledge of the material, participates uncertainly in the discussion and solution of a situational clinical problem, demonstrates practical skills during the examination of the patient and the interpretation of clinical, laboratory and instrumental research data with significant errors.
Satisfactorily «2»	The applicant does not possess the material, does not participate in the discussion and solution of a situational clinical problem, does not demonstrate practical skills during the examination of the patient and the interpretation of clinical, laboratory and instrumental research data. The applicant does not possess the material, does not participate in the discussion and solution of a situational clinical problem, does not demonstrate practical skills during the examination of the patient and the interpretation of clinical, laboratory and instrumental research data.

A credit is awarded to an applicant who has completed all the tasks of the work program of the academic discipline, actively participated in practical classes, completed and defended an individual assignment and has an average current grade of at least 3.0 and has no academic debt.

The credit is given: in the last lesson before the start of the examination session - in the tape system of study, in the last lesson - in the cyclical system of study. The credit score is the arithmetic mean of all components on a traditional four-point scale and has a value that is rounded using the statistical method to two decimal places.

9. DISTRIBUTION OF POINTS OBTAINED BY HIGHER EDUCATION STUDENTS

Points in the academic discipline for applicants who have successfully completed the program are converted into a traditional four-point scale according to the absolute criteria given in the table:

National assessment for discipline	Total points for the discipline
Perfectly («5»)	185 – 200
Good («4»)	151 – 184
Satisfactorily («3»)	120 – 150
Satisfactorily («2»)	Lower 120

The multi-point scale (200-point scale) characterizes the actual success of each applicant in mastering the academic discipline. The conversion of the traditional assessment into a 200-point one is performed by the University's information and technology department using the "Contingent" program according to the appropriate formula: Average success score (current success in the discipline) x 40.

The ECTS rating scale evaluates the achievements of applicants in the academic discipline

who are studying in the same year of the same specialty, according to the points they received, by ranking, namely:

ECTS grade	Statistical indicator
A	Top 10% of applicants
B	Next 25% of applicants
C	Next 30% of applicants
D	Next 25% of applicants
E	Next 10% of applicants

The ECTS scale establishes the applicant's belonging to the group of the best or worst among the reference group of fellow students (faculty, specialty), that is, his rating. When converting from a multi-point scale, as a rule, the boundaries of the grades "A", "B", "C", "D", "E" do not coincide with the boundaries of the grades "5", "4", "3" according to the traditional scale. The grade "A" on the ECTS scale cannot be equal to the grade "excellent", and the grade "B" - to the grade "good", etc. Applicants who received grades "FX" and "F" ("2") are not included in the list of ranked applicants. Such applicants automatically receive an "E" grade after retaking. The "FX" grade is given to applicants who have scored the minimum number of points for current educational activities, but who have not passed the final test. A grade of "F" is given to students who have attended all classroom classes in the academic discipline, but have not achieved a grade point average (3.00) for their current academic activity and are not admitted to the final examination.

10. METHODOLOGICAL SUPPORT

- Work program of the academic discipline
- Syllabus
- Multimedia presentations
- Methodological developments for lectures
- Methodological developments for practical classes
- Methodological recommendations for independent work of higher education students

List of didactic teaching aids

No. No. pp.	Name of the equipment used.	Name of equipment used. Numbers of topics in which the equipment is used	Notes
1.	Terminal station All topics 30 units	All topics	30 unit
2.	Internet resources of the department All topics 30 units	All topics	30 unit
3.	Software All topics	All topics	
4.	Multimedia projector No. 1-5 1 unit	№ 1-5	1 unit
5.	Lecture presentations (on electronic media) No. 1-5	№ 1-5	

11. QUESTIONS FOR PREPARATION FOR THE FINAL EXAM

1. Basic terms of quality management.
2. Stages of development of quality management in the world.
3. F. Taylor's concept.

4. W. Shewhart's concept.
5. The concept of total quality control (TQC).
6. The concept of quality management within the entire company (CWQC).
7. The concept of total quality management (TQM).
8. The concept of E. Deming.
9. The concept of J. Juran.
10. The concept of Ettinger - Sittig.
11. The concept of G. Tagutti.
12. The concept of F. Crosby.
13. ISO 9000 series standards.
14. ISO 10000 series standards.
15. ISO 13485 standard.
16. ISO 14000 series standards.
17. ISO 19011 standard.
18. . ISO 22000 standard.
19. ISO 26000 standard.
20. SA 8000 standard.
21. UN Global Compact.
22. ISO 27000 series standards.
23. ISO 31000 series standards.
24. ISO 37001 standard.
25. OHSAS 18001 standard
26. ISO 45001 standard.
27. The concept of good pharmaceutical practices (GxP) and their role in quality assurance at all stages of the life cycle of medicines.
28. ICH Q8.
29. Good Laboratory Practice.
30. Good Clinical Practice.
31. Good Regulatory Practice.
32. Good Manufacturing Practice.
33. Good Storage Practice.
34. Good Distribution Practice.
35. Good Pharmacy Practice.
36. Good Pharmacovigilance Practices.
37. ICH Q9.
38. ICH Q10.
39. Integrated Quality Management Systems of Pharmaceutical Organizations.
40. State Pharmacopoeia of Ukraine.
41. Structure of the State System for Regulation of the Circulation of Medicinal Products in Ukraine.
42. Ministry of Health of Ukraine.
43. State Expert Center of the Ministry of Health of Ukraine.
44. Directorate of Pharmaceutical Supply of the Ministry of Health of Ukraine.
45. State Service of Ukraine for Medicines and Drug Control.
46. Certification and licensing as components of the quality system in pharmacy.
47. The essence of statistical methods of quality control.
48. Checklist.
49. Pareto diagram.
50. Ishikawa cause-and-effect diagram.
51. Histogram.
52. Scatter diagram.
53. Control chart.

54. The essence of documenting the quality management system at a pharmaceutical enterprise.
55. Quality manual.
56. Process implementation methods.
57. Third-level quality management system documents.
58. Fourth-level quality management system documents.
59. "Inter-process" documents.
60. Formation of a document management procedure.
61. Quality risk management process.
62. Failure mode and effect analysis (FMEA).
63. Failure Mode, Effects and Criticality Analysis (FMECA).
64. Fault Tree Analysis (FTA).
65. Hazard Analysis and Critical Control Points (HACCP).
66. Hazard Analysis and Performance Analysis (HAZOP).
67. Preliminary Hazard Analysis (PHA).
68. Risk Ranking and Filtering.
69. Validation: Definition, Objects, Types.
70. Validation Staffing.
71. Validation Documentation.
72. Validation of Analytical Methods.
73. Cleaning Validation.
74. Qualification: Definition, Objects.
75. User Requirements Specification (URS).
76. Factory Acceptance Testing (FAT).
77. Installation qualification (IQ).
78. Operation qualification (OQ).
79. Performance qualification (PQ).
80. Concept of audit, classification of audits.
81. Audit criteria and evidence.
82. Principles of auditing.
83. Sequence of work for managing the audit program.
84. Sequence of work for conducting an audit.
85. Audit methods.
86. Follow-up of audit results.

12. RECOMMENDED READING

Basic literature

1. DSTU ISO 9000:2015 (ISO 9000:2015, IDT). Quality management systems. Basic provisions and glossary of terms. Kyiv, SE "UkrNDNTS", 2016.
2. DSTU ISO 9001:2015 (ISO 9001:2015, IDT). Quality management systems. Requirements. Kyiv, SE "UkrNDNTS", 2016.
3. DSTU ISO/TS 9002:2017 (ISO/TS 9002:2016, IDT). Quality management systems. Guidelines for the application of ISO 9001:2015. Kyiv, SE "UkrNDNTS", 2019.
4. DSTU ISO 9004:2018 (ISO 9004:2018, IDT). Quality management. Organizational quality. Guidelines for achieving sustainable success. Kyiv, SE "UkrNDNC", 2019.
5. DSTU ISO 10005:2019 (ISO 10005:2018, IDT). Quality management. Guidelines for quality programs. Kyiv, SE "UkrNDNC".
6. DSTU ISO 10006:2018 (ISO 10006:2017, IDT). Quality management. Guidelines for quality management in projects. Kyiv, SE "UkrNDNC", 2019.
7. DSTU ISO 10007:2018 (ISO 10007:2017, IDT). Quality management. Guidelines for configuration management. Kyiv, SE "UkrNDNC".

8. DSTU ISO/TR 10013:2003 (ISO/TR 10013:2001, IDT). Guidelines for the development of quality management system documentation. Kyiv, State Enterprise "UkrNDNTs".
9. DSTU ISO 10014:2008 (ISO 10014:2008, IDT). Quality management. Guidelines for the realization of financial and economic benefits. Kyiv, State Consumer Standard of Ukraine, 2008.
10. DSTU ISO 10015:2021 (ISO 10015:2019, IDT). Quality management. Guidelines for competence management and personnel development. Kyiv, State Enterprise "UkrNDNTs".
11. DSTU ISO/TR 10017:2005 (ISO/TR 10017:2003, IDT). Guidelines for the application of statistical methods in accordance with ISO 9001:2000. Kyiv, State Committee for Consumer Protection of Ukraine, 2007.
12. DSTU ISO 10018:2021 (ISO 10018:2020, IDT). Quality management. Guidelines for personnel recruitment. Kyiv, State Enterprise "UkrNDNTs".
13. DSTU-N ISO 10019:2007 (ISO 10019:2005, IDT) Guidelines for the selection of consultants and the use of their services. Kyiv, State Committee for Consumer Protection of Ukraine, 2008.
14. DSTU EN ISO 13485:2018 (EN ISO 13485:2016, IDT). Medical devices. Quality management system. Requirements for regulation. State Enterprise "UkrNDNTs".
15. DSTU ISO 14001:2015 (ISO 14001:2015, IDT). Environmental management systems. Requirements and application guidelines. Kyiv, SE "UkrNDNC".
16. DSTU ISO 19011:2019 (ISO 19011:2018, IDT). Guidelines for conducting audits of management systems. Kyiv, SE "UkrNDNC".
17. DSTU ISO 22000:2019 (ISO 22000:2018, IDT). Food safety management systems. Requirements for any organization in the food chain. Kyiv, SE "UkrNDNC".
18. DSTU ISO 26000:2019 (ISO 26000:2010, IDT). Guidelines for social responsibility. Kyiv, SE "UkrNDNC".
19. DSTU ISO/IEC 27001:2023 (ISO/IEC 27001:2022, IDT) Information security, cybersecurity and privacy protection. Information security management systems. Requirements. Kyiv, SE "UkrNDNTS".
20. International standard SA8000:2001 Social responsibility.
21. DSTU ISO 31000:2018 (ISO 31000:2018, IDT). Risk management. Principles and guidelines. Kyiv, SE "UkrNDNTS".
22. DSTU EN IEC 31010:2022 (EN IEC 31010:2019, IDT; IEC 31010:2019, IDT). Risk management - risk assessment methods. Kyiv, SE "UkrNDNTS".
23. DSTU ISO 37001:2018 (ISO 37001:2016, IDT). Management systems for combating corruption. Requirements and guidelines for application. Kyiv, SE "UkrNDNTS", 2019.
24. DSTU ISO 45001:2019 (ISO 45001:2018, IDT). Occupational health and safety management systems. Requirements and guidelines for application. Kyiv, SE "UkrNDNTS".
25. DSTU OHSAS 18002:2015 (OHSAS 18002:2008, IDT). Occupational health and safety management systems. Basic principles for implementing OHSAS 18001:2007 requirements. Kyiv, SE "UkrNDNTS".
26. Guideline ST-N MOZU 42-3.0:2011 Medicinal products. Pharmaceutical development (ICH Q8). Kyiv, Ministry of Health of Ukraine, 2011.
27. Guideline ST-N MOZU 42-6.0:2008 Medicinal products. Good laboratory practice. Kyiv, Ministry of Health of Ukraine, 2009.
28. Guideline ST-N MOZU 42-6.0:2014 Medicinal products. Preclinical safety studies as a basis for clinical trials with human participation and registration of medicinal products (ICH M3(R2)). Kyiv, Ministry of Health of Ukraine, 2014.
29. Guideline ST-N MOZU 42-7.0:2008 Medicinal products. Good clinical practice. Kyiv, Ministry of Health of Ukraine, 2009.
30. Guideline ST-N MOZU 42-7.4:2022 Medicinal products. Bioequivalence studies. Kyiv, Ministry of Health of Ukraine, 2022.
31. Guideline ST-N MOZU 42-4.0:2020 Medicinal products. Good manufacturing practice.

- Kyiv, Ministry of Health of Ukraine, 2020.
32. Guideline ST-N MOZU 42-5.1:2011 Medicinal products. Good storage practice. Kyiv, Ministry of Health of Ukraine, 2011.
 33. Guideline ST-N MOZU 42-5.0:2014 Medicinal products. Good distribution practice. Kyiv, Ministry of Health of Ukraine, 2014.
 34. Good pharmacy practice: Quality standards for pharmacy services (Joint IFF/WHO guideline with NAP) WHO; Standard, International document dated 01.01.2011.
 35. Guideline ST-N MOZU 42-1.1:2013 Medicinal products. Good regulatory practice. Kyiv, Ministry of Health of Ukraine, 2013.
 36. Guideline ST-N MOZU 42-8.5:2015 Medicinal products. Good pharmacovigilance practices. Kyiv, Ministry of Health of Ukraine, 2015.
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2. Lebedynets V. O. Methodology for assessing the effectiveness of processes of quality management systems of manufacturing pharmaceutical enterprises. Management, economics and quality assurance in pharmacy. 2017. No. 2 (50). P. 11–18.
3. Trokhymchuk V. V., Ubogov S. G. Scientific and practical approaches to the formation of integrated management systems at wholesale and retail pharmaceutical enterprises. Medicines of Ukraine Plus. 2018. No. 2 (35). P. 29–33.
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5. Karamavrova T. V., Lebedynets V. O., Plyaka L. V. Determination of approaches to assessing the personal qualities of auditors of pharmaceutical systems. Social Pharmacy in Health Care. 2018. No. 4 (03). P. 1–9.
6. Lebedynets V. O. Chornyi D. S. Validation of computerized systems of the importer and distributor of medicines. Quality management in pharmacy: materials of the 12th scientific-practical conference, Kharkiv, May 18. 2018 – Kh.: NUPh, 2018. – P. 221–229.
7. Lebedynets V. O. Determination of the main measures for the development of a quality management system for a distribution pharmaceutical company. Management and marketing as part of modern economy, science, education, practice: collection of scientific papers of the annual V international scientific and practical distance conference, Kharkiv, March 30–31, 2017 – Kh.: NUPh, 2017. – P. 50–59.

13. Electronic information resources

1. International Organization for Standardization (ISO) Access mode: <https://www.iso.org/home.html>
2. International Council for Harmonization of Technical Requirements for Medicinal Products for Human Use (ICH) – Access mode: <https://www.ich.org/>
3. European Medicines Agency (EMA) – Access mode: <https://www.ema.europa.eu/en/>
4. European Directorate for the Quality of Medicines and Health Protection (EDQM) – Access mode: <https://www.edqm.eu/en/>
5. Legislation of Ukraine – Access mode: <https://zakon.rada.gov.ua/laws/>
6. Normative and directive documents of the Ministry of Health of Ukraine – Access mode: <https://moz.gov.ua/>

7. State Enterprise “State Expert Center of the Ministry of Health of Ukraine” – Access mode: <https://www.dec.gov.ua/>
8. State Service of Ukraine for Medicines and Drug Control (State Service) – Access mode: <https://www.dls.gov.ua/>
9. State Enterprise "Ukrainian Scientific Pharmacopoeial Center for the Quality of Medicines" - Access mode: <https://sphu.org/viddil-dfu>