MINISTRY OF HEALTHCARE OF UKRAINE

ODESSA NATIONAL MEDICAL UNIVERSITY

Department of General and Clinical Pharmacology and Pharmacognosy

APPROVED

Vice-rector for scientific and pedagogical activity

_____ Eduard BURIACHKIVSKYI

«28» 08 2023 y.

WORKING PROGRAM ON THE DISCIPLINE MC 41 "QUALITY SYSTEMS IN PHARMACY"

Level of higher education: second (master's)

Field of knowledge: 22 "Healthcare"

Specialty: 226 "Pharmacy, Industrial Pharmacy"

Educational-professional program: Pharmacy, Industrial Pharmacy

2023–2024

The working program is developed based on the educational-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" in the field of knowledge 22 "Healthcare", approved by the Academic Council of the Odessa National Medical University (protocol No. 8 dated June 29, 2023).

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The working program has been discussed at the meeting of the Department of General and Clinical Pharmacology and Pharmacognosy (protocol No. 1 from "28" 08 2023y.).

Head of the department _____ Yaroslav ROZHKOVSKYI

Approved by a guarantor of the EPP _____ Liana UNHURIAN

The working program has been approved at the meeting of the subject cycle methodical commission on pharmaceutical disciplines of ONMedU.
Protocol No. __ dated "__" _____ 20__y.

Head of the subject cycle methodical commission
on pharmaceutical disciplines of ONMedU _____ Natalia FIZOR

Reviewed and approved at the department meeting. _____
Protocol No. __ dated "___" _____ 20__ y.

Head of the department _____ (_____)
(signature) *(Name, SURNAME)*

Reviewed and approved at the department meeting. _____
Protocol No. __ dated "___" _____ 20__ y.

Head of the department _____ (_____)
(signature) *(Name, SURNAME)*

1. Description of the discipline

Name of indicators	Field of knowledge, specialty, specialization, level of high education	Characteristics of the discipline
Total: Credits: 3 Hours: 90 Content modules: 1	Field of knowledge 22 “Healthcare” Specialty 226 “Pharmacy, Industrial Pharmacy” Level of higher education second (master’s)	*Day-time study* *Obligatory discipline*
		Year of study V
		Semester X
		Lectures – 20 hours
		Practical classes – 30 hours
		Self-study classes – 40 hours
		including individual tasks – 0 hours
		Form of final control – credit

2. Goal and objectives of the educational discipline, competencies, program learning outcomes

Goal: to develop theoretical knowledge and practical skills in higher education students regarding the application of general principles and basic methods of development, implementation, maintenance, and improvement of Quality Management Systems (QMS) in pharmaceutical enterprises/organizations in accordance with the provisions of international standards, Good Pharmaceutical Practices (GxP), and other industry regulations.

Objectives: to familiarize higher education students with the regulatory framework for quality management of medicinal products, to provide systemic knowledge and practical skills in developing quality systems in pharmacy, in quality management activities conducted throughout the lifecycle of medicinal products, in drafting corrective and preventive action plans to address non-conformities and optimize QMS processes, and in preparing and conducting QMS audits.

The process of studying the discipline is aimed at developing elements of the following **competencies**:

– general competencies (GC):

GC01. Ability for abstract thinking, analysis, and synthesis, readiness to learn and be up-to-date.

GC02. Knowledge and understanding of the subject area and awareness of professional activities.

GC04. Ability to communicate in English at a level that ensures effective professional activity.

GC05. Ability to assess and ensure the quality of work performed.

GC06. Ability to work in a team.

GC08. Ability to preserve and enhance moral, cultural, and scientific values and achievements of society based on understanding the history and patterns of development of the subject area, its place in the general system of knowledge about nature and society, and in the development of society, technology, and technologies, to use various types and forms of physical activity for active recreation and maintaining a healthy lifestyle.

GC09. Ability to use information and communication technologies.

GC10. Ability to act socially responsibly and consciously.

GC11. Ability to apply knowledge in practical situations.

GC13. Ability to show initiative and entrepreneurship.

GC15. Knowledge and understanding of the subject area and understanding of professional activities.

GC16. Ability to conduct experimental research at an appropriate level.

– specialized competencies (SC):

SC02. Ability to collect, interpret, and apply data necessary for professional activities, conducting research, and implementing innovative projects in the field of pharmacy.

SC03. Ability to solve pharmaceutical problems in new or unfamiliar environments with incomplete or limited information, taking into account social and ethical aspects of responsibility.

SC04. Ability to clearly and unambiguously convey own knowledge, conclusions, and arguments in the field of pharmacy to professionals and non-professionals, including learners.

SC12. Ability to ensure proper storage of medicinal products of natural and synthetic origin and other pharmaceutical goods according to their physico-chemical properties and the rules of Good Storage Practice (GSP) in healthcare facilities.

SC13. Ability to organize the operation of a pharmacy to provide the population, healthcare facilities with medicinal products and other pharmaceutical goods, and implement appropriate reporting and accounting systems, conducting product analysis, administrative management in accordance with pharmaceutical legislation requirements.

SC17. Ability to carry out pharmaceutical development and participate in the production of medicinal products of natural and synthetic origin in pharmaceutical enterprises according to Good Manufacturing Practice (GMP) requirements.

SC19. Ability to organize and conduct quality control of medicinal products of natural and synthetic origin according to the requirements of the current edition of the State Pharmacopoeia, methods of quality control (MQC), technological instructions, etc.; prevent the spread of counterfeit, falsified, and unregistered medicinal products.

SC20. Ability to develop and evaluate quality control methods for medicinal products of natural and synthetic origin, including active pharmaceutical ingredients, medicinal plant raw materials, and excipients, using physical, chemical, physico-chemical, biological, microbiological, and pharmacotechnological methods; conduct standardization of medicinal products in accordance with current requirements.

SC24. Ability to use knowledge of regulatory, legislative acts, and recommendations of Good Pharmaceutical Practices in professional activities.

SC25. Ability to demonstrate and apply communication skills, fundamental principles of pharmaceutical ethics and deontology, based on moral obligations and values, ethical norms of professional behavior, and responsibility according to WHO guidelines.

SC26. Ability to organize and participate in the production of medicinal products in pharmaceutical enterprises, including selection and justification of the technological process, equipment in accordance with Good Manufacturing Practice (GMP) requirements with appropriate development and documentation. Determining the stability of medicinal products.

SC27. Ability to organize and conduct the procurement of medicinal plant raw materials in accordance with the rules of Good Agricultural and Collection Practices (GACP) as a guarantee of the quality of medicinal plant raw materials and medicinal products based on it.

SC29. Ability to develop and implement a Quality Management System for pharmaceutical enterprises according to current standards, conduct quality audits, and risk management for pharmaceutical product quality.

Program learning outcomes (PLO):

PLO01. Possess and apply specialized conceptual knowledge in the field of pharmacy and related areas, taking into account modern scientific achievements.

PLO02. Critically analyze scientific and applied problems in the field of pharmacy.

PLO03. Have specialized knowledge and skills for solving professional problems and tasks, including further development of knowledge and procedures in the field of pharmacy.

PLO04. Communicate fluently in English, orally and in writing, to discuss professional issues and activity results, present scientific research, and innovative projects.

PLO05. Evaluate and ensure the quality and effectiveness of activities in the field of pharmacy.

PLO06. Develop and make effective decisions to solve complex pharmacy tasks personally and through collaborative discussion; formulate goals for personal and collective activities considering social and production interests, overall strategy, and existing constraints, and determine optimal ways to achieve these goals.

PLO08. Develop and implement innovative projects in the field of pharmacy, as well as relevant interdisciplinary projects, considering technical, social, economic, ethical, legal, and environmental aspects.

PLO09. Formulate, argue, clearly and specifically convey to professionals and non-professionals, including higher education students, information based on own knowledge and professional experience, on the main trends in the development of world pharmacy and related fields.

PLO11. Identify the advantages and disadvantages of natural and synthetic medicinal products of different pharmacological groups, taking into account their chemical, physicochemical, biopharmaceutical, pharmacokinetic, and pharmacodynamic characteristics, as well as the type of dosage form. Recommend medicinal products and other pharmacy items to consumers, providing advisory assistance and pharmaceutical care.

PLO13. Record cases of adverse effects when using natural and synthetic medicinal products; evaluate factors that may affect the processes of absorption, distribution, deposition, metabolism, and excretion of medicinal products, determined by the condition and characteristics of the human body and the pharmaceutical characteristics of the medicinal products.

PLO22. Ensure and carry out quality control of natural and synthetic medicinal products and document their results; issue certificates of quality and analysis taking into account the requirements of the current edition of the State Pharmacopoeia, methods of quality control (MQC), technological instructions, etc.; take measures to prevent the spread of substandard, counterfeit, and unregistered medicinal products.

PLO23. Determine the basic chemico-pharmaceutical characteristics of natural and synthetic medicinal products; select and/or develop quality control methodologies to standardize them using physical, chemical, physicochemical, biological, microbiological, and pharmacotechnological methods according to current requirements.

PLO24. Engage in professional activities based on humanistic and ethical principles; identify future professional activities as socially significant for human health.

PLO25. Adhere to sanitary and hygiene regulations and safety requirements when performing professional activities.

PLO26. Argue information for decision-making, take responsibility for them in standard and non-standard professional situations; adhere to the principles of deontology and ethics in professional activities.

PLO27. Perform professional activities using creative methods and approaches.

PLO28. Conduct professional communication in the state language, utilize oral communication skills in a foreign language, analyze texts of a professional nature, and translate information from foreign sources.

PLO29. Engage in professional activities using information technologies, databases, navigation systems, Internet resources, software tools, and other information and communication technologies.

PLO30. Adhere to communication norms in professional interaction with colleagues, management, consumers, and effectively work in a team.

PLO31. Utilize methods for assessing performance indicators; identify reserves for increasing work efficiency.

PLO32. Analyze information obtained from scientific research, generalize, systematize, and use it in professional activities.

PLO34. Utilize data from clinical, laboratory, and instrumental studies to monitor the effectiveness and safety of pharmaceuticals.

PLO36. Plan and implement professional activities based on the regulatory framework and recommendations of relevant pharmaceutical practices.

PLO37. Promote health preservation, including disease prevention, rational prescribing and use of medicines. Conscientiously fulfill professional duties, adhere to legislation regarding the promotion and advertising of pharmaceuticals. Possess psychological communication skills to establish trust and mutual understanding with colleagues, physicians, patients, and consumers.

PLO40. Ensure quality control of pharmaceuticals and document the results. Implement quality risk management at all stages of the pharmaceutical product lifecycle.

As a result of studying the discipline, the higher education students:

–……. should know:

– methods of implementing knowledge in solving practical issues;
– normative-legal and legislative framework of regulating requirements for professional activities;
– modern trends in the industry's development and analysing the features of the contemporary professional environment and professional activities;
– modern information and communication technologies;
– principles of organizing quality management systems in pharmacy;
– structure and functions of regulatory bodies in Ukraine in the field of pharmaceutical quality management;
– statistical methods in quality management of production processes in pharmacy;
– principles of regulating and documenting processes of the pharmaceutical quality system;
– risk management methods for the quality of medicinal products;
– principles of organizing activities for validation of production processes and qualification of equipment and auxiliary systems in organizations – subjects of the pharmaceutical market;
– principles of conducting QMS audits.

–…… should be able to:

– apply professional knowledge to solve practical issues;
– conduct analysis of professional information, make informed decisions, acquire contemporary knowledge;
– demonstrate initiative, engage in constant search for new opportunities beyond existing resources, engage in self-development and self-realization;
– engage in professional activities that require knowledge updating and integration;
– utilize modern information and communication technologies in practical activities;
– develop, implement, maintain, and improve QMS of pharmaceutical enterprises/organizations;
– apply statistical methods in quality management of production processes in pharmacy;
– document processes of pharmaceutical quality systems;
– apply risk management methods for the quality of pharmaceuticals;
– implement validation of production processes and qualification of equipment and auxiliary systems in organizations operating in the pharmaceutical market;
– conduct QMS audits.

3. Content of the discipline

Content module 1. The regulatory framework for quality management systems of pharmaceutical enterprises/organizations.

Topic 1. The evolution of the global development of quality management science and its role in pharmacy.

Key terms of quality management. Stages of quality management development worldwide. The concept of F. Taylor. The concept of W. Shewhart. Total Quality Control (TQC) concept. Company-Wide Quality Control (CWQC) concept. Total Quality Management (TQM) concept. The concept of E. Deming. The concept of J. Juran. The concept of Ettinger – Sittig. The concept of G. Taguchi. The concept of F. Crosby.

Topic 2. Regulatory framework for quality management of medicinal products.

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. Good Pharmaceutical Practices (GxP) concept and their role in ensuring quality at all stages of the life cycle of medicinal products. ICH Q8. Good Laboratory Practice. Good Clinical Practice. Good Regulatory Practice. Good Manufacturing Practice. Good Storage Practice. Good Distribution Practice. Good Pharmacy Practice. Pharmacovigilance Practices. ICH Q9. ICH Q10. Integrated Quality Management Systems for Pharmaceutical Organizations. State Pharmacopoeia of Ukraine.

Topic 3. Regulatory authorities of Ukraine in the field of quality management of medicinal products.

Structure of the state regulatory system for the circulation of medicinal products in Ukraine. The Ministry of Health of Ukraine. The State Expert Center of the Ministry of Health of Ukraine. The Directorate of Pharmaceutical Provision of the Ministry of Health of Ukraine. The State Service of Ukraine on Medicines and Drugs Control. Certification and licensing as components of the quality system in pharmacy.

Topic 4. Statistical methods of quality control.

Essence of statistical methods of quality control. Check sheet. Pareto chart. Ishikawa Cause and Effect Diagram. Histogram. Scatter diagram. Control chart. Stratification.

Topic 5. Regulation and documentation of pharmaceutical quality management processes.

The essence of documenting the quality management system at a pharmaceutical enterprise. Quality manual. Process execution methodologies. Third-level quality management system documents. Fourth-level quality management system documents. "Inter-process" documents. Formulating the document control procedure.

Topic 6. Risk assessment for the quality of medicinal products at all stages of their lifecycle.

The process of quality risk management. 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 and Operability Analysis (HAZOP). Preliminary Hazard Analysis (PHA). Ranking and filtering of risks.

Topic 7. Organization of activities for validating production processes and qualifying equipment and auxiliary systems in organizations that are pharmaceutical market entities.

Validation: definition of concepts, objects, types. Validation staffing. Validation documents. Validation of analytical methods. Cleaning validation. Qualification: definition of concepts, objects. User Requirement Specification (URS). Design qualification (DQ). Factory Acceptance Testing (FAT) / Site Acceptance Testing (SAT). Installation qualification (IQ). Operational qualification (OQ). Performance qualification (PQ).

Topic 8. Audits of pharmaceutical quality systems.

Concept of audit. Classification of audits. Audit criteria. Audit evidence. Principles of auditing. Process flow for the management of an audit programme. Audit methods. Process flow for the performing an audit. Conducting audit follow-up.

4. The structure of the discipline

Title of the topic	Number of hours			
	Total	including		
		lectures	practical classes	self-study classes
Content module 1. The regulatory framework for quality management systems of pharmaceutical enterprises/organizations.				
Topic 1. The evolution of the global development of quality management science and its role in pharmacy	12	2	4	6
Topic 2. Regulatory framework for quality management of medicinal products	18	6	4	8
Topic 3. Regulatory authorities of Ukraine in the field of quality management of medicinal products	12	2	4	6
Topic 4. Statistical methods of quality control	8	2	2	4
Topic 5. Regulation and documentation of pharmaceutical quality management processes	10	2	4	4
Topic 6. Risk assessment for the quality of medicinal products at all stages of their lifecycle	10	2	4	4
Topic 7. Organization of activities for validating production processes and qualifying equipment and auxiliary systems in organizations that are pharmaceutical market entities	10	2	4	4
Topic 8. Audits of pharmaceutical quality systems	10	2	4	4
Total with content module 1	*90*	*20*	*30*	*40*
Individual tasks				*0*
Total hours	**90**	**20**	**30**	**40**

5. Topics of lectures / seminars / practical / laboratory classes

5.1. Topics of lectures classes

No.	Title of the topic	Number of hours
1	**2**	**3**
1	Topic 1. The evolution of the global development of quality management science and its role in pharmacy	2
2	Topic 2. Regulatory framework for quality management of medicinal products	6
3	Topic 3. Regulatory authorities of Ukraine in the field of quality management of medicinal products	2
4	Topic 4. Statistical methods of quality control	2
5	Topic 5. Regulation and documentation of pharmaceutical quality management processes	2

1	2	3
6	Topic 6. Risk assessment for the quality of medicinal products at all stages of their lifecycle	2
7	Topic 7. Organization of activities for validating production processes and qualifying equipment and auxiliary systems in organizations that are pharmaceutical market entities	2
8	Topic 8. Audits of pharmaceutical quality systems	2
	Total	**20**

5.2. Topics of seminars classes

Seminars classes are not provided.

5.3. Topics of practical classes

No.	Title of the topic	Number of hours
1	Topic 1. The evolution of the global development of quality management science and its role in pharmacy	4
2	Topic 2. Regulatory framework for quality management of medicinal products	4
3	Topic 3. Regulatory authorities of Ukraine in the field of quality management of medicinal products	4
4	Topic 4. Statistical methods of quality control	2
5	Topic 5. Regulation and documentation of pharmaceutical quality management processes	4
6	Topic 6. Risk assessment for the quality of medicinal products at all stages of their lifecycle	4
7	Topic 7. Organization of activities for validating production processes and qualifying equipment and auxiliary systems in organizations that are pharmaceutical market entities	4
8	Topic 8. Audits of pharmaceutical quality systems	4
	Total	**30**

5.4. Topics of laboratory classes

Laboratory classes classes are not provided.

6. Self-study classes of the higher education students

No.	Title of the topic	Number of hours
1	**2**	**3**
1	Topic 1. The evolution of the global development of quality management science and its role in pharmacy	6
2	Topic 2. Regulatory framework for quality management of medicinal products	8
3	Topic 3. Regulatory authorities of Ukraine in the field of quality management of medicinal products	6
4	Topic 4. Statistical methods of quality control	4

1	2	3
5	Topic 5. Regulation and documentation of pharmaceutical quality management processes	4
6	Topic 6. Risk assessment for the quality of medicinal products at all stages of their lifecycle	4
7	Topic 7. Organization of activities for validating production processes and qualifying equipment and auxiliary systems in organizations that are pharmaceutical market entities	4
8	Topic 8. Audits of pharmaceutical quality systems	4
Individual tasks		0
	Total	**40**

7. Teaching methods

During the study of the discipline, the main organizational forms of teaching are: lectures, practical classes, self-study classes. The following teaching methods are applied:

- *according to the type of cognitive activity:* analytical, synthetic, inductive, deductive;
- *according to the main stages of the process:* formation of knowledge, application of knowledge, generalization, consolidation, verification;
- *based on a systemic approach:* stimulation and motivation; control and self-control;
- *based on sources of knowledge:* verbal – narration, explanation, conversation;
- *based on the level of independent cognitive activity:* problem-solving; partially exploratory; research-oriented;
- *based on interactivity:* skill development, situational tasks, simulation of professional activities, testing.

8. Methods of control and evaluation (including criteria for evaluating learning outcomes)

Current control	
The current control is conducted during practical classes. The form of assessment of current educational activities includes monitoring the theoretical and practical preparation of higher education students, which is carried out through oral questioning, testing, and evaluation of practical tasks. The results of current control serve as an indicator of the level of assimilation of the educational program by higher education students and the completion of self-study. For each topic the higher education student receives a grade on the traditional (4-point) scale, taking into account the approved criteria.	
Verification of learning outcomes	*Criteria for passing*
Assessment of oral response	**5** – The higher education student demonstrates systematic, deep knowledge within the requirements of the working program, provides comprehensive, accurate, and clear answers without any leading questions. **4** – The higher education student knows the main points of the study material, provides correct answers to questions, although not exhaustive, but answers without mistakes to additional questions. **3** – The higher education student has a satisfactory level of knowledge of the basic points of the study material, unable to independently provide a clear and concise answer to

	questions, but answers correctly to leading questions. **2** – The higher education student lacks mastery of the study material, with vague understanding of the subject matter.
Assessment of test control	**5** – 91–100 % correct answers **4** – 90–71 % correct answers **3** – 70–60,5 % correct answers **2** – Less than 60,5 % correct answers
Assessment of practical task performance	**5** – The higher education student independently and correctly performs practical tasks, utilizes sources of information and necessary materials independently. **4** – The higher education student executes the main aspects and tasks of the practical task, may make inaccuracies during task execution, and works with the necessary materials with the assistance of the teacher. **3** – The higher education student only performs individual assignments of the practical task, lacks the skills necessary for completing the practical task. **2** – The higher education student does not know how to execute practical tasks, lacks clear understanding of the subject matter and the necessary skills for completing the practical task.

Final control	
The final control involves evaluating the assimilation of educational material by higher education students solely based on the results of their performance in specific types of tasks during practical classes and self-study classes. The final control is conducted during the last session of the discipline before the start of the examination period. The final control for the discipline is determined based on the results of current control and is expressed on a binary categorical scale: “credited” or “not credited”.	
Conditions for admission to the final control	Only those higher education students who have fulfilled the requirements of the working program of the discipline are admitted to the final assessment, namely: higher education students who have no academic debts and who have obtained an average grade of at least 3.00 for their current educational activities are eligible. The average grade is calculated based on the grades obtained by the higher education student on the traditional (4-point) scale during the study of the discipline, by calculating the arithmetic mean rounded to two decimal places.
Type of final control	*Criteria for passing*
Credit	«Credited»: average grade ≥ 3,00 «Not credited»: average grade < 3,00

9. Distribution of points received by higher education students

The final control grade (average grade on the traditional scale) of the discipline for higher education students who have successfully mastered the working program of the discipline is converted into points on a multi-point (200-point) scale as follows:

Grade on the traditional scale	*Points on the multi-point scale*
Excellent («5»)	185 – 200
Good («4»)	151 – 184
Satisfactory («3»)	120 – 150
Unsatisfactory («2»)	Below 120

The multi-point scale characterizes the actual success of each higher education student in mastering the educational component. Conversion of the grade on the traditional scale into points on the multi-point scale is carried out by the Information Technology Department of the Odessa National Medical University.

According to the obtained scores on the 200-point scale, the achievements of higher education students are assessed according to the ECTS grading scale. Further ranking according to the ECTS grading scale allows evaluating the achievements of higher education students in the educational component, who study in the same course of the same specialty, based on the scores they obtained.

The ECTS scale is a relative-comparative grading scale that determines the belonging of a higher education student to the group of better or worse performers among the reference group of peers (faculty, specialty). The grade "A" on the ECTS scale cannot equate to the grade "excellent", and the grade "B" cannot equate to the grade "good", and so on. When converting from the multi-point scale, the boundaries of grades "A", "B", "C", "D" and "E" on the ECTS scale do not coincide with the boundaries of grades "5", "4", "3" on the traditional scale. Higher education students who receive grades "FX" and "F" ("2") are not included in the ranked list of higher education students. The grade "FX" is given to higher education students who have earned the minimum number of points for current educational activities but have not passed the final assessment. The grade "F" is given to higher education students who have attended all classes in the discipline but have not achieved the average grade (3.00) for current educational activities and are not admitted to the final control.

Higher education students studying in the same course (same specialty) are ranked based on the number of points earned in the discipline according to the ECTS scale as follows:

Grade on the ECTS scale	***Statistical indicator***
A	The best 10% of higher education students
B	The next 25% of higher education students
C	The next 30% of higher education students
D	The next 25% of higher education students
E	The next 10% of higher education student

10. Methodological resources

- Methodical instructions for lectures.
- Methodical instructions for practical classes.
- Methodical instructions for self-study classes.
- Instructional and methodological materials for current and final control (database of test tasks, list of tasks for control practical skills and theoretical knowledge during practical classes).

11. Questions for preparation for the final control

1. Key terms of quality management.
2. Stages of quality management development worldwide.
3. The concept of F. Taylor.
4. The concept of W. Shewhart.
5. Total Quality Control (TQC) concept.
6. Company-Wide Quality Control (CWQC) concept.
7. Total Quality Management (TQM) concept.
8. The concept of E. Deming.
9. The concept of J. Juran.
10. The concept of Ettinger – Sittig.
11. The concept of G. Taguchi.
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. Good Pharmaceutical Practices (GxP) concept and their role in ensuring quality at all stages of the life cycle of medicinal products.
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. Pharmacovigilance Practices.
37. ICH Q9.
38. ICH Q10.
39. Integrated Quality Management Systems for Pharmaceutical Organizations.
40. State Pharmacopoeia of Ukraine.
41. Structure of the state regulatory system for the circulation of medicinal products in Ukraine.
42. The Ministry of Health of Ukraine.
43. The State Expert Center of the Ministry of Health of Ukraine.
44. The Directorate of Pharmaceutical Provision of the Ministry of Health of Ukraine.
45. The State Service of Ukraine on Medicines and Drugs Control.
46. Certification and licensing as components of the quality system in pharmacy.
47. Essence of statistical methods of quality control.
48. Check sheet.

49. Pareto chart.
50. Ishikawa Cause and Effect Diagram.
51. Histogram.
52. Scatter diagram.
53. Control chart.
54. Stratification.
55. The essence of documenting the quality management system at a pharmaceutical enterprise.
56. Quality manual.
57. Process execution methodologies.
58. Third-level quality management system documents.
59. Fourth-level quality management system documents.
60. "Inter-process" documents.
61. Formulating the document control procedure.
62. The process of quality risk management.
63. Failure Mode and Effects Analysis (FMEA).
64. Failure Mode, Effects, and Criticality Analysis (FMECA).
65. Fault Tree Analysis (FTA).
66. Hazard Analysis and Critical Control Points (HACCP).
67. Hazard and Operability Analysis (HAZOP).
68. Preliminary Hazard Analysis (PHA).
69. Ranking and filtering of risks.
70. Validation: definition of concepts, objects, types.
71. Validation staffing.
72. Validation documents.
73. Validation of analytical methods.
74. Cleaning validation.
75. Qualification: definition of concepts, objects.
76. User Requirement Specification (URS).
77. Design qualification (DQ).
78. Factory Acceptance Testing (FAT) / Site Acceptance Testing (SAT).
79. Installation qualification (IQ).
80. Operational qualification (OQ).
81. Performance qualification (PQ).
82. Concept of audit, classification of audits.
83. Audit criteria and audit evidence.
84. Principles of auditing.
85. Process flow for the management of an audit programme.
86. Audit methods.
87. Process flow for the performing an audit.
88. Conducting audit follow-up.

12. Recommended literature

Basic literature

1. ISO 9000:2015 Quality management systems — Fundamentals and vocabulary.
2. ISO 9001:2015 Quality management systems — Requirements.
3. ISO/TS 9002:2016 Quality management systems — Guidelines for the application of ISO 9001:2015.
4. ISO 9004:2018 Quality management — Quality of an organization — Guidance to achieve sustained success.

5. ISO 10001:2018 Quality management — Customer satisfaction — Guidelines for codes of conduct for organizations.
6. ISO 10002:2018 Quality management — Customer satisfaction — Guidelines for complaints handling in organizations.
7. ISO 10003:2018 Quality management — Customer satisfaction — Guidelines for dispute resolution external to organizations.
8. ISO 10004:2018 Quality management — Customer satisfaction — Guidelines for monitoring and measuring.
9. ISO 10005:2018 Quality management — Guidelines for quality plans.
10. ISO 10006:2017 Quality management — Guidelines for quality management in projects.
11. ISO 10007:2017 Quality management — Guidelines for configuration management.
12. ISO 10012:2003 Measurement management systems — Requirements for measurement processes and measuring equipment.
13. ISO 10013:2021 Quality management systems — Guidance for documented information.
14. ISO 10014:2021 Quality management systems — Managing an organization for quality results — Guidance for realizing financial and economic benefits.
15. ISO 10015:2019 Quality management — Guidelines for competence management and people development.
16. ISO/TR 10017:2021 Quality management – Guidance on statistical techniques for ISO 9001:2015.
17. ISO 10018:2020 Quality management — Guidance for people engagement.
18. ISO 10019:2005 Guidelines for the selection of quality management system consultants and use of their services.
19. EN ISO 13485:2016/A11:2021 Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2016).
20. ISO 14001:2015 Environmental management systems — Requirements with guidance for use.
21. ISO 14004:2016 Environmental management systems — General guidelines on implementation.
22. ISO 14050:2020 Environmental management — Vocabulary.
23. ISO 19011:2018 Guidelines for auditing management systems.
24. ISO 22000:2018 Food safety management systems — Requirements for any organization in the food chain.
25. ISO 26000:2010 Guidance on social responsibility.
26. Social Accountability 8000:2014 Standard.
27. ISO/IEC 27000:2018 Information technology — Security techniques — Information security management systems — Overview and vocabulary.
28. ISO/IEC 27001:2022 Information security, cybersecurity and privacy protection — Information security management systems — Requirements.
29. ISO/IEC 27002:2022 Information security, cybersecurity and privacy protection — Information security controls.
30. ISO 31000:2018 Risk management — Guidelines.
31. IES 31010:2019 Risk management — Risk assessment techniques.
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