MINISTRY OF HEALTH OF UKRAINE

ODESSA NATIONAL MEDICAL UNIVERSITY

Faculty of Pharmacy

Department of General and Clinical Pharmacology and Pharmacognosy

Syllabus of the discipline

MC 41 "QUALITY SYSTEMS IN PHARMACY"

Scope of the discipline	Total: Credits: 3 Hours: 90 Semester X Year of study V
Days, time, location	According to the class schedule, in classroom 111 of the Department of General and Clinical Pharmacology and Pharmacognosy Odesa, Marshal Malynovskyi Street, 37
Teacher(s)	Yaroslav ROZHKOVSKYI, D.Med.Sci., professor, Head of the Department Olha KARPOVA, PhD, assistant professor
Contact information	Odesa, Marshal Malynovskyi Street, 37 Department of General and Clinical Pharmacology and Pharmacognosy email: yaroslav.rozhkovskyi@onmedu.edu.ua olha.karpova@onmedu.edu.ua In-person and online consultations: according to the department's schedule

COMMUNICATION

Communication with higher education students will be conducted through face-to-face meetings. In case of transitioning to distance learning, communication with higher education students will be conducted via email and programs: Microsoft Teams, Telegram, and Viber.

COURSE ANNOTATION

Subject of study of the discipline: formation of theoretical knowledge and practical skills in students for planning and implementation of quality management activities for processes affecting the quality of pharmaceutical products at all stages of their life cycle: from development, research, registration, and production to wholesale and retail distribution.

Prerequisites and postrequisites of the course (place of the discipline in the educational program): "Information Technologies in Pharmacy", "Computer Modeling in Pharmacy", "Pharmaceutical Law and Legislation", "Pharmacognosy", "Organization and Economics of Pharmacy", "Pharmaceutical and medical commodity science", "Pharmaceutical Management and Marketing", "Occupational Safety in the Field", "Drug Technology", "Pharmaceutical Chemistry", "Standardization of Medicines".

Goal of the discipline: 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 of the discipline: 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.

Expected outcomes:

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.

COURSE DESCRIPTION

Forms and methods of teaching:

The course will be taught in the form of lectures (20 hours) and practical classes (30 hours), organization of self-study classes of the higher education students (40 hours).

The following teaching methods will be 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.

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.

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

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

Topic 4. Statistical methods of quality control.

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

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

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

Topic 8. Audits of pharmaceutical quality systems.

List of recommended literature (basic)

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.
32. ISO 37001:2016 Anti-bribery management systems – Requirements with guidance for use.
33. OHSAS 18001:2007 Occupational Health and Safety Management Systems. Requirements.
34. OHSAS 18002:2008 Occupational health and safety management systems — Guidelines for the implementation of OHSAS 18001:2007.
35. ISO 45001:2018 Occupational health and safety management systems – Requirements with guidance for use.
36. CPMP/QWP/155/96 Note for Guidance on Development Pharmaceutics, 1998.
37. CPMP/QWP/054/98 Decision Trees for the Selection of Sterilisation Methods. Annex to Note for Guidance on Development Pharmaceutics (CPMP/QWP/155/98), 2000.
38. EMEA/CHMP/167068/2004 – ICH. – Part I: Note for Guidance on Pharmaceutical Development (ICH Topic Q 8 (R2) Pharmaceutical Development). – Part II: Annex to Note for Guidance on Pharmaceutical Development (ICH Topic Q 8 Annex Pharmaceutical Development), June 2009 (EMEA/CHMP/167068/2004 – ICH.
39. Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.
40. EMA/CPMP/ICH/286/1995 (ICH M3(R2)) Guideline on non-clinical safety studies for the conduct of human clinical trials and marketing authorisation for pharmaceuticals – December 2009.
41. CPMP/ICH/135/95 (E 6) Note for Guidance on Good Clinical Practice, 2002.
42. Integrated Addendum to: Guideline For Good Clinical Practice E6(R2), 2017.
43. CPMP/QWP/EWP/1401/98 Rev.1/Corr** Guideline on the Investigation of Bioequivalence, 2010.
44. EMA/CHMP/600958/2010/Corr.* Appendix IV of Guideline on the Investigation of Bioequivalence (CPMP/QWP/EWP/1401/98 Rev.1): Presentation of Biopharmaceutical and Bioanalytical Data in Module 2.7.1, 2011.
45. National Medicines Regulatory Authorities (NMRAs): Marketing authorization of pharmaceutical products with special reference to multisource (generic) products – 2nd ed.
46. The Rules Governing Medicinal Products in the European Union. Volume 4. EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use.

47. Guide to good storage practices for pharmaceuticals (Annex 9). WHO Expert Committee on Specifications for Pharmaceuticals Preparations. Thirty-seventh Report. Geneva, World Health Organization, 2003: 125–136.

48. CPMP/QWP/609/96/Rev 2 Guideline on declaration of storage conditions: A: in the product information of medicinal products; B: for active substances. Annex to note for guidance on stability testing of new drug substances and products. Annex to note for guidance on stability testing of existing active substances and related finished products, 2007.

49. Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (Text with EEA relevance) (2013/C 343/01).

50. Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services [Annex 8]. WHO Technical Report Series, No. 961, 2011.

51. EMA/541760/2011 Rev. 2* Guideline on good pharmacovigilance practices (GVP). Module I – Pharmacovigilance systems and their quality systems.

52. EMA/816573/2011 Rev. 2* Guideline on good pharmacovigilance practices (GVP). Module II – Pharmacovigilance system master file.

53. EMA/119871/2012 Rev. 1* Guideline on good pharmacovigilance practices (GVP). Module III – Pharmacovigilance inspections.

54. EMA/228028/2012 Rev. 1* Guideline on good pharmacovigilance practices (GVP). Module IV – Pharmacovigilance audits.

55. EMA/838713/2011 Rev. 2* Guideline on good pharmacovigilance practices (GVP). Module V – Risk management systems.

56. EMA/873138/2011 Rev. 1* Guideline on good pharmacovigilance practices (GVP). Module VI – Management and reporting of adverse reactions to medicinal products.

57. EMA/816292/2011 Rev. 1* Guideline on good pharmacovigilance practices (GVP). Module VII – Periodic safety update report.

58. EMA/813938/2011 Rev 2* Corr** Guideline on good pharmacovigilance practices (GVP). Module VIII – Post-authorisation safety studies.

59. EMA/827661/2011 Guideline on good pharmacovigilance practices (GVP). Module IX – Signal management.

60. EMA/169546/2012 Guideline on good pharmacovigilance practices (GVP). Module X – Additional monitoring.

61. EMA/118465/2012 Guideline on good pharmacovigilance practices (GVP). Module XV – Safety communication.

62. EMA/204715/2012 Rev 2* Guideline on good pharmacovigilance practices (GVP). Module XVI – Risk minimisation measures: selection of tools and effectiveness indicators.

63. EMA/168402/2014 Corr* Guideline on good pharmacovigilance practices (GVP) Product- or Population-Specific Considerations II: Biological medicinal products.

64. EMA/INS/GMP/79766/2011 Quality Risk Management (ICH Q9), 31 January 2011.

65. EMA/INS/GMP/79818/2011 Pharmaceutical Quality System (ICH Q10), 31 January 2011.

66. Derzhavna Farmakopeya Ukrayini : v 3 t. / DP «Ukrayinskij naukovij farmakopejnij centr yakosti likarskih zasobiv». – 2-e vid. – Harkiv: DP «Ukrayinskij naukovij farmakopejnij centr yakosti likarskih zasobiv», 2015. [in Ukrainian]

67. EMA/CHMP/CVMP/QWP/BWP/70278/2012-Rev 1 Guideline on process validation for finished products – information and data to be provided in regulatory submissions.

EVALUATION

Forms and methods of current control: control of theoretical and practical training of higher education students, which is conducted through oral questioning, testing, and evaluation of practical tasks performance.

Forms and methods of final control: credit.

Assessment of knowledge (distribution of points):

<table>
<tr><td colspan="2">Current control</td></tr>
<tr><td colspan="2">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.</td></tr>
<tr><td>Verification of learning outcomes</td><td>Criteria for passing</td></tr>
<tr><td>Assessment of oral response</td><td>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.</td></tr>
<tr><td>Assessment of test control</td><td>5 – 91–100 % correct answers
4 – 90–71 % correct answers
3 – 70–60,5 % correct answers
2 – Less than 60,5 % correct answers</td></tr>
<tr><td>Assessment of practical task performance</td><td>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.</td></tr>
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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

The possibility and conditions for obtaining additional (bonus) points: not provided.

SELF-STUDY CLASSES OF THE HIGHER EDUCATION STUDENTS

Self-study classes of higher education seekers, which is provided by the topic of the class, alongside classroom activities, is assessed during the current control of the topic at the respective session.

POLICY OF THE ACADEMIC DISCIPLINE

Policy regarding deadlines and retakes

- Absences from classes for disrespectful reasons are compensated according to the department's schedule of make-up work and consultations.
- Absences from classes for respectful reasons are compensated according to an individual schedule with the permission of the dean's office.

Policy on academic integrity

Compliance with academic integrity by higher education students is mandatory, namely:

- independent performance of all types of work, tasks, and forms of control provided for by the working program of the discipline;
- citing sources of information when using ideas, developments, statements, or information;
- compliance with copyright and related rights legislation;
- providing accurate information about the results of one's own educational (scientific) activities, used research methodologies, and sources of information.

Unacceptable in educational activities for participants in the educational process are:

- using family or professional connections to obtain a positive or higher grade during any form of learning outcome assessment or advantages in research work;
- using prohibited auxiliary materials or technical means during control measures (cheat sheets, summaries, micro earphones, phones, smartphones, tablets, etc.);
- undergoing learning outcome assessment procedures by fake persons.

For violations of academic integrity, higher education students may be held to the following academic responsibility:

- reduction of current and final control points;
- repeating the evaluation;
- appointment of additional control measures (additional individual tasks, control works, tests, etc.);
- conducting additional checks of other works authored by the violator.

Attendance and punctuality policy

To receive a passing grade, attendance and participation in classroom activities (lectures and practical sessions) are mandatory.

Higher education student is allowed to be late for no more than 10 minutes.

Use of mobile devices

Mobile devices may be used by higher education students with the permission of the teacher, if they are needed to complete an assignment.

Behavior in the classroom

The behavior of higher education students and teachers in classrooms should be professional and calm, strictly adhering to the rules established by the Regulations on academic integrity and ethics of academic relations at the Odesa National Medical University, in accordance with the Code of academic ethics and relations of the university community of the Odesa National Medical University, and the Regulations on prevention and detection of academic plagiarism in the research and educational work of higher education students, researchers, and teachers of the Odesa National Medical University.