

**Odessa National Medical University**  
**Faculty of Pharmacy**  
**Department of General Pharmacy with the Course of Clinical Pharmacology**

**Syllabus of the academic discipline**  
**"QUALITY SYSTEMS IN PHARMACY"**

<b>Volume</b>	credits (ECTS) - 3 total hours - 90
<b>Year of study</b>	five
<b>Semester</b>	nine
<b>Days, time, place</b>	In accordance with the approved schedule of classes.
<b>Teachers</b>	Nikogosyan L.R., Head of the Department, Doctor of Medical Sciences, Professor Berbek V.L., Associate Professor, PhD in Pharmaceutical Sciences, Matyushkina M.V., PhD in Pharmaceutical Sciences, Assistant
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<b>Consulting</b>	according to the schedule of the department

**COMMUNICATION** info.odmu.edu.ua / chair / general\_pharmacy /  
Microsoft Teams

**ANNOTATION OF THE COURSE**

**The subject of study of the discipline "Quality Systems in Pharmacy"** is the formation of a system of theoretical knowledge and practical skills for students to plan and carry out work on quality management of processes that affect the quality of pharmaceutical products at all stages of its life cycle: from development, research, registration and production to wholesale and retail sales.

**Prerequisites and post - requisites of the course :** "Hygiene in Pharmacy and Ecology", "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" ,"Labor Protection and Labor Protection in the Industry" ,"Technology of Medicines", "Pharmaceutical Chemistry", "Standardization of Medicines".

**The purpose of teaching of the discipline "Quality systems in pharmacy"** is the mastery of students abilities to systems thinking and

integrated practical skills in the planning and implementation of activities of control, security and quality management processes that affect the quality of pharmaceutical products at all stages of its lifecycle: from development, research, registration and production to wholesale and retail sales.

**The main objectives of studying the discipline "Quality Systems in Pharmacy"** is the formation of systemic knowledge and practical skills regarding quality management work carried out at all stages of the life cycle of a medicinal product, the development of pharmaceutical quality systems and the preparation and conduct of their internal audits (self-inspections), the creation of an educational base defining the professional competence and general erudition of the Master of Pharmacy; ensuring the ability of the future graduate to successfully carry out professional and further educational activities.

### **Expected results**

*The student should know:*

- methods of implementing knowledge in solving practical issues
- current trends in the development of the industry and analyze them
- features of the modern professional environment and professional activity
- structure and features of professional activity
- mechanisms of adaptation and algorithms of actions in a new situation
- modern information and communication technologies
- methods for assessing the quality of work performed
- the legal and regulatory framework of Ukraine, a set of good pharmaceutical practices that regulate the requirements for professional activities
- principles of organizing a quality management system for pharmaceutical organizations, quality audit and risk management for the quality of pharmaceutical products
- principles of organization and implementation of quality control and standardization of medicines

*The student should be able to:*

- use professional knowledge to solve practical situations
- analyze professional information, make informed decisions, acquire modern knowledge
- show initiative; carry out a constant search for new opportunities outside the available resources, engage in self-development and self-realization
- carry out professional activities requiring renewal and integration of knowledge
- adapt to the new and act according to specific situations
- apply in practice modern information and communication technologies
- ensure the quality of work performed
- apply knowledge of regulatory and legal acts of Ukraine and recommendations of good pharmaceutical practices in practice
- apply the knowledge of current standards with the issues of quality management of pharmaceutical products

- apply knowledge of the requirements of the current State Pharmacopoeia of Ukraine and good practices in pharmacy

## DESCRIPTION OF THE COURSE

### Forms and methods of teaching

For full-time students the course will be presented in the form of lectures (20 h.) and practical (30 h.) lessons, the organization of independent work of students (40 h.).

The following teaching methods are used: *verbal* - story, explanation, conversation, instruction, lecture, discussion; *visual* - demonstration of films, visual equipment (means of small-scale mechanization), illustrations, materials, demonstration of operations and processes of manufacturing drugs in the conditions of pharmacies and industrial enterprises; *practical methods* - hands-on exercises; *inductive methods* (generalization of the results of observations and experiments). Preference is given to active and interactive methods and multimedia teaching (multimedia lectures, educational films).

### Content of the academic discipline

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

**Topic 2.** Regulatory framework for quality management of medicines in the world and Ukraine.

**Topic 3.** State system for quality assurance of medicines. Certification and licensing of subjects of the pharmaceutical market of Ukraine.

**Topic 4.** Statistical methods of quality control.

**Theme 5.** Regulation and document the e process of the pharmaceutical system quality.

**Theme 6.** Evaluation p claim for quality of drug money on the stages of its life cycle.

**Topic 7.** Organization of activities for the validation of production processes and qualification of equipment and auxiliary systems in organizations - subjects of the pharmaceutical market.

**Topic 8.** Internal audits (self-inspection) of pharmaceutical quality systems.

### List of recommended literature

#### Basic (basic)

1. Kovalenko, SN Quality management : Textbook . n persons . // S. N. Kovalenko, V. A. Lebedinets, St. N. Kovalenko. - Kh . : NTMT, 2013 .-- 324 p.
2. Lebedinets , VA Quality management systems // Pharmaceutical Encyclopedia / Ch. ed. V.P. Chernykh . - 2nd ed . , Suppl . - M .: Publishing house MORION, 2010. - S. 139-140.

3. Quality management systems. Requirements: DSTU ISO 9001: 2009 - [introduction 2009-09-01]. - M. : Gospotrebstandart of Ukraine, 2009. - 28 p. - (National standard of Ukraine).

4. Management for the sustainable success of the organization. Quality management approach: DSTU ISO 9004: 2012 (and SO 9004: 2009, and DT ) - [introduction 2013-07-01]. - M. : Ministry of Economic Development of Ukraine, 2013 - 48 p. - (National standard of Ukraine).

5. Fomichev, SA Fundamentals of quality management : Textbook . n persons . // S. A. Fomichev, A. A. Starostina, N. I. Skryabin. - M. : Publishing house of MAUP, 2012 .-- 192 p.

6. Shapoval, MI Quality management : P idruch . // M.I.Shapoval. - M. : Tov- but " Knowledge ", 2013. - 484 p.

### **Subsidiary**

1. Gromovik BP Management and marketing in pharmacy: textbook / BP Gromovik , GD Gasyuk , AG Levitskaya; ed. Dr. Pharm. Sciences, prof. B.P. Gromovik . - M. : Medicine, 2008 .-- 752 p.

2. Gromovik BP Organization and economics of pharmacy: textbook / BP Gromovik , SI Tereshchuk , IL Chukhrai; ed. prof. B.P. Gromovik and Assoc. S.I. Tereshchuk - Vinnytsia New Book, 2009 .-- 816 p.

3. Kirichenko, L.S., Merezhko N.V. Fundamentals of standardization, metrology, quality management: Textbook . allowance . // L. S. Kirichenko, N. Merezhko . - M. : Publishing house Kiev. nat. torg.- ehkon . University , 2001 .-- 446 p.

4. Medicines. Pharmaceutical quality system ( ICH Q 10): ST-N MZU 42-4.3: 2011 - [introduction 2011-10-03]. - M. : Ministry of Health of Ukraine, 2011 .-- 30 p. - (Management).

5. Steinborn L . GMP / ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers . Sixth Ed , Vol . 2: Regulations , Standards, and Guidelines. - NY: CRC Press, 2009 .-- 448 p.

6. Conformity assessment. Requirements for bodies providing audit and certification of management systems : ISO / IEC 17021: 2011 - [Valid from 2011-02-01]. - Second edition, 2011 .-- 44 p. - (International standard).

### **Informational resources**

- Lecture materials, methodological developments for seminars and an independent robot and at the Department of General Pharmacy. URL : [http://http://info.odmu.edu.ua/chair/general\\_pharmacy/](http://http://info.odmu.edu.ua/chair/general_pharmacy/).

- Official website of the Ministry of Health of Ukraine [www.moz.gov.ua](http://www.moz.gov.ua)

- Website library ONMedU the URL : <http://libblog.odmu.edu.ua>

- website of the journal "Pharmacist Practitioner" URL : [fp.com.ua](http://fp.com.ua)

- Official site of the magazine "Pharmacist" URL : [www.provisor.com.ua](http://www.provisor.com.ua)

- Compendium: medicinal drugs . URL : <http://compendium.com.ua/>

- State Register of Medicines of Ukraine. URL : <http://www.drlz.com.ua/>

- Database "Equalizer" LLC "Business-Credit" URL : <http://eq.bck.com.ua/>

## GRADE

<b>Current control</b>	
<p>Carried out on each seminary class according to specific goals. The form of assessment of the current educational activity is standardized and include control of theoretical training, which is conducted by the survey, the implementation of situational problems, as well as a test of writing of the survey.</p> <p>The results of the current control is an indicator of the level of assimilation of students of educational programs and perform independent work. For each topic the student must obtain est e GCC on a 4-point (traditional) scale with a view of the approved criteria.</p>	
<i>Verification of learning outcomes</i>	<i>By Criteria for per couple</i>
<i>Test Control Evaluations</i>	2 - < 80% 3 - 80 - 89% 4 - 90 - 95% 5 - 96 - 100%
<i>Assessment of the oral response</i>	<p><b>2</b> - The student does not reproduce Scholastic first material has a vague idea of the object study</p> <p><b>3</b> - The student has difficulty in reproducing the main educational material, with errors and inaccuracies he defines the basic concepts and definitions of the topic</p> <p><b>4</b> - The student demonstrates knowledge and understanding of the main provisions of the educational material</p> <p><b>5</b> - The student has systemic, solid knowledge within the requirements of the curriculum, consciously uses them in standard and non-standard situations . Knows how to independently analyze, evaluate, generalize obsessed material</p>
<b>Final control</b>	
<i>General grading system</i>	Participation in work during the semester 100% on a 200-point scale
<i>Grading scales</i>	traditional 4-point scale, multi -point (200-point) scale, ECTS rating scale

<i>Conditions for admission to final control</i>	The student attended all lectures and seminars and received at least 120 points for current academic performance	
<i>View the final control</i>	<i>The technique of the final control</i>	<i>To the offset criteria</i>
Offset	All topics submitted to the current control must be credited. Grades from a 4- point scale are converted into points on a multi- point (200 point) scale in accordance with the Regulation "Criteria, rules and procedures for assessing the results of educational activities of students "	The maximum number of points is 200.  The minimum number of points is 120
<i>The calculation of the number of points</i> is conducted on the basis of the obtained student assessments on a 4-point (national) scale of time studying the discipline, by calculations average arithmetic, rounded of to two digits after the decimal point. The resulting value is converted into points on a multi- point scale by the information and computing center of the university.		

### **Independent work of students:**

- ✓...work with lecture material, which provides for the study of lecture notes and educational literature;
- ✓...search (selection) and review of literature and electronic sources of information on an individually set problem of the course;
- ✓...homework or home control work, involving problem solving, exercise and so on;
- ✓...study of material submitted for independent study;
- ✓...writing an abstract on a given problem;
- ✓...preparation for test.

### **COURSE POLICY**

#### *Deadline and retake policy*

Students who have completed all types of work stipulated by the curriculum, completed all training sessions and, while studying the module, scored at least the minimum number of points are allowed to the final control.

Testing missed practical classes, regardless of the cause skipping, and consultations take place according to the cathedral graphics of consultation. Working off of the missed practical lessons is carried out with an entry in the journal of the

development of the department and a mark on the permit form from the dean's office. Skipping a lecture without a good reason is worked out by a student through an interview with a lecturer, or a presentation of a missed topic. Retaking the current and final modules to improve the assessment is not allowed, except for cases stipulated by the "Regulations on the diploma is, the state sample with honors"

### *Academic Virtue Policy*

Respect for academic virtue by education seekers includes:

◆...independent fulfillment of educational tasks, tasks of current and final control of learning outcomes (for persons with special educational needs, this requirement is applied taking into account their individual needs and capabilities);

◆...links to sources of information when using ideas, developments, statements, information;

◆...observance of the norms of legislation on copyright and related rights;

◆...provision of reliable information about the results of one's own (scientific, creative) activities, used research methods and sources of information.

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

- the use of family or official ties to obtain a positive or highest mark in the implementation of any form of control of learning outcomes or advantages in scientific work;

- use of prohibited auxiliary materials or technical means (cribs, notes, earpieces, phones, smartphones, tablets, etc.) during control activities;

- passing the procedures for monitoring the learning outcomes by dummies.

For violation of academic virtue, education seekers may be held liable for such academic responsibility.

- decrease in the results of the assessment of control work, exams, tests, etc.;

- re-passing the assessment (tests, exams, tests, etc.);

- appointment of additional control measures (additional individual tasks, control papers, tests, etc.);

- re-passing the corresponding educational component of the educational program;

- additional verification of other works of authorship of the offender;

- deprivation of the right to participate in competitions for scholarships, grants, and the like;

- Post subject provides training funding (research), the institution that issued the grant to study (research), prospective employers, higher education of the applicant parents to completely in violation;

- exclusion from the ranking of applicants for an academic scholarship or the accrual of penalty points in such a ranking;

- deprivation of an academic scholarship;
- deprivation of tuition fees provided by the University;
- deductions from the University.

*Policy on attendance and lateness:* attendance at all classes: lectures, practical classes, current and final control is mandatory (exception: good reason). Delay by more than 5 minutes without a valid reason is not allowed. Within two days, in any form convenient for the student, inform the dean's office about the reasons that make it impossible to attend classes and perform other tasks stipulated by the curriculum.

*Mobile devices:* prohibited cheating is, under the control of knowledge (including the use of mobile technical communication).

*Audience behavior:*

- attend lectures, laboratory classes according to the schedule in dressing gowns;
- do not be late for classes;
- do not talk during class;
- turn off the mobile phone.