MINISTRY OF HEALTH OF UKRAINE

ODESA NATIONAL MEDICAL UNIVERSITY

Faculty of Pharmacy

Department of General and Clinical Pharmacology and Pharmacognosy

APPROVE

Vice-Rector for Scientific and Pedagogical Work

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«__2__» September 2024

METHODOLOGICAL RECOMMENDATIONS FOR PRACTICAL CLASSES IN THE ACADEMIC DISCIPLINE QUALITY SYSTEM IN PHARMACY

Level of higher education: second (master's)

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PRACTICAL LESSON No. 1

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

Goal:to control the basic level of knowledge of higher education students regarding the basic terms of quality management and stages of development of quality management in the world and to form practical skills in applying theoretical knowledge about the evolution of the global development of quality management science in pharmacy.

Basic concepts:quality, quality control, quality management, quality system, quality loop/circle, individual quality control, shop quality control, acceptance quality control, statistical quality control, comprehensive quality management.

Equipment:laptop, multimedia projector.

1. Plan:

Organizational activities (welcome, checking attendance, announcement of the topic, objectives of the lesson, motivation of higher education students to study the topic).

The pharmaceutical industry in developed countries is one of the most dynamic and profitable, but at the same time it acts as a special market segment regulated by state authorities and controlled by insurance medicine. The pharmaceutical industry also occupies a significant place in the economy of Ukraine, as it is an important segment of the national market, largely determines the national and defense security of the country, is characterized by a large knowledge-intensive and developed cooperation. The current situation in the pharmaceutical market of Ukraine can be a powerful incentive for restructuring the industry, increasing competition and transition to EU technical standards. Those enterprises that successfully restructure and withstand tough competition will be able to compete in international markets.

2. Control of the reference level of knowledge:

- requirements for the theoretical readiness of higher education applicants to perform practical classes (knowledge requirements, list of didactic units);
- questions (test tasks) to test basic knowledge on the topic of the lesson.

3. Knowledge requirements

Higher education students should know the main categories of quality management and the stages of development of quality management in the world.

4. List of didactic units

1. Quality, quality management, quality management system / quality system, quality loop/circle as categories.
2. Individual quality control as a form of quality management.
3. Shop quality control as a form of quality management.
4. Acceptance quality control as a form of quality management.

5. Statistical quality control as a form of quality management.
6. The concept of total quality control.
7. The concept of "Quality Management throughout the company."
8. The concept of product quality assurance based on international standards ISO 9000 and the concept of total quality management.

5. Test tasks:

1. The set of organizational structure, methods, processes and resources necessary to implement quality management is:

A) quality loop
B) quality system
C) quality management
D)quality circle
E) quality management

2. The following is aimed at managing the quality of each specific product:

A) individual quality control
B) shop quality control
WITH)incoming quality control
D)statistical quality control
E) general quality control

3. The separation of technical quality control from production operations occurred at the following stage of the evolution of the science of quality management:

A) individual quality control
B)shop quality control
C)incoming quality control
D) statistical quality control
E) general quality control

4. The required product quality was achieved through the use of technical control tools and methods at the following stages of the evolution of the science of quality management:

A) shop quality control
B)incoming quality control
C)statistical quality control
D)general quality control
E) total quality management

5. The basic philosophy of the concept is based on the principle of “there is no limit to improvement”:

A) general quality control
C) quality management throughout the company
C) total quality management
D) general principles of the world market

E) principles of new products

6. Formation of professional skills and abilities:

- contenttasks;
- recommendations (instructions) on how to perform tasks;
- requirements to the results of the work, including the design.

Task content

1. Install conformity betweenthe specified category and its definition. Enter the results of the analysis in the table.

Definition	**Category**			
	Quality	**Managerquality**	**Quality system**	**Quality Circle**
Actions taken during development, production and implementation of the object in order to form, ensure and maintain a given level of quality.				
A management system for leading and managing an organization with regard to quality.				
The degree to which the set of inherent characteristics of an object meets the requirements established in regulatory documents.				
Conceptual model of interdependent activities that affect quality at different stages of the object's life cycle.				

2. Installcorrespondence between forms of quality management and their main characteristics. Enter the results of the analysis in the table.

Main	**Forms of quality management**

characteristics	**Individual quality control**	**Workshop quality control**	**Acceptance quality control**	**Statistical quality control**	**Comprehensive quality management**	**Total quality management**
Direction to manage the quality of each specific product.						
Selectivequality control products based on mathematical processing control data.						
Implementationquality control at the product development stage.						
Comprehensive and systematic problem solving quality assurance at all stages of the product life cycle.						
Implementation of usetechnical quality control methods separate from production operations.						

3. Enter data on the main provisions of quality management concepts in the table.

Name of the quality management concept	Basic provisions of the quality management concept
The concept of total quality control.	
The concept of "Quality Management throughout the company."	
The concept of total quality management.	

Recommendations (instructions) for completing tasks:

To complete the tasks, you must use the lecture material and sources from the list of recommended literature.

Requirements for work results, including design:

In the process of completing the tasks, all the corresponding rows and columns of the tables must be filled in. To fill in the tables for task 1 and task 2, use the "+" or "√" signs.

Summary: In the process of conducting the lesson, the goal of the lesson is achieved, namely: higher education applicants are monitored for the basic level of knowledge regarding the basic terms of quality management and the stages of development of quality management in the world, and practical skills are formed for the application of theoretical knowledge about the evolution of the global development of quality management science in pharmacy.

List of recommended literature:

1. Shapoval M. I. Quality management: a textbook. / M. I. Shapoval. – Kyiv, 2007. 471 p.

2.Good practices in pharmacy: a manual for students of higher education institutions / V. O. Lebedynets, O. V. Tkachenko, Yu. I. Gubin and others. Kharkiv: National University of Pharmacy: Golden Pages, 2017. 296 p.

PRACTICAL LESSON No. 2

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

Goal:to control the basic level of knowledge of the basic concepts of quality management among higher education students and to develop practical skills in applying theoretical knowledge about the basic principles of quality management concepts in pharmacy.

Basic concepts:quality, quality management, quality management, quality system, comprehensive quality management.

Equipment:laptop, multimedia projector.

1. Plan:

Organizational activities (welcome, checking attendance, announcement of the topic, objectives of the lesson, motivation of higher education students to study the topic).

The pharmaceutical industry in developed countries is one of the most dynamic and profitable, but at the same time it acts as a special market segment regulated by state authorities and controlled by insurance medicine. The pharmaceutical industry also occupies a significant place in the economy of Ukraine, as it is an important segment of the national market, largely determines the national and defense security of the country, is characterized by a large knowledge-intensive and developed cooperation. The current situation in the pharmaceutical market of Ukraine can be a powerful incentive for restructuring the industry, increasing competition and transition to EU technical standards. Those enterprises that successfully restructure and withstand tough competition will be able to compete in international markets.

2. Control of the reference level of knowledge:

- requirements for the theoretical readiness of higher education applicants to perform practical classes (knowledge requirements, list of didactic units);
- questions (test tasks) to test basic knowledge on the topic of the lesson.

3. Knowledge requirements:

Higher education students should know the basic concepts of quality management.

4. List of didactic units

1. Walter Shewhart's concept
2. Edward Deming's concept
3. Concept by Joseph Juran
4. Armand Feigenbaum's concept
5. The Ottinger-Sittig concept
6. Concept by Kaoru Ishikawa
7. The concept of Geniti Taguti
8. Concept by Philip Crosby

5. Test tasks

1. Strict administrative and economic coercion of performers and unquestioning adherence to quality standards were provided for by the principles:

A) F. Taylor
C) W. Shewhart
C) E. Deming
D) A. Feigenbaum
E) K. Ishikawa

2. The cyclical model of quality management was first proposed by:

A) J. Sittig
B) W. Shewhart
C) E. Deming
D) A. Feigenbaum
E) J. Ettinger

3. Obsession with quality, everyone is one team, scientific approach are the main postulates:

A) B. Joyner
B) E. Deming
D) J. Jurana
C) G. Tagutti
E) J. Sittig

4. Unlike the A. Feigenbaum model, the Ettinger-Sittig quality management model, the first stage of the quality management cycle, provides for:

A) preparation for designing a quality assurance system
C) demand research
D) planning of production processes
C)quality assurance system design
E) stage of system implementation by stages

5. Management of deviation from the nominal is a fundamental principle of the quality management concept:

A) K. Ishikawa
C) G. Tagutti
D)W. Shewhart
C) J. Jurana
E). Deming

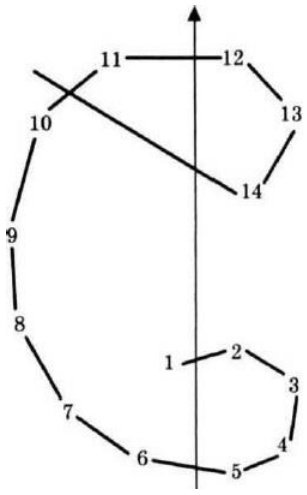
6. Formation of professional skills and abilities:

- contenttasks;
- recommendations (instructions) on how to perform tasks;

− requirements to the results of the work, including the design.

Task content

1. Enter data on the main stages of quality management work according to J. Juran in the table.

Spiral J. Jurana	**Stage numbe r**	**Stage name**
	1	
	2	
	3	
	4	
	5	
	6	
	7	
	8	
	9	
	10	
	11	
	12	

2. Indicate in the table the components of the five-level model of the quality management system according to A. Feigenbaum.

Level number	**Level name**	**Level components**	
First level		1	
		2	
		3	
		4	
		5	
Second level		6	
		7	
		8	
		9	
Third level		10	
		11	
		12	
Fourth level		13	
		14	
		15	
		16	
Fifth level		17	

3. Carry out a comparative analysis of the scientific principles in the quality management approaches of E. Deming, K. Ishikawa, and F. Crosby. Enter the results of the analysis in a table.

Principles of concepts quality management	**Approach**		
	E. Deming	**K. Ishikawa**	**F. Crosby**
A satisfied customer is an incentive in any activity.			
Zero defect rate.			
A continuous process of management, quality assurance and its further improvement.			
Involvement of all personnel in quality management activities.			
Determining the cost of poor quality work.			
Commitment of top management to continuous quality improvement.			
First and foremost, quality, not short-term profits.			
Introducing a program of education and support for self-improvement for all employees.			
Moral encouragement of employees for fulfilling quality requirements.			
Reducing the need for mass inspections as a means of achieving quality.			

Recommendations (instructions) for completing tasks:

To complete the tasks, you must use the lecture material and sources from the list of recommended literature.

Requirements for work results, including design:

In the process of completing the tasks, all the corresponding rows and columns of the tables must be filled in. To fill in the table of task 3, use the "+" or "√" signs.

Summary: In the process of conducting the lesson, the goal of the lesson is achieved, namely: higher education students are monitored for the basic level of knowledge regarding the basic concepts of quality management and practical skills are formed for the application of theoretical knowledge about the basic provisions of quality management concepts in pharmacy.

List of recommended literature:

1. Shapoval M. I. Quality management: a textbook. / M. I. Shapoval. – Kyiv,

2007. 471 p.

2.Good practices in pharmacy: a manual for students of higher education institutions / V. O. Lebedynets, O. V. Tkachenko, Yu. I. Gubin and others. Kharkiv: National University of Pharmacy: Golden Pages, 2017. 296 p.

PRACTICAL LESSON No. 3

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

Goal:to control the basic level of knowledge of higher education applicants regarding the provisions of international standards that establish requirements for a quality management system, and to form practical skills in developing, implementing, maintaining and improving quality management systems in pharmacy in accordance with the provisions of international standards.

Basic concepts:standard, international standard, international organization for standardization, national standard, national standardization body, mandatory certification, voluntary certification, social responsibility.

Equipment:laptop, multimedia projector.

1. Plan:

Organizational activities (welcome, checking attendance, announcement of the topic, objectives of the lesson, motivation of higher education students to study the topic).

Since the 1990s, various industry versions of international quality standards have been formed. The creation of effective and efficient quality management systems at the enterprise that comply with the provisions of international standards is a guarantee of satisfaction of consumer requirements and, accordingly, the economic success of the enterprise.

2. Control of the reference level of knowledge:

- requirements for the theoretical readiness of higher education applicants to perform practical classes (knowledge requirements, list of didactic units);
- questions (test tasks) to test basic knowledge on the topic of the lesson.

3. Knowledge requirements:

Higher education students should know the provisions of international standards that establish requirements for a quality management system, and the general principles of developing, implementing, maintaining, and improving quality management systems in pharmacy in accordance with the provisions of international standards.

List of didactic units

1. Main types of standards.
2. ISO 9000 series standards.
3. ISO 10000 series standards.
4. ISO 13485 standard.
5. ISO 14000 series standards.
6. ISO 19011 standard.
7. ISO 22000 standard.
8. Social responsibility standards
9. ISO 27000 series standards.
10. ISO 31000 series standards.

11. ISO 37001 standard.
12. Standards for occupational health and safety management systems.

4. Test tasks:

1. International standards have the status of mandatory for all participating countries:
A) Yes
B) No
C) Yes, if provided for by the applicable legislation in the participating country.

2. Standards aimed at improving/developing various aspects of the quality management system:
A) ISO 31000 series standards
B) ISO 27000 series standards
C) ISO 14000 series standards
D) ISO 10000 series standards
E) ISO 9000 series standards

3. A certificate of compliance with the requirements of this standard is mandatory for the registration of medical devices:
A) ISO 9001:2015
B) ISO 10012:2003
C) ISO 10013:2021
E) EN ISO 13485:2016
E) ISO 31000:2018

4. Key standard of a series of international standards in the field of environmental management of enterprises:
A) ISO 14001:2015
B) ISO 14050:2020
C) ISO 9001:2015
D) ISO 10013:2021
E) ISO 19011:2018

5. To replace the standardOHSAS 18001 standard introduced:
A) SA 8000:2014
B) ISO 26000:2010
C) ISO 45001:2018
D) ISO 10004:2018
E) UN Global Compact

5. Formation of professional skills and abilities:

- contenttasks;
- recommendations (instructions) on how to perform tasks;
- requirements to the results of the work, including the design.

Task content

1. Complete the table regarding the scope of the ISO 9000 series of standards using the following data:

A) The standard contains a complete list of quality system elements.

B)The standard is intended for organizations with an implemented quality management system that strive to achieve sustainable success without being limited to basic requirements.

C) A standard that provides guidance and examples on the application of ISO 9001:2015 requirements.

D) The standard contains the basic concepts, principles and terminology of quality management systems.

Standard designation	**Scope of the standard**
ISO 9000:2015	
ISO 9001:2015	
ISO/TS 9002:2016	
ISO 9004:2018	

2. Complete the table on the scope of the ISO 10000 series of standards using the following data:

A) The standard provides guidance on the development and maintenance of documentation necessary to ensure the effective operation of the quality management system.

B) Standard for codes of corporate ethics when interacting with customers.

C) The standard contains guidelines for involving personnel in implementing a quality management system in an organization.

D) Standard for monitoring customer satisfaction.

E) The standard contains guidelines for the development and application of quality programs.

E) The standard is intended to assist organizations in selecting a quality management system consultant.

THERE ARE)The standard establishes guidelines for managing the processes of metrological confirmation of the suitability of measuring equipment.

G)The standard contains guidelines for competency management and staff development.

WITH)Standard for handling customer complaints.

K)Standard for resolving disputes outside organizations.

Standard designation	**Scope of the standard**

ISO 10001:2018	
ISO 10002:2018	
ISO 10003:2018	
ISO 10004:2018	
ISO 10005:2018	
ISO 10012:2003	
ISO 10013:2021	
ISO 10015:2019	
ISO 10018:2020	
ISO 10019:2005	

3. Fill in the table regarding the scope of international standards implemented, in particular, by organizations that are entities in the pharmaceutical market, using the following data:

A) The standard provides guidance on how to incorporate socially responsible behavior into an organization's existing strategies, systems, practices, and processes.

B) The standard specifies requirements for systemsmanagement of anti-corruption measures.

C) The standard establishes requirements for the development, implementation, maintenance and improvement of an environmental management system.

D) The standard establishes requirements for a food safety management system.

E) The standard establishes requirements for a quality management system if an organization is to provide services related to medical devices.

E) Contains principles in the areas of human rights, labor relations, environmental protection and anti-corruption to build the company's operations.

E) The standard contains a description of the principles and processes on which risk management is based.

G) The standard specifies requirements that enable an organization to develop, implement and maintain policies and methods for managing social protection issues.

C) The standard establishes requirements for an occupational health and safety management system (twice).

K)The standard establishes requirements for an information security management system.

L)The standard contains recommendations for planning and conducting

management system audits.

Standard designation	Scope of the standard
EN ISO 13485:2016/A11:2021	
ISO 14001:2015	
ISO 19011:2018	
ISO 22000:2018	
ISO 26000:2010	
SA8000:2014	
UN Global Compact	
ISO/IEC 27001:2022	
ISO 31000:2018	
ISO 37001:2016	
OHSAS 18001:2007	
ISO 45001:2018	

Recommendations (instructions) for completing tasks

To complete the tasks, you must use the lecture material and sources from the list of recommended literature.

Requirements for work results, including design

During the task execution, all relevant rows and columns of the tables must be filled in.

Summary: In the process of conducting the lesson, the goal of the lesson is achieved, namely: higher education students are monitored for the basic level of knowledge regarding the provisions of international standards that establish requirements for a quality management system, and practical skills are formed for the development, implementation, maintenance and improvement of quality management systems in pharmacy in accordance with the provisions of international standards.

List of recommended literature:

1. DSTU ISO 9000:2015 (ISO 9000:2015, IDT). Quality management systems. Basic provisions and glossary of terms. Kyiv, State Enterprise "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. Configuration management guidelines. Kyiv, SE "UkrNDNC".

8. DSTUISO 10012:2005 (ISO 10012:2003, IDT). Measurement control systems. Requirements for measurement processes and measuring equipment. Kyiv, Derzhspozhyvstandart of Ukraine, 2007.

9. DSTUISO/TR 10013:2003(ISO/TR 10013:2001, IDT). Guidelines for the development of quality management system documentation. Kyiv, State Enterprise "UkrNDNC".

10. DSTU ISO 10014:2008 (ISO 10014:2008, IDT). Quality management. Guidelines for the realization of financial and economic benefits. Kyiv, Derzhspozhyvstandart of Ukraine, 2008.

11. DSTU ISO 10015:2021 (ISO 10015:2019, IDT). Quality management. Guidelines for competence management and personnel development. Kyiv, SE "UkrNDNC".

12. DSTU ISO/TR 10017:2005 (ISO/TR 10017:2003, IDT). Guidelines for the application of statistical methods in accordance with ISO 9001:2000. Kyiv, Derzhspozhyvstandart of Ukraine, 2007.

13. DSTU ISO 10018:2021 (ISO 10018:2020, IDT). Quality management. Guidelines for personnel recruitment. Kyiv, SE "UkrNDNC".

14. DSTU-N ISO 10019:2007 (ISO 10019:2005, IDT) Guidelines for the selection of consultants and the use of their services. Kyiv, Derzhspozhyvstandart of Ukraine, 2008.

15. DSTU EN ISO 13485:2018 (EN ISO 13485:2016, IDT). Medical devices. Quality management system. Regulatory requirements. State Enterprise "UkrNDNC".

16. DSTUISO 14001:2015 (ISO 14001:2015,IDT). Environmental management systems. Requirements and guidelines for application. Kyiv, State Enterprise "UkrNDNC".

17. DSTU ISO 19011:2019 (ISO 19011:2018, IDT). Guidelines for conducting audits of management systems. Kyiv, SE "UkrNDNC".

18. DSTUISO 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 on social responsibility. Kyiv, State Enterprise "UkrNDNC".

19. DSTU ISO/IEC 27001:2023 (ISO/IEC 27001:2022, IDT) Information security, cybersecurity and privacy protection. Information security management systems. Requirements. Kyiv, State Enterprise "UkrNDNC".

20. International Standard SA8000:2001 Social Responsibility.
21. DSTUISO 31000:2018 (ISO31000:2018, IDT). Risk management. Principles and guidelines. Kyiv, SE "UkrNDNC".
22. DSTU EN IEC 31010:2022 (EN IEC 31010:2019, IDT; IEC 31010:2019, IDT). Risk management - risk assessment methods. Kyiv, State Enterprise "UkrNDNC".
23. DSTU ISO 37001:2018 (ISO 37001:2016, IDT). Anti-corruption management systems. Requirements and guidelines for application. Kyiv, SE "UkrNDNC", 2019.
24. DSTU ISO 45001:2019 (ISO 45001:2018, IDT). Occupational health and safety management systems. Requirements and guidelines for application. Kyiv, SE "UkrNDNC".
25. DSTU OHSAS 18002:2015 (OHSAS 18002:2008, IDT). Management systems
Occupational health and safety. Basic principles of implementing OHSAS 18001:2007 requirements. Kyiv, SE "UkrNDNC".

Electronic information resources:
1. International organization from standardization(ISO) Access mode:https://www.iso.org/home.html
2. Legislation of Ukraine – Access mode https://zakon.rada.gov.ua/laws/

PRACTICAL LESSON No. 4

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

Goal:to control the basic level of knowledge of higher education students regarding the rules of good pharmaceutical practices and other industry standards and to form practical skills in developing, implementing, maintaining and improving quality management systems in pharmacy in accordance with the rules of good practices and other industry standards.

Basic concepts:pharmaceutical development, good laboratory practice, good clinical practice, bioavailability, bioequivalence, good regulatory practice, good manufacturing practice, good storage practice, good distribution practice, good pharmacy (pharmaceutical) practice, pharmacovigilance, pharmaceutical quality system, integrated quality management systems, State Pharmacopoeia of Ukraine.

Equipment:laptop, multimedia projector.

1. Plan:

1. Organizational activities (welcome, checking attendance, announcing the topic, the objectives of the lesson, motivating higher education students to study the topic).

WHO, when developing a national medical strategy, determines that medicines must be of high quality, safe and effective. Quality assurance of medicines is a comprehensive concept that must be guaranteed at all stages of the life cycle of medicines - from initial development, being on the market and until the cessation of production and medical use of products. This is achieved through industry standards for quality management in pharmacy - a set of good practices GxP.

2. Control of the reference level of knowledge:

- requirements to the theoretical readiness of higher education students to perform practical classes (knowledge requirements, list of didactic units);
- question (test tasks) to check basic knowledge on the topic of the lesson.

3. Knowledge requirements:

Higher education students should know the rules of good pharmaceutical practices and other industry standards and the general principles of developing, implementing, maintaining and improving quality management systems in pharmacy in accordance with the rules of good practices and other industry standards.

4. List of didactic units

1. The concept of good pharmaceutical practices (GxP) and their role in ensuring quality at all stages of the life cycle of medicines.
2. ICH Q8.
3. Good laboratory practice.
4. Good clinical practice.
5. Good regulatory practice.
6. Good Manufacturing Practices.

7. Good storage practices.
8. Good distribution practices.
9. Good pharmacy practice.
10. Good pharmacovigilance practices.
11. ICH Q9.
12. ICH Q10.
13. Integrated quality management systems of pharmaceutical organizations.
14. State Pharmacopoeia of Ukraine.

5. Test tasks

1. At the stages of pharmaceutical development of a medicinal product, an industry standard is applied:

A) ICH Q8
B) Guidance on bioequivalence studies
C) GCP
D) All options are correct.

2. Principles and recommendations for quality risk management within the pharmaceutical quality system are established by the guideline

A) ICH Q8
B) ICH Q9
C) ICH Q10
D) ICH M3(R2)

3. The provisions on the pharmaceutical quality system are established by the following guidelines:

A) GPP
B) GMP
C) GVP
D) ICH Q10
E) ICH Q8

4. For pharmaceutical manufacturing enterprises, a typical example is an integrated management system developed based on the requirements:

A) GMP, ISO 45001
B) GVP, ISO 9004
C) GMP, ISO 9001
D) GDP, ISO 14001
E) GMP, SA 8000

5. Legal act containing methods for quality control of medicinal products:

A) Instruction
B) Pharmacopoeia
C) Industry standard
D) Certificate

6. Formation of professional skills and abilities:

- contenttasks;
- recommendations (instructions) on how to perform tasks;
- requirements to the results of the work, including the design.

Task content

1. Indicate in the table the industry standards that regulate the relevant stages of the life cycle of medicines and indicate whether the requirements of certain standards are mandatory. Use the following data to fill in the table: GPP, ICH Q8, GVP, GMP, GRP, GDP, ICH M3(R2), GSP, GCP, GLP.

Life cycle stages medicines	**An industry standard that governs the appropriate stage of the life cycle of medicines**	**Are the requirements of the standard mandatory? to execution?**	
		Yes	**No**
Pharmaceutical development	1.		
Preclinical safety and efficacy studies	1.		
	2.		
	3.		
Clinical trials for human use	1.		
	2.		
	3.		
	4.		
State registration	1.		
	2.		
	3.		
	4.		
	5.		
Industrial production	1.		
	2.		
	3.		
	4.		
Wholesale sales	1.		
	2.		
Retail sales	1.		
	2.		
	3.		
Use in routine medical practice (post-registration period)	1.		
	2.		

2. Establish a correspondence between the stage of formation of an integrated

quality management system at a pharmaceutical enterprise and the standards that should be implemented at each corresponding stage. Enter the results of the analysis in the table.

Standards to be phased in	**Sequence of stages of forming an integrated quality management system at a pharmaceutical enterprise**			
	Stage I	**Stage II**	**Stage III**	**Stage IV**
ISO 9001:2015				
ISO 14001:2015, ISO 45001:2018, ISO 26000:2010				
GDP, GSP, GPP				
GMP				

Recommendations (instructions) for completing tasks

To complete the tasks, you must use the lecture material and sources from the list of recommended literature.

Requirements for work results, including design

During the task completion process, all relevant rows and columns of the tables must be filled in. To fill in the tables, use the "+" or "√" signs.

Summary: In the process of conducting the lesson, the goal of the lesson is achieved, namely: higher education students are monitored for the basic level of knowledge of the rules of good pharmaceutical practices and other industry standards, and practical skills are formed in the development, implementation, maintenance and improvement of quality management systems in pharmacy in accordance with the rules of good practices and other industry standards.

List of recommended literature:

1. Guideline ST-N MOZU 42-3.0:2011 Medicinal products. Pharmaceutical development (ICH Q8). Kyiv, Ministry of Health of Ukraine, 2011.

2. Guideline ST-N MOZU 42-6.0:2008 Medicinal products. Good laboratory practice. Kyiv, Ministry of Health of Ukraine, 2009.

3. Guideline ST-N MOZU 42-6.0:2014 Medicinal products. Preclinical safety studies as a basis for clinical trials involving humans and registration of medicinal products (ICH M3(R2)). Kyiv, Ministry of Health of Ukraine, 2014.

4. Guideline ST-N MOZU 42-7.0:2008 Medicinal products. Good clinical practice. Kyiv, Ministry of Health of Ukraine, 2009.

5. Guideline ST-N MOZU 42-7.4:2022 Medicinal products. Bioequivalence studies. Kyiv, Ministry of Health of Ukraine, 2022.

6. Guideline ST-N MOZU 42-1.1:2013 Medicinal products. Good regulatory practice. Kyiv, Ministry of Health of Ukraine, 2013.

7. Guideline ST-N MOZU 42-4.0:2020 Medicinal products. Good manufacturing practice. Kyiv, Ministry of Health of Ukraine, 2020.

8. Guideline ST-N MOZU 42-5.1:2011 Medicinal products. Good storage practices. Kyiv, Ministry of Health of Ukraine, 2011.

9. Guideline ST-N MOZU 42-5.0:2014 Medicinal products. Good distribution practice. Kyiv, Ministry of Health of Ukraine, 2014.

10. The procedure for conducting an examination of registration materials for medicinal products submitted for state registration (re-registration), as well as an examination of materials on amendments to registration materials during the validity of the registration certificate, approved by Order of the Ministry of Health of Ukraine dated August 26, 2005 No. 426 (as amended).

11. Procedure for conducting clinical trials of medicinal products and examination of clinical trial materials and the Model Regulations on Ethics Commissions, approved by Order of the Ministry of Health of Ukraine dated September 23, 2009 No. 690 (as amended).

12. Licensing conditions for conducting business activities in the production of medicines, wholesale and retail trade in medicines, import of medicines (except for active pharmaceutical ingredients), approved by Resolution of the Cabinet of Ministers of Ukraine dated November 30, 2016 No. 929 (as amended).

13. Procedure for quality control of medicinal products during wholesale and retail trade, approved by order of the Ministry of Health of Ukraine dated September 29, 2014 No. 677 (as amended).

14.Good Pharmacy Practice: Quality Standards for Pharmacy Services (Joint IFF/WHO guideline on NAP)WHO; Standard, International document dated 01.01.2011.

15. Guideline ST-N MOZU 42-8.5:2015 Medicinal products. Good pharmacovigilance practices. Kyiv, Ministry of Health of Ukraine, 2015.

16. Guideline ST-N MOZU 42-4.2:2011 Medicinal products. Quality risk management (ICH Q9). Kyiv, Ministry of Health of Ukraine, 2011.

17. Guideline ST-N MOZU 42-4.3:2011 Medicinal products. Pharmaceutical quality system (ICH Q10). Kyiv, Ministry of Health of Ukraine, 2011.

18. State Pharmacopoeia of Ukraine: in 3 volumes / State Enterprise “Ukrainian Scientific Pharmacopoeial Center for the Quality of Medicines”. – 2nd ed. – Kharkiv: State Enterprise “Ukrainian Scientific Pharmacopoeial Center for the Quality of Medicines”, 2015.

19. Law of Ukraine “On Medicinal Products” dated 04.04.1996 No. 123/96-VR (as amended).

20. The procedure for conducting pharmacovigilance, approved by the order of the Ministry of Health of Ukraine dated 27.12.2006 No. 898 (as amended).

Electronic information resources:

1. International Council for Harmonization of Technical Requirements for

Medicinal Products for Human Use (ICH) – Access mode:https://www.ich.org/

2. EuropeanMedicines Agency (EMA) Access mode:https://www.ema.europa.eu/en/

2. European Directorate for the Quality of Medicines and Healthcare Products (EDQM) – Access mode:https://www.edqm.eu/en/

3. Legislation of Ukraine – Access mode:https://zakon.rada.gov.ua/laws/

4. Normative and directiveDocuments of the Ministry of Health of Ukraine Access mode:https://moz.gov.ua/

5. State Enterprise "State Expert Center of the Ministry of Health of Ukraine" - Access mode:https://www.dec.gov.ua/

6. DP"Ukrainian Scientific Pharmacopoeia Quality Center" medical"Tools" - Access mode: https://sphu.org/viddil-dfu

PRACTICAL LESSON No. 5

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

Goal:to control the basic level of knowledge of higher education students regarding the structure of the state system for regulating the circulation of medicines in Ukraine and to develop practical skills in applying theoretical knowledge about the regulatory authorities of Ukraine in the field of quality management of medicines.

Basic concepts:central executive body in the field of healthcare, specialized expert organization authorized by the central executive body in the field of healthcare in the field of circulation of medicinal products, state registration of a medicinal product, state re-registration of a medicinal product, applicant, medicinal product according to a complete dossier, generic medicinal product, hybrid medicinal product, biosimilar, medicinal product with a well-studied medical use, fixed combination, informed consent, traditional medicinal product, bulk production, orphan medicinal product, registration dossier, state register of medicinal products, benefit/risk ratio of a medicinal product, unexpected adverse reaction, expected adverse reaction, non-serious adverse reaction, serious adverse reaction.

Equipment:laptop, multimedia projector.

1. Plan:

Organizational activities (welcome, checking attendance, announcement of the topic, objectives of the lesson, motivation of higher education students to study the topic).

The central executive body in the field of healthcare and other authorized bodies, expert institutions apply good regulatory practice in the field of circulation of medicines in order to ensure the effectiveness, safety, quality and accessibility of medicines.

2. Control of the reference level of knowledge:

- requirements to the theoretical readiness of higher education students to perform practical classes (knowledge requirements, list of didactic units);
- question (test tasks) to check basic knowledge on the topic of the lesson.

3. Knowledge requirements:

Higher education students should know the structure of the state system for regulating the circulation of medicines in Ukraine.

4. List of didactic units:

1. Ministry of Health of Ukraine.
2. State Expert Center of the Ministry of Health of Ukraine.

5. Test tasks

1. The procedure carried out to establish the effectiveness, safety and quality of a medicinal product and is a condition for its introduction into the pharmaceutical market is called:

A) Standardization
B) Licensing
D) State re-registration
C) State registration

2. A medicinal product for which the applicant can demonstrate that the active substance of a medicinal product with well-studied therapeutic properties within the EU has had a recognized efficacy and an acceptable level of safety in all pharmaceutical forms for at least 10 years, belongs to the following type of medicinal product:
A) Biosimilar
B) Hybrid
D) Generic
C) A drug with a well-studied medical use
E) Traditional medicine

3. A medicinal product containing a new active substance belongs to the following type of medicinal product:
A) Orphan drug
B) Innovative drug
D) Hybrid drug
C) Biosimilar
E) Orphan drug

4. An adverse reaction, the nature or severity of which is consistent with the available information about the medicinal product in the instructions for medical use of the medicinal product, and which poses a threat to life, requires hospitalization of the patient, can be characterized as:
A) Presumed frivolous
C) Unpredictable serious
D) Unpredictable, not serious
C) Presumed serious
E) This adverse reaction cannot be classified.

5. In accordance with current legislation, pharmaceutical professionals must report all cases of suspected adverse reactions if the adverse reactions are of the following type:
A) Unexpected adverse reaction
C) Serious adverse reaction
D) Non-serious adverse reaction
C) Anticipated adverse reaction

6. Formation of professional skills and abilities:
- contenttasks;
- recommendations (instructions) on how to perform tasks;
- requirements to the results of the work, including the design.

Task content

1. EnterEnter the data on the type of medicinal product in the table according to the definition given. Use the following data to fill in the table: biosimilar,generic medicinal product, traditional medicinal product, bulk products, medicinal product with a complete dossier, orphan medicinal product, fixed combination, medicinal product with a well-studied medical use, hybrid medicinal product, informed consent.

Definition	**Typemedicinal product**
A medicinal product whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.	
A medicinal product that has passed all stages of the technological process, except for the stage of filling and/or final packaging and labeling.	
A medicinal product for which the applicant can prove that the active substance of the medicinal product with well-studied therapeutic properties within the EU and/or Ukraine has had recognized efficacy and an acceptable level of safety in any dosage form for at least 10 years.	
A medicinal product intended for the diagnosis, prevention or treatment of a rare disease.	
A medicinal product that is registered with the same qualitative and quantitative composition of active substances in the same dosage form as another medicinal product, the registration holder for which has granted permission to another applicant to use the documentation of the registration dossier for his registered medicinal product.	
A medicinal product for which the applicant can prove that the relevant product has been used in medical practice for a period of at least 30 years preceding the date of submission of the traditional medicinal product for registration, including at least 15 years in the EU and/or Ukraine.	
A biological medicinal product that is similar in quality, efficacy and safety to a registered reference biological product whose patent protection period has expired.	
A medicinal product that differs in the salt form of the active substance, therapeutic indications, dosage, pharmaceutical form or route of administration compared to the reference medicinal product.	

A medicinal product that contains a new active ingredient.	
A combination of several active ingredients in one dosage form for therapeutic purposes.	

2. Enter the data on the type of adverse reaction associated with the use of the medicinal product in the table, according to the definition given. Indicate whether it is necessary to report the case of an adverse reaction of a certain type to the State Expert Center of the Ministry of Health of Ukraine. Use the following data to fill in the table: unexpected adverse reaction, expected adverse reaction, non-serious adverse reaction, serious adverse reaction.

Definition	**Type of adverse reaction**	**Do I need to report to the SEC of the Ministry of Health? Ukraineabout the case of side effects reactions of this type?**	
		Yes	**No**
An adverse reaction that does not lead to death, is not life-threatening, does not require hospitalization or an increase in the length of hospitalization, does not cause persistent or significant incapacity or disability and congenital anomalies or developmental defects and does not have any other significant medical assessment.			
An adverse reaction whose nature or severity is inconsistent with available information about the medicinal product in the instructions for medical use of the medicinal product.			
An adverse reaction that results in death, is life-threatening, requires hospitalization or prolongs hospitalization, causes persistent or significant incapacity or disability, or is a congenital anomaly or developmental defect, or has other important medical significance.			

An adverse reaction, the nature or severity of which is consistent with the available information about the medicinal product in the instructions for medical use of the registered medicinal product.			

Recommendations (instructions) for completing tasks

To complete the tasks, you must use the lecture material and sources from the list of recommended literature.

Requirements for work results, including design

In the process of completing the tasks, all the corresponding rows and columns of the tables must be filled in. To fill in the table of task 2, use the "+" or "√" signs.

Summary: In the process of conducting the lesson, the goal of the lesson is achieved, namely: higher education applicants are monitored for the basic level of knowledge regarding the structure of the state system for regulating the circulation of medicines in Ukraine and practical skills are formed in the application of theoretical knowledge about the regulatory authorities of Ukraine in the field of quality management of medicines.

List of recommended literature:

1. Law of Ukraine "On Medicinal Products" dated 04.04.1996 No. 123/96-VR (as amended).

2. The procedure for conducting an examination of registration materials for medicinal products submitted for state registration (re-registration), as well as an examination of materials on amendments to registration materials during the validity of the registration certificate, approved by Order of the Ministry of Health of Ukraine dated August 26, 2005 No. 426 (as amended).

3. The procedure for conducting pharmacovigilance, approved by the order of the Ministry of Health of Ukraine dated 27.12.2006 No. 898 (as amended).

Electronic information resources

1. Legislation of Ukraine – Access mode:https://zakon.rada.gov.ua/laws/

2. Normative and directiveMinistry of Health documents Ukraine– Access mode:https://moz.gov.ua/

3. State Enterprise "State Expert Center of the Ministry of Health of Ukraine" - Access mode:https://www.dec.gov.ua/

PRACTICAL LESSON No. 6

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

Goal:to control the basic level of knowledge of higher education students regarding the structure of the state system for regulating the circulation of medicines in Ukraine and to develop practical skills in applying theoretical knowledge about the regulatory authorities of Ukraine in the field of quality management of medicines.

Basic concepts:central executive body in the areas of quality control and safety

of medicines, certification of quality systems, certificate for the quality system of the enterprise.

Equipment:laptop, multimedia projector.

1. Plan:

Organizational activities (welcome, checking attendance, announcement of the topic, objectives of the lesson, motivation of higher education students to study the topic).

The central executive body in the field of healthcare and other authorized bodies, expert institutions apply good regulatory practice in the field of circulation of medicines in order to ensure the effectiveness, safety, quality and accessibility of medicines.

2. Control of the reference level of knowledge:

- requirements to the theoretical readiness of higher education students to perform practical classes (knowledge requirements, list of didactic units);
- question (test tasks) to check basic knowledge on the topic of the lesson.

3. Knowledge requirements:

Higher education students should know the structure of the state system for regulating the circulation of medicines in Ukraine.

4. List of didactic units:

1. Directorate of Pharmaceutical Supply of the Ministry of Health of Ukraine.
2. State Service of Ukraine for Medicines and Drug Control.
3. Certification and licensing as components of a quality system in pharmacy.

5. Test tasks:

1. The list of tasks of the State Service of Ukraine for Medicinal Products and Drug Control does not include the following task:

A) Licensing of import of medicines;

B) Formation of a license register for the production of medicinal products;

D) Monitoring compliance with licensing conditions for wholesale and retail trade in medicines;

C) Issuance of permits to business entities for the right to import narcotic drugs;

E) Revision of the National List of Essential Medicines.

2. Approval of the Register of Reimbursable Medicinal Products is a priority task of the following state unit:

A) State Enterprise "State Expert Center of the Ministry of Health of Ukraine";

C) Territorial bodies of the State Service of Ukraine for Medicines and Drug Control;

D) Directorate of Pharmaceutical Supply of the Ministry of Health of Ukraine.

3. A state enterprise that falls under the jurisdiction of the State Service of Ukraine for Medicines and Drug Control and has the right to develop the State Pharmacopoeia is:

A) State Enterprise "State Expert Center of the Ministry of Health of Ukraine";

C) SE "Ukrainian Research and Training Center for Standardization, Certification and Quality";

D) SE "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products";

C) SE "Ukrainian Pharmaceutical Institute of Quality";

E) There is no such organization in the management of the State Medical Service.

4. In which structural unit can arbitration analysis of medicinal products be carried out in the event of an application from business entities?

A) SE "Ukrainian Research and Training Center for Standardization, Certification and Quality";

C) SE "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicines;

D) SE "Central Laboratory for the Analysis of the Quality of Medicines and Medical Products";

C) SE "Ukrainian Pharmaceutical Institute of Quality".

5. The functions of the national standardization body in Ukraine are performed by the following state enterprise:

A) State Enterprise "State Expert Center of the Ministry of Health of Ukraine";

C) SE "Ukrainian Pharmaceutical Institute of Quality";

D) SE "Ukrainian Research and Training Center for Standardization, Certification and Quality";

C) SE "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products";

E) State Enterprise "Central Laboratory for the Analysis of the Quality of Medicines and Medical Products".

6. Formation of professional skills and abilities:

- contenttasks;
- recommendations (instructions) on how to perform tasks;
- requirements to the results of the work, including the design.

Task content

1. Establish a correspondence between the names of the regulatory bodies of Ukraine in the field of quality management of medicines and the main functions that these structural bodies perform. Enter the results of the analysis in the table.

Main functions	**Regulatory authorities of Ukraine in the field of quality management of medicines**		
	DP "State Expertcenter of the Ministry of Health of Ukraine"	**Directorate of Pharmaceutical provision of the Ministry of Health Ukraine**	**Civil Service of Ukraine on medicines and drug control**

Ensuring industry certification of laboratories for quality control of medicines and laboratories of blood system entities.			
Conducting expert work in the field of state registration of medicines.			
Ensuring the licensing of business activities for the import of medicines.			
Registration of disinfectants and formation of a register of disinfectants.			
Ensuring the organization of work and taking measures to detect, seize and prevent trafficking falsified, low-quality, unregistered medicines in Ukraine.			
Standardization of medical, including pharmaceutical, services.			
Review and approval of the Register medicines that are subject to reimbursement.			
View the National List essential medicines.			
Ensuring the licensing of business activities for the production of medicines.			
Implementation of pharmacovigilance.			
Organization of the submission of proposals in accordance with the established procedure regarding the determination of the maximum permissible quantity of narcotic drugs, psychotropic substances and precursors contained in medicinal			

products.			
Conducting expert work in the field of preclinical studies of medicines.			
Ensuring the formation and maintenance of a licensed register for the production of medicinal products.			
Approval of the Register of maximum wholesale prices for certain medicines purchased with budget funds and included in the national list.			
Formation of a database of entities undergoing compliance certification GDP requirements.			
Conducting an examination of documents submitted for obtaining licenses to conduct business activities in the wholesale and retail trade of medicines.			
Ensuring the licensing of business activities for the procurement and testing of donor blood and blood components.			
Conducting expert work in the field of clinical trials of medicines.			
Approval of the Register of Reference Prices for Insulin Drugs.			

2. Establish a correspondence between the names of state-owned enterprises that fall under the jurisdiction of the State Service of Ukraine for Medicines and Drug Control and the main functions that these enterprises perform. Enter the results of the analysis in the table.

Main functions	**State-owned enterprises falling under the jurisdiction of the State Service of Ukraine for Medicines and Drug Control**		
	Central Laboratoryo n the analysis of the quality of medicines and medical products	Ukrainian Pharmaceutic al Institute qualities	Ukrainian Scientific Pharmacopoei acenter for quality of medicines means
Conducting inspections of drug production conditions to determine compliance of drug production with the requirements of good manufacturing and distribution practices.			
Conducting specialized expertise to issue expert opinions on the right to import into the territory of Ukraine, export from the territory of Ukraine of narcotic drugs, psychotropic substances and precursors.			
Conducting training for organization specialists on the rules of good manufacturing and distribution practices for the production of medicines and medical devices.			
Development and support of the National SystemPharmacopoeial standard samples of the State Pharmacopoeia of Ukraine.			

Qualification of analytical instruments and equipment.			
Conducting arbitration analysis of medicines upon submission The State Medical Service and upon requests from business entities.			
Development, support and publishingState Pharmacopoeia of Ukraine.			

Recommendations (instructions) for completing tasks.

To complete the tasks, you must use the lecture material and sources from the list of recommended literature.

Requirements for work results, including design.

During the task completion process, all relevant rows and columns of the tables must be filled in. To fill in the tables, use the "+" or "√" signs.

Summary: In the process of conducting the lesson, the goal of the lesson is achieved, namely: higher education applicants are monitored for the basic level of knowledge regarding the structure of the state system for regulating the circulation of medicines in Ukraine and practical skills are formed in the application of theoretical knowledge about the regulatory authorities of Ukraine in the field of quality management of medicines.

List of recommended literature:

1. Law of Ukraine "On Medicinal Products" dated 04.04.1996 No. 123/96-VR (as amended).

2. The procedure for conducting an examination of registration materials for medicinal products submitted for state registration (re-registration), as well as an examination of materials on amendments to registration materials during the validity of the registration certificate, approved by Order of the Ministry of Health of Ukraine dated August 26, 2005 No. 426 (as amended).

3. The procedure for conducting pharmacovigilance, approved by the order of the Ministry of Health of Ukraine dated 27.12.2006 No. 898 (as amended).

4. Licensing conditions for conducting business activities in the production of medicines, wholesale and retail trade in medicines, import of medicines (except for active pharmaceutical ingredients), approved by Resolution of the Cabinet of Ministers of Ukraine dated November 30, 2016 No. 929 (as amended).

5. Procedure for quality control of medicinal products during wholesale and retail trade, approved by order of the Ministry of Health of Ukraine dated September 29, 2014 No. 677 (as amended).

Electronic information resources:

1. Legislation of Ukraine – Access mode:https://zakon.rada.gov.ua/laws/
2. Normative and directiveMinistry of Health documents Ukraine– Access mode:https://moz.gov.ua/
3. State Enterprise "State Expert Center of the Ministry of Health of Ukraine" - Access mode:https://www.dec.gov.ua/
4. State Service of Ukraine for Medicines and Drug Control (State Service) – Access mode:https://www.dls.gov.ua/
5. SE "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicines" - Access mode: https://sphu.org/viddil-dfu

PRACTICAL LESSON No. 7

Topic 4. Statistical methods of quality control.

Goal:to control the basic level of knowledge of higher education students regarding the methodological principles of using statistical quality control methods and to develop practical skills in the application of elementary quality control tools in pharmacy.

Basic concepts:quality analysis, process analysis, process control, statistical acceptance control, checklist, Pareto diagram, Ishikawa cause-and-effect diagram, histogram, scatter diagram, control chart, stratification.

Equipment:laptop, multimedia projector.

1. Plan:

Organizational activities (welcome, checking attendance, announcement of the topic, objectives of the lesson, motivation of higher education students to study the topic).

Today, high product quality is considered one of the important conditions for the development of the economy, on which the pace of industrial growth of the country, the efficiency of the use of labor resources, the success of foreign trade and its national prestige depend. In an effort to enter the world markets with fierce competition, domestic enterprises are actively implementing quality management systems that would meet recognized international requirements and stimulate continuous improvement of products. Effective quality management of production processes is impossible without the use of statistical methods capable of timely, efficiently and objectively reflecting changes in the process.

2. Control of the reference level of knowledge:

− requirements to the theoretical readiness of higher education students to perform practical classes (knowledge requirements, list of didactic units);

− question (test tasks) to check basic knowledge on the topic of the lesson.

3. Knowledge requirements:

ApplicantsHigher education institutions should know the methodological principles of using statistical methods of quality control.

List of didactic units

1. The essence of statistical methods of quality control.
2. Checklist.
3. Pareto chart.
4. Ishikawa cause-and-effect diagram.
5. Histogram.
6. Scatter diagram.
7. Control card.
8. Stratification.

4. Test tasks:

1. Terminological principles for the implementation of statistical methods are set out in the international standard:

A) ISO 31000:2018
B) ISO/TR 10017:2021
WITH)ISO 10000 series standards
D) ISO 9000 series standards

2. What quality control tool allows you to visualize the amount of loss depending on various defects, focusing on eliminating those defects that lead to the greatest losses?

A) Scatter plot
B) Pareto diagram
C) Cause-and-effect diagram
D) Control charts

3. What quality control tool allows you to track the nature of the process and influence it, preventing it from deviating from the requirements imposed on the process by the standard?

A) Scatter plot
B) Stratification
C) Ishikawa diagram
D) Control charts

4. What control tool is used to identify the dependence between two parameters and provides the opportunity to determine the type and density of the relationship between them?

A) Scatter diagram
B) Pareto diagram
C) Cause-and-effect diagram
D) Checklist

5. What quality control tool allows you to identify the most significant factors affecting the final result?

A) Checklist
B) Pareto diagram
C) Cause-and-effect diagram
D) Histogram

5. Formation of professional skills and abilities:

- contenttasks;
- recommendations (instructions) on how to perform tasks;
- requirements to the results of the work, including the design.

6. Task content:

1. Fill in the table by indicating in the appropriate rows the numbers that correspond to the characteristics of statistical quality control methods:

1. The method makes it possible to identify the main factors that make the most significant contribution to the problem under consideration.
2. The method facilitates the process of collecting data on controlled parameters and identifying defects.
3. The method is based on the rule: most defects are caused by multiple causes.
4. A method that uses the concepts of upper and lower boundary lines.
5. A method that involves dividing the obtained data into separate groups depending on the selected stratifying factor.
6. A graphical method of investigating the most significant cause-and-effect relationships between factors and consequences in the situation under study.
7. The method is intended for graphical representation of data grouped by hit frequency in a certain interval.
8. A visual document for recording data during control, on which the controlled parameters are marked.
9. The method allows you to organize the original data to facilitate their further analysis.
10. The method is designed to identify the dependence of one variable on another.
11. The method allows you to assess how often the values of the studied parameter fall within the permissible range or go beyond it. The main task of the method is to determine those several types of defects that have an absolute and relative majority.
12. When applying this method, you can use the "5M" rule: materials, methods, measuring, men, machines (twice).
13. A graphical method used to examine the change in control data over time.
14. The method is used to visually display the distribution of specific parameter values by repetition frequency over a certain period of time.

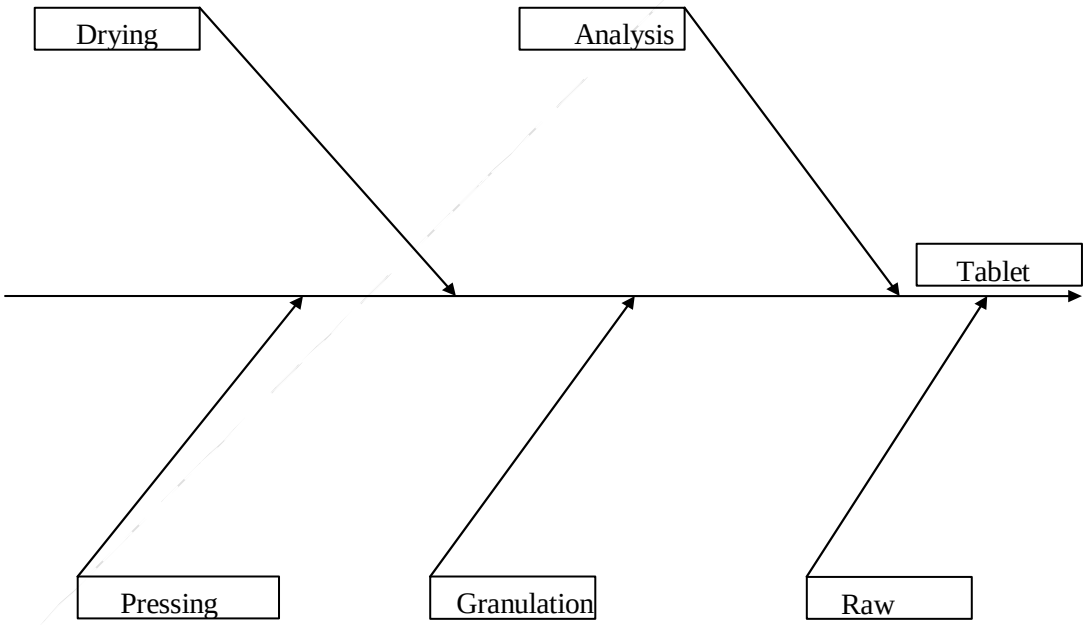
Name of statistical quality control method	**Method characteristics**
Checklist	
Pareto chart	
Ishikawa Cause and Effect Diagram	
Histogram	
Scatter diagram	
Control card	
Stratification	

2. Construct a cause-and-effect diagram that identifies the causes that can affect the quality of the finished drug in tablet form. Use the following data to complete the task:

1. Basic pressing.
2. Particle size of the excipients of the medicinal product.
3. Punch feed depth.

4. Drying temperature.
5. Particle size of the active pharmaceutical ingredient of the medicinal product.
6. Relative humidity.
7. Air speed.
8. Chopper speed.
9. Sample analysis method.
10. Moisture content in excipients of the medicinal product.
11. Pressing speed.
12. Shelf life of the active pharmaceutical ingredient of the medicinal product.
13. Mixer speed.
14. Sampling.
15. Moisture content in the active pharmaceutical ingredient of a medicinal product.
16. Sawing speed.
17. Pre-pressing.

On the diagram, mark the numbers that correspond to potential reasons that could affect the result.



Recommendations (instructions) for completing tasks

To complete the tasks, you must use the lecture material and sources from the list of recommended literature.

Requirements for work results, including designIn the process of completing task 1, all relevant rows of the table must be filled in.

Present the results of task 2 in the form of a cause-and-effect diagram.

Summary: In the process of conducting the lesson, the goal of the lesson is achieved, namely: higher education applicants are monitored for the basic level of

knowledge regarding the methodological principles of using statistical quality control methods and practical skills are formed regarding the application of elementary quality control tools in pharmacy.

List of recommended literature:

1. DSTU 3514-97 Statistical methods of quality control and regulation. Terms and definitions.

2. DSTU ISO/TR 10017:2005 (ISO/TR 10017:2003, IDT). Guidelines for the application of statistical methods in accordance with ISO 9001:2000. Kyiv, Derzhspozhyvstandart of Ukraine, 2007.

PRACTICAL LESSON No. 8

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

Goal:to control the basic level of knowledge of higher education students regarding the regulation and documentation of pharmaceutical quality system processes and to develop practical skills in documenting the quality management system at a pharmaceutical enterprise.

Basic concepts:quality manual, quality policy, quality objectives, process implementation methodology, standard operating procedure, work instructions, protocol (as a form of record), "inter-process" documents.

Equipment:laptop, multimedia projector.

1. Plan:

Organizational activities (welcome, checking attendance, announcement of the topic, objectives of the lesson, motivation of higher education students to study the topic).

Document management processes for any pharmaceutical company are one of the cornerstones of the management system. The use of modern effective methods and tools for document management is critically important and necessary at all stages of document management. The implementation of a project to implement a quality management system at a pharmaceutical company requires the establishment of clear algorithms for performing document and record management activities as processes that achieve the planned results, as well as systematic tracking of the performance indicators of these processes and the implementation of actions for their continuous improvement.

2. Control of the reference level of knowledge:

− requirements to the theoretical readiness of higher education students to perform practical classes (knowledge requirements, list of didactic units);

− question (test tasks) to check basic knowledge on the topic of the lesson.

3. Knowledge requirements:

Higher education students should know the essence of regulating and documenting pharmaceutical quality system processes.

List of didactic units

1. The essence of documenting the quality management system at a pharmaceutical enterprise.
2. Quality guideline.
3. Process execution methods.
4. Third-level quality management system documents.
5. Level 4 quality management system documents.
6. "Inter-process" documents.
7. Formation of a document management procedure.

4. Test tasks

1. What documents of a pharmaceutical company are managed in accordance with the requirements of the ISO 9001 standard?

A) All documents of the pharmaceutical company

B) Documents that regulate activities that affect product quality

C) Documents, the circulation of which is regulated by the internal requirements of the pharmaceutical enterprise

2. Which standard provides guidelines for the development and maintenance of quality management system documentation?

A) EN ISO 9001:2015

B) ISO 9001:2015

C) ISO/TR 10013:2001

D) ISO 9004:2018

3. SystemDocument flow of a pharmaceutical enterprise is regulated by the following regulatory documents:

A) GMP

C) Licensing conditions for conducting business activities in the production of medicines, wholesale and retail trade in medicines.

C) Internal requirements of the pharmaceutical company

D) All options are correct.

4. To which level of quality management system documents do the organization's documents that describe the distribution of responsibilities and authorities within the process belong?

A) To the first level

B) To the second level

C) To the third level

D) Up to the fourth level

E) These are “inter-process” documents

5. In which document does an organization document its own quality management system?

A) Quality Guideline

C) Documented Quality Policy

C) Documented Quality Objectives

D) Process execution methodologies

E) Job descriptions

5. Formation of professional skills and abilities:

- contenttasks;
- recommendations (instructions) on how to perform tasks;
- requirements to the results of the work, including the design.

Task content

1. Installcorrespondence between the designation of the standard and the main provisions of this standard. Enter the results of the analysis in the table.

Main provisions of the standard	**Name of the international standard**	
	ISO 9001:2015	**ISO/TR 10013:2001**
According to the requirements of the standard, the organization must document its quality management system.		
The standard defines for all processes of the quality management system, in particular the document management process, the criteria and methods necessary to control these processes.		
The standard contains guidelines for the development of quality management system documentation.		
The standard requires taking the necessary measures to continuously improve all processes of the quality management system, including the document management process.		

2. Provide a description of the sections of the Quality Manual. Enter the relevant data in the table.

Quality Guidelines Sections	**Document section description**
Information about the organization	
Regulatory references	
Organizational context	
Leadership	
Planning	

Software	
Functioning	
Performance evaluation	
Improve	
Applications	

Recommendations (instructions) for completing tasks.

To complete the tasks, you must use the lecture material and sources from the list of recommended literature.

Requirements for work results, including design.

In the process of completing the tasks, all the corresponding rows and columns of the tables must be filled in. To fill in the table of task 1, use the "+" or "√" signs.

Summary: In the process of conducting the lesson, the goal of the lesson is achieved, namely: higher education students are monitored for the basic level of knowledge regarding the regulation and documentation of pharmaceutical quality system processes and practical skills are formed regarding the documentation of the quality management system at a pharmaceutical enterprise.

List of recommended readings

1. DSTU ISO 9001:2015 (ISO 9001:2015, IDT). Quality management systems. Requirements. Kyiv, SE "UkrNDNTS", 2016.

2. DSTU ISO/TR 10013:2003 (ISO/TR 10013:2001, IDT). Guidelines for the development of quality management system documentation. Kyiv, State Enterprise "UkrNDNC".

3. Good practices in pharmacy: a manual for students of higher education. / V. O. Lebedynets, O. V. Tkachenko, Yu. I. Gubin and others. Kharkiv: National University of Pharmacy: Golden Pages, 2017. 296 p.

PRACTICAL LESSON No. 9

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

Goal:to control the basic level of knowledge of higher education students regarding the regulation and documentation of pharmaceutical quality system processes and to develop practical skills in documenting the quality management system at a pharmaceutical enterprise.

Basic concepts:quality manual, quality policy, quality objectives, process implementation methodology, standard operating procedure, work instructions, protocol (as a form of record), "inter-process" documents.

Equipment:laptop, multimedia projector.

1. Plan:

Organizational activities (welcome, checking attendance, announcement of the topic, objectives of the lesson, motivation of higher education students to study the topic).

Document management processes for any pharmaceutical enterprise are one of the cornerstones of the management system. The use of modern effective methods and tools for document management is critically important and necessary at all stages of document management. The implementation of a project to implement a quality management system at a pharmaceutical enterprise requires the establishment of clear algorithms for performing document and record management activities as processes that achieve the planned results, as well as systematic tracking of the performance indicators of these processes and the implementation of actions for their continuous improvement.

2. Control of the reference level of knowledge:

- requirements to the theoretical readiness of higher education students to perform practical classes (knowledge requirements, list of didactic units);
- question (test tasks) to check basic knowledge on the topic of the lesson.

3. Knowledge requirements

Higher education students should know the essence of regulating and documenting pharmaceutical quality system processes.

List of didactic units

1. The essence of documenting the quality management system at a pharmaceutical enterprise.
2. Quality guideline.
3. Process execution methods.
4. Third-level quality management system documents.
5. Level 4 quality management system documents.
6. "Inter-process" documents.
7. Formation of a document management procedure.

4. Test tasks

1. Which standard provides for the definition of criteria and methods for all processes of the quality management system (in particular the document management process) necessary to ensure the effectiveness of their functioning and control?

A) ISO 9000:2015
B) ISO 9001:2015
C) ISO/TR 10013:2001
D) ISO 9004:2018

2. To which level of quality management system documents do the documents of a pharmaceutical enterprise that contain requirements for raw materials, materials, equipment, premises, and personnel belong?

A) To the first level
B) To the second level
C) To the third level
D) Up to the fourth level
E) These are “inter-process” documents

3. What quality management system documents are necessary to confirm the proper performance of operations and to monitor and analyze them?

A) Protocols
B) Documented procedures
C) Standard Operating Procedures
D) Work instructions
E) “Inter-process” documents

4. Which employees of the organization participate in the development of the organization's quality management system documentation?

A) Employees involved in the quality management system processes
B) Owners (managers) of quality management system processes
C) Organizational leadership
D) All options are correct.

5. Which documents of the organization describe who, what, in what sequence and in connection with which processes carries out activities at the level of each individual process?

A) Protocols
B) Job descriptions
C) Standard Operating Procedures
D) Documented procedures

5. Formation of professional skills and abilities:

- contenttasks;
- recommendations (instructions) on how to perform tasks;
- requirements to the results of the work, including the design.

Task content

1. Fill in the table by indicating in the appropriate rows the numbers that correspond to the quality management system documents of a certain level:

1. Documents,which contain general rules for performing certain tasks in the organization as a whole.
2. Documents containing requirements for the characteristics of raw materials, materials, equipment, premises, products, and personnel.
3. Documents that describe the interrelated processes and activities necessary to implement a quality management system.
4. Documents required to confirm the proper execution of operations and processes.
5. A conceptual document describing a quality management system.
6. A document that reflects all the activities of the enterprise that affect the quality of products.
7. Documents that describe the distribution of responsibilities and authorities within the process.
8. Documents describing algorithms for performing operations within the processes of the quality management system.
9. Documents that must be kept during or after the execution of processes and operations at various levels.
10. A document containing commitments to meet requirements and continually improve the performance of the quality management system.
11. Documents that describe the progress of activities at the level of each individual process.
12. A document containing quality objectives that are formulated on the basis of the quality policy defined by the organization.
13. Documents that indicate the parameters of the work and/or contain characteristics of their results.

Quality management system document groups	**Quality management system documents**
First level quality management system documents.	
Second-level quality management system documents.	
Third-level quality management system documents.	
Level 4 quality management system documents.	

"Inter-process" documents.	

2. Match the name of the document with its developer. Enter the results of the analysis in the table.

Document name	**Document developer**		
	Head process	**Employee, responsible for execution described operations**	**Employee, which performs operation**
Job description			
Operating instructions			
Process implementation methodology			
Test protocol			
Standard operating procedure			
Technical conditions			
Checklist			

Recommendations (instructions) for completing tasks.

To complete the tasks, you must use the lecture material and sources from the list of recommended literature.

Requirements for work results, including design.

In the process of completing the tasks, all the corresponding rows of the table must be filled in. To fill in the table of task 2, use the "+" or "√" signs.

Summing up. In the process of conducting the lesson, the goal of the lesson is achieved, namely: for higher education applicants is carried outcontrol of the reference equalknowledge on regulating and documenting pharmaceutical quality system processes and the formation of practical skills on documenting the quality management system at a pharmaceutical enterprise.

List of recommended literature:

1. DSTU ISO 9001:2015 (ISO 9001:2015, IDT). Quality management systems. Requirements. Kyiv, SE "UkrNDNTS", 2016.

2. DSTUISO/TR 10013:2003 (ISO/TR 10013:2001, IDT). Guidelines for the development of quality management system documentation. Kyiv, State Enterprise "UkrNDNC".

3.Good practices in pharmacy: a manual for students of higher education

institutions / V. O. Lebedynets, O. V. Tkachenko, Yu. I. Gubin and others. Kharkiv: National University of Pharmacy: Golden Pages, 2017. 296 p.

PRACTICAL LESSON No. 10

Topic 6. Risk assessment for the quality of medicines at all stages of their life cycle.

Goal:to control the basic level of knowledge of higher education students regarding the methodological principles of risk assessment for the quality of medicines at all stages of their life cycle and to develop practical skills in the application of risk management tools for the quality of medicines.

Basic concepts:risk, quality risk management, failure nature and consequences analysis; failure nature, consequences and criticality analysis; fault tree analysis, operational safety analysis and critical control points, operational safety and availability analysis, preliminary operational safety analysis, risk ranking and filtering.

Equipment:laptop, multimedia projector.

1. Plan:

Organizational activities (welcome, checking attendance, announcement of the topic, objectives of the lesson, motivation of higher education students to study the topic).

There is always some degree of risk involved in the production of medicines. An effective approach to quality risk management can further ensure that the patient receives a high quality medicine by establishing preventive measures to identify and control potential quality issues during development and production.

2. Control of the reference level of knowledge:

- requirements to the theoretical readiness of higher education students to perform practical classes (knowledge requirements, list of didactic units);
- question (test tasks) to check basic knowledge on the topic of the lesson.

3. Knowledge requirements:

Higher education students should know the methodological principles of conducting risk assessments for the quality of medicines at all stages of their life cycle.

List of didactic units

1. Quality risk management process.
2. Failure Mode and Effects Analysis (FMEA).
3. Failure Mode, Effects and Criticality Analysis (FMECA).
4. Fault Tree Analysis (FTA).
5. Hazard Analysis and Critical Control Points (HACCP).
6. Operational Safety and Operability Analysis (HAZOP).
7. Preliminary Operational Safety Analysis (PHA).
8. Risk ranking and filtering.

4. Test tasks

1. Principles and examples of risk management tools for the quality of medicinal products are presented in the following guideline:

A) ICH Q8

B) ICH Q9(R1)
C) ICH Q10
D) ICH M3(R2)

2. The collection of initial information relevant to the overall risk assessment is carried out at the following stage of quality risk management:
A) Start of the quality risk management process
B) Overall risk assessment
C) Risk control
D) Risk Overview

3. The purpose of risk control is to:
A) Quantitative risk assessment
C) Qualitative description of the risk range
C) Reducing risk to an acceptable level
D) Gathering baseline information relevant to the risk

4. In which risk management method does “guide words” apply to characterize deviations from planned parameters?
A) Failure Mode Effects Analysis (FMEA)
B) Failure Mode, Effects and Criticality Analysis (FMECA)
C) Hazard Analysis and Critical Control Points (HACCP)
D) Hazard and Operational Performance Analysis (HAZOP)

5. What risk management method is used in the early stages of project development?
A) Hazard Analysis and Critical Control Points (HACCP)
B) Hazard and Operational Performance Analysis (HAZOP)
C) Preliminary Operational Safety Analysis (PHA)
D) Risk ranking and filtering method
E) Answers A) and B) are correct.

5. Formation of professional skills and abilities:
- contenttasks;
- recommendations (instructions) on how to perform tasks;
- requirements to the results of the work, including the design.

Task content

1. List the stages of the quality risk management process and describe each stage of the process. Enter the relevant data in the table.

Sequence of stages of the management process risks to quality	**Stage name**	**Stage characteristics**

Stage I		
Stage II		
Stage III		
Stage IV		

2. Complete the table by entering the numbers in the appropriate rows that correspond to the characteristics of the quality risk management methods.

1. The method allows you to identify the factors of system errors by establishing causal chains.
2. Within this method, “guide words” are used to characterize deviations from planned parameters.
3. The method is designed to assess the nature of potential failures for a process, as well as their possible consequences on the outcome of the process.
4. Method provides detection factors, related from risk, whichused as filters for risk grading.
5. The method ensures the identification and monitoring of critical process control points (twice).
6. The method is designed to assess the nature of potential failures and investigate the severity of their consequences.
7. The risk management method is applied in the early stages of project development.

Name of the quality risk management method	**Method characteristics**
Failure Mode and Effects Analysis (FMEA)	
Analysis of the nature, consequences and criticality of failures (Failure Mode, Effects, and Criticality Analysis, FMECA)	
Fault Tree Analysis (FTA)	

Operational safety analysis and critical control points (Hazard Analysis and Critical Control Points, HACCP)	
Operational safety and performance analysis (Hazard and Operability Analysis, HAZOP)	
Preliminary analysis of operational safety (Preliminary Hazard Analysis, PHA)	
Risk ranking and filtering	

Recommendations (instructions) for completing tasks.

To complete the tasks, you must use the lecture material and sources from the list of recommended literature.

Requirements for work results, including design.

During the task execution, all relevant rows and columns of the tables must be filled in.

Summary. In the process of conducting the lesson, the goal of the lesson is achieved, namely: higher education students are monitored for the basic level of knowledge regarding the methodological principles of conducting risk assessment for the quality of medicines at all stages of their life cycle and practical skills are formed in the application of risk management tools for the quality of medicines.

List of recommended literature:

1. Guideline ST-N MOZU 42-4.2:2011 Medicinal products. Quality risk management (ICH Q9). Kyiv, Ministry of Health of Ukraine, 2011.

2. DSTU ISO 31000:2018 (ISO 31000:2018, IDT). Risk management. Principles and guidelines. Kyiv, State Enterprise "UkrNDNC".

3.Good practices in pharmacy: a manual for students of higher education institutions / V. O. Lebedynets, O. V. Tkachenko, Yu. I. Gubin and others. Kharkiv: National University of Pharmacy: Golden Pages, 2017. 296 p.

PRACTICAL LESSON No. 11

Topic 6. Risk assessment for the quality of medicines at all stages of their life cycle.

Goal:to control the basic level of knowledge of higher education students regarding the methodological principles of risk assessment for the quality of medicines at all stages of their life cycle and to develop practical skills in the application of risk management tools for the quality of medicines.

Basic concepts:analysis of the nature and consequences of failures; analysis of the nature, consequences and criticality of failures; fault tree analysis, operational safety analysis and critical control points, operational safety and operability analysis, preliminary operational safety analysis, risk ranking and filtering.

Equipment:laptop, multimedia projector.

1. Plan:

Organizational activities (welcome, checking attendance, announcement of the topic, objectives of the lesson, motivation of higher education students to study the topic).

There is always some degree of risk involved in the production of medicines. An effective approach to quality risk management can further ensure that the patient receives a high quality medicine by establishing preventive measures to identify and control potential quality issues during development and production.

2. Control of the reference level of knowledge:

- requirements to the theoretical readiness of higher education students to perform practical classes (knowledge requirements, list of didactic units);
- question (test tasks) to check basic knowledge on the topic of the lesson.

3. Knowledge requirements:

Higher education students should know the methodological principles of conducting risk assessments for the quality of medicines at all stages of their life cycle.

List of didactic units

1. Failure Mode and Effects Analysis (FMEA).
2. Failure Mode, Effects and Criticality Analysis (FMECA).
3. Fault Tree Analysis (FTA).
4. Hazard Analysis and Critical Control Points (HACCP).
5. Operational Safety and Operability Analysis (HAZOP).
6. Preliminary Operational Safety Analysis (PHA).
7. Risk ranking and filtering.

4. Test tasks:

1. The following methods are used to manage risks to the quality of medicinal products:

A) Pareto charts

B) Control charts
C) Cause-and-effect diagrams
D) These methods are not used for risk management
E) The correct answers are A), B), C)

2. Which risk management method ensures the identification and monitoring of critical process control points?
A) Preliminary Operational Safety Analysis (PHA) B) Fault Tree Analysis (FTA)
B) Hazard Analysis and Critical Control Points (HACCP)
C) Hazard Analysis and Operational Capability (HAZOP) Analysis
D)The correct answers are C) and D)

3. Which risk management method is designed to identify individual failures rather than their combination?
A) Failure Mode Effects Analysis (FMEA)
B) Failure Mode, Effects and Criticality Analysis (FMECA)
C) Preliminary Operational Safety Analysis (PHA)
D)Risk ranking and filtering method
E) Answers A) and B) are correct.

4. Which risk management method involves identifying risk-related factors that are used as filters for risk grading?
A) Failure Mode Effects Analysis (FMEA)
B) Hazard and Operational Performance Analysis (HAZOP)
C) Fault Tree Analysis (FTA)
D) Risk ranking and filtering method

5. Which risk management method allows you to identify multiple factors of system failure by establishing causal chains?
A) Fault Tree Analysis (FTA)
B) Failure Mode Effects Analysis (FMEA)
C) Hazard Analysis and Operational Capability (HAZOP) Analysis
D) Preliminary Operational Safety Analysis (PHA)

5. Formation of professional skills and abilities:

- contenttasks;
- recommendations (instructions) on how to perform tasks;
- requirements to the results of the work, including the design.

Task content

1. List the advantages and disadvantages of quality risk management methods in the table.

Name of the quality risk management method	Advantages of the method	Disadvantages of the method
Analysis of the nature and consequences of failures (Failure Mode and Effects Analysis, FMEA)		
Analysis of the nature, consequences and criticality of failures (Failure Mode, Effects, and Criticality Analysis, FMECA)		
Fault Tree Analysis (FTA)		
Hazard Analysis and Critical Control Points Control Points, HACCP)		
Operational safety and performance analysis (Hazard and Operability Analysis, HAZOP)		
Preliminary Hazard Analysis (PHA) PHA)		
Risk ranking and filtering (Risk ranking and filtering)		

2. Complete the table by marking the number in the appropriate row that corresponds to the description of the scope of the quality risk management method.

1. The method is used to identify and manage risks associated with physical, chemical and biological hazards.
2. The method is used to manage risks associated with processes, equipment and technical means in the production of active substances and medicinal products.
3. The method is used in the pharmaceutical industry mainly for failures and risks associated with production processes (twice).
4. The method is used to determine priorities for inspection/audit of production sites by regulatory authorities.
5. The method is used to investigate complaints or deviations to achieve a full understanding of their root causes and ensure that planned improvements will fully resolve the problem and not lead to other problems.
6. The method is used in the early stages of project development as a preliminary tool for further research.

Name of the quality risk management method	**Scope of application of the method**
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)	
Risk ranking and filtering	

Recommendations (instructions) for completing tasks.

To complete the tasks, you must use the lecture material and sources from the list of recommended literature.

Requirements for work results, including design.

During the task execution, all relevant rows and columns of the tables must be filled in.

Summary. In the process of conducting the lesson, the goal of the lesson is achieved, namely: higher education students are monitored for the basic level of knowledge regarding the methodological principles of conducting risk assessment for the quality of medicines at all stages of their life cycle and practical skills are formed in the application of risk management tools for the quality of medicines.

List of recommended literature:

1. Guideline ST-N MOZU 42-4.2:2011 Medicinal products. Quality risk management (ICH Q9). Kyiv, Ministry of Health of Ukraine, 2011.

2. DSTU ISO 31000:2018 (ISO 31000:2018, IDT). Risk management. Principles and guidelines. Kyiv, State Enterprise "UkrNDNC".

3. Good practices in pharmacy: a manual for students of higher education. / V. O. Lebedynets, O. V. Tkachenko, Yu. I. Gubin and others. Kharkiv: National University of Pharmacy: Golden Pages, 2017. 296 p.

PRACTICAL LESSON No. 12

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.

Goal:to control the basic level of knowledge of higher education students regarding the organization of activities for the validation of production processes at pharmaceutical enterprises and to develop practical skills for implementing this type of activity at pharmaceutical enterprises.

Basic concepts:validation, process validation, prospective validation, concurrent validation, revalidation, critical quality indicator, critical process parameter, acceptance criteria, specificity, accuracy, precision, limit of detection, limit of quantification, linearity, range of application, robustness, purification validation.

Equipment:laptop, multimedia projector.

1. Plan:

Organizational activities (welcome, checking attendance, announcement of the topic, objectives of the lesson, motivation of higher education students to study the topic).

In accordance with the requirements of good manufacturing practice, the manufacturer's overall policy regarding the intentions and approach to validation and regarding the persons responsible for the development, verification, approval and documentation of each validation step should be documented.

2. Control of the reference level of knowledge:

- requirements to the theoretical readiness of higher education students to perform practical classes (knowledge requirements, list of didactic units);
- question (test tasks) to check basic knowledge on the topic of the lesson.

3. Knowledge requirements:

Higher education students should know the basic principles of organizing activities for the validation of production processes and qualification of equipment and auxiliary systems at pharmaceutical enterprises.

List of didactic units

1. Validation: definition, objects, types.
2. Human resources for validation.
3. Validation documentation.
4. Validation of analytical methods.
5. Cleaning validation.

4. Test tasks

1. The validation protocol does not include:

A) Critical process parameters

B) Number of validation cycles

C) Type of validation

D) Assessment of deviations and non-conformities
E) Acceptable test results

2. Validation, in which the batches produced during the validation protocol allow for implementation, is:
A) Retrospective validation
B) Prospective validation
C) Revalidation
D) Concurrent validation
E) Qualification

3. The ability of an analytical method to provide values directly proportional to the concentration of the analyte in the sample is understood to mean the following validation characteristic of the analytical method:
A) Precision
B) Specificity
C) Detection limit
D) Application range
E) Linearity

4. The ability to identify the analyte in the presence of other substances that may be present in the sample is understood to mean the following validation characteristic of the analytical method:
A) Correctness
B) Specificity
C) Reproducibility
D) Precision
E) Linearity

5. The cleaning validation protocol does not include:
A) Description of identified deviations in cleaning procedures
B) Acceptable levels of purification
C) Description of equipment to be cleaned
D) Types of samples
E) Sampling methods

5. Formation of professional skills and abilities:

- contenttasks;
- recommendations (instructions) on how to perform tasks;
- requirements to the results of the work, including the design.

Task content

1. Indicate in the table the terms related to validation, the definitions of which are given in the table, using the following data: validation, process validation, prospective validation, concurrent validation, revalidation; revalidation, purification validation:

Term	Definition
	Validation carried out before the start of mass production of products intended for sale.
	Validation, carried out in exceptional cases based on significant patient benefits, in which the batches produced during the validation protocol allow for implementation.
	Repeating process validation to provide assurance that process/equipment changes made in accordance with change control procedures have not adversely affected process performance and product quality.
	Documented evidence that the procedure has been approved Cleaning will consistently remove the previous preparation or cleaning agents used from the equipment to a level below the established maximum permissible level of carry-over residues.
	Documented confirmation that a process, occurring within established parameters, can be carried out efficiently and with reproducible results and results in a medicinal product that meets predetermined specifications and quality characteristics.

2. Indicate in the table the names of typical validation characteristics used in the validation of analytical methods, the definitions of which are given in the table. To fill in the table, use the following data: specificity, accuracy, precision, limit of detection, limit of quantification, linearity, range of application, robustness.

Name of the typical validation characteristics	Definition
	The ability of the technique to give values that are directly proportional to concentration of the analyte in the sample.
	It characterizes the degree of correspondence between a known true value or reference value and the value obtained by this method.

	It represents the minimum amount of analyte in a sample that can be detected.
	A measure of the ability of an analytical technique to be unaffected by small changes in the conditions under which the technique is performed, as specified by the analyst.
	Expresses the degree of closeness of results for a series of measurements performed using this method on different samples of the same homogeneous sample.
	The interval between the minimum and maximum concentrations of an analyte in a sample for which the analytical technique has been shown to have the required precision, accuracy, and linearity.
	Ability to unambiguously assess the analyte in the presence of other components that may be present in the sample.
	It represents the minimum amount of analyte in a sample that can be quantified with the required accuracy and precision.

Recommendations (instructions) for completing tasks

To complete the tasks, you must use the lecture material and sources from the list of recommended literature.

Requirements for work results, including design

During the task execution, all relevant rows and columns of the tables must be filled in.

Summing up. In the process of conducting the lesson, the goal of the lesson is achieved, namely: higher education applicants are monitored for the basic level of knowledge regarding the organization of activities for the validation of production processes at pharmaceutical enterprises and the formation of

practical skills for implementing this type of activity at pharmaceutical enterprises.

List of recommended literature:

1. Guideline ST-N MOZU 42-4.0:2020 Medicinal products. Good manufacturing practice. Kyiv, Ministry of Health of Ukraine, 2020.

2. Guideline ST-N MOZU 42-3.5:2016 Medicinal products. Process validation. Kyiv, Ministry of Health of Ukraine, 2016.

3. Good practices in pharmacy: a manual for students of higher education. / V. O. Lebedynets, O. V. Tkachenko, Yu. I. Gubin and others. Kharkiv: National University of Pharmacy: Golden Pages, 2017. 296 p.

PRACTICAL LESSON No. 13

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.

Goal:to control the basic level of knowledge of higher education applicants regarding the organization of activities for the validation of production processes and qualification of equipment and auxiliary systems at pharmaceutical enterprises and to form practical skills for the implementation of these activities at pharmaceutical enterprises.

Basic concepts:validation documentation, critical quality indicator, critical process parameter, qualification, installation qualification, functional qualification, performance qualification, requalification.

Equipment:laptop, multimedia projector.

1. Plan:

Organizational activities (welcome, checking attendance, announcement of the topic, objectives of the lesson, motivation of higher education students to study the topic).

In accordance with the requirements of good manufacturing practice, the manufacturer's overall policy regarding the intentions and approach to validation and regarding the persons responsible for the development, verification, approval and documentation of each validation step should be documented.

2. Control of the reference level of knowledge:

- requirements to the theoretical readiness of higher education students to perform practical classes (knowledge requirements, list of didactic units);
- question (test tasks) to check basic knowledge on the topic of the lesson.

3. Knowledge requirements

Higher education students should know the basic principles of organizing activities for the validation of production processes and qualification of equipment and auxiliary systems at pharmaceutical enterprises.

List of didactic units

1. Validation documentation.
2. Qualification: definition of the concept, objects.
3. Qualification stages.

4. Test tasks

1. A certain characteristic of a product that must be within a certain range or have a certain distribution to ensure the required product quality:

A) Critical quality indicator
B) Application range
C) Eligibility criterion
D) Hard work

E) Critical process parameter

2. Process parameter whose variability may affect a critical quality indicator:
A) Eligibility criteria
C) Critical process parameter
C) Critical quality indicator
D)"Worst case scenario"
E) Application range

3. Documented evidence that the equipment or systems installed or modified comply with the approved design is:
A) Project Qualification
B) Installation qualification
C) Functional qualification
D) Performance Qualification
E) Accreditation

4. Documented evidence that technical means, systems and equipment, when used together, can function with reproducible results based on an approved process management method and product specification is:
A) Retraining
B) Project Qualification
C) Installation qualification
D) Functional qualification
E) Performance Qualification

5. Establish the essential elements of quality and reduce any risks to an acceptable level.GMP at this stage of system qualification:
A) Project Qualification
B) Installation qualification
C) Development of user requirements specification
D) Performance Qualification
THERE ARE)Acceptance tests at the enterprise

5. Formation of professional skills and abilities:

- contenttasks;
- recommendations (instructions) on how to perform tasks;
- requirements to the results of the work, including the design.

Task content

1. Indicate in the table the purpose of the validation documents using the following data:

- The document contains an organizational chart of validation activities.
- A document that specifies the type of validation being performed.
- A document that contains the summarized results of the validation tests

performed.

- A document that specifies the number of production cycles required for validation.
- The document contains a plan and schedule for the validation work.
- A document that specifies critical process parameters, critical quality indicators, and associated acceptance criteria.
- A document specifying the subject of qualification/validation.
- The document contains a list of all premises, systems, equipment and processes that are subject to qualification/validation.
- A document containing conclusions and recommendations for correcting identified deficiencies.

Document name	**Purpose of the document**
Validation Master Plan	1. 2. 3.
Measurement validation protocol	1. 2. 3. 4.
Validation report	1. 2.

2. Describe each stage of qualification of equipment, premises, support systems or other systems. Enter the relevant data in the table.

Qualification stages	**Characteristics of qualification stages**
User requirements specification (URS)	
Design qualification (DQ)	
Factory acceptance testing (FAT) / Site acceptance testing (SAT)	
Installation qualification (IQ)	
Operational qualification (OQ)	

Performance qualification (PQ)	

Recommendations (instructions) for completing tasks

To complete the tasks, you must use the lecture material and sources from the list of recommended literature.

Requirements for work results, including design

During the task execution, all relevant rows and columns of the tables must be filled in.

Summary. In the process of conducting the lesson, the goal of the lesson is achieved, namely: higher education applicants are monitored for the basic level of knowledge regarding the organization of activities for the validation of production processes and qualification of equipment and auxiliary systems at pharmaceutical enterprises, and practical skills for implementing these activities at pharmaceutical enterprises are formed.

List of recommended literature:

1. Guideline ST-N MOZU 42-4.0:2020 Medicinal products. Good manufacturing practice. Kyiv, Ministry of Health of Ukraine, 2020.

2. Guideline ST-N MOZU 42-3.5:2016 Medicinal products. Process validation. Kyiv, Ministry of Health of Ukraine, 2016.

3. Good practices in pharmacy: a manual for students of higher education. / V. O. Lebedynets, O. V. Tkachenko, Yu. I. Gubin and others. Kharkiv: National University of Pharmacy: Golden Pages, 2017. 296 p.

PRACTICAL LESSON No. 14

Topic 8. Audits of pharmaceutical quality systems.

Goal:to control the basic level of knowledge of pharmaceutical quality system audits among higher education students and to develop practical skills in conducting audits at pharmaceutical enterprises.

Basic concepts:audit, audit object, audit group, internal audit, external audit, combined audit, joint audit, audit criteria, audit evidence, audit program.

Equipment:laptop, multimedia projector.

1. Plan:

Organizational activities (welcome, checking attendance, announcement of the topic, objectives of the lesson, motivation of higher education students to study the topic).

A modern pharmaceutical company is a rather complex, and at the same time, quite well-established system. One of the most common tools for assessing the functioning of this system is conducting audits, since this procedure is defined by both the rules of good manufacturing practice and the requirements of ISO 9001:2015.

2. Control of the reference level of knowledge:

− requirements for the theoretical readiness of higher education students to perform practical classes (knowledge requirements, list of didactic units);

− questions (test tasks) to test basic knowledge on the topic of the lesson.

3. Knowledge requirements:

Higher education students should know the basic principles of conducting audits of pharmaceutical quality systems.

List of didactic units

1. The concept of audit, classification of audits, audit criteria and evidence.
2. Principles of auditing.
3. Sequence of work for managing the audit program, audit methods.

4. Test tasks

1. ProcedureThe conduct of audits is determined by the requirements of the following regulatory documents:

A) ISO 19011:2018 B) GMP

C) ICH Q9(R1)

D) ISO 9001:2015

E) All options are correct except C)

2. An audit of a pharmaceutical company carried out by a state body to assess compliance with GXP requirements belongs to the following type of audit:

A) Combined audit

C) Third-party audit

C) Second-party audit

D) Internal audit
E) Joint audit

3. When conducting an audit of a pharmaceutical company to assess compliance with the requirements of good manufacturing practice, what documentation is used as an audit criterion?

A) GMP
C) All documents of the pharmaceutical company
C) Pharmaceutical company documents that regulate activities that affect product quality
D) Documents,whose circulation is regulated by the internal requirements of the pharmaceutical company
E) Documented enterprise procedures

4. When conducting an audit of a pharmaceutical company, what documentation is used as audit evidence?

A) GMP
C) Licensing conditions for conducting business activities in the production of medicines, wholesale and retail trade in medicines
C) Pharmaceutical company documents
D) All options are correct.

5. Is it possible to conduct an audit without direct communication with the persons representing the audit object?

A) Yes.
C) This is impossible under any circumstances.
C) Yes, if provided for in the audit program.

4. Formation of professional skills and abilities:

- contenttasks;
- recommendations (instructions) on how to perform tasks;
- requirements to the results of the work, including the design.

Task content

1. Complete the table on the classification of audits using the following data:

1. External supplier audit
2. Certification audit
3. Audit for legal purposes
4. Audit of another interested party
5. Internal audit
6. Accreditation audit
7. Audit for regulatory purposes

First-party audit	Second-party audit	Third-party audit

2. List examples of auditing methods in the table.

Degree of involvement auditor and auditee	**Auditor's location**	
	On site	**Off-site**
In direct communication		
Without direct communication		

Recommendations (instructions) for completing tasks.

To complete the tasks, you must use the lecture material and sources from the list of recommended literature.

Requirements for work results, including design.

During the task execution, all relevant rows and columns of the tables must be filled in.

Summing up. In the process of conducting the lesson, the goal of the lesson is achieved, namely: higher education applicants are monitored for the basic level of knowledge about audits of pharmaceutical quality systems and practical skills are formed for conducting audits at pharmaceutical enterprises.

List of recommended literature:

1. DSTU ISO 9001:2015 (ISO 9001:2015, IDT). Quality management systems. Requirements. Kyiv, SE "UkrNDNTS", 2016.

2. DSTU ISO 19011:2019 (ISO 19011:2018, IDT). Guidelines for conducting

audits of management systems. Kyiv, State Enterprise "UkrNDNC".

3. Good practices in pharmacy: a manual for students of higher education. / V. O. Lebedynets, O. V. Tkachenko, Yu. I. Gubin and others. Kharkiv: National University of Pharmacy: Golden Pages, 2017. 296 p.

4. Lebedynets V. O., Karamavrova T. V. Analysis of the functioning of the internal audit process at domestic pharmaceutical enterprises. Social Pharmacy in Health Care. 2017. No. 03 (03). Pp. 58–65.

5. Karamavrova T. V., Lebedynets V. O., Plyaka L. V. Defining approaches to assessing the personal qualities of auditors of pharmaceutical systems. Social Pharmacy in Health Care. 2018. No. 4 (03). pp. 1–9.

PRACTICAL LESSON No. 15

Topic 8. Audits of pharmaceutical quality systems.

Goal:to control the basic level of knowledge of pharmaceutical quality system audits among higher education students and to develop practical skills in conducting audits at pharmaceutical enterprises.

Basic concepts:audit, audit object, audit group, internal audit, external audit, combined audit, joint audit, audit criteria, audit evidence, audit program.

Equipment:laptop, multimedia projector.

1. Plan:

Organizational activities (welcome, checking attendance, announcement of the topic, objectives of the lesson, motivation of higher education students to study the topic).

A modern pharmaceutical company is a rather complex, and at the same time, quite well-established system. One of the most common tools for assessing the functioning of this system is conducting audits, since this procedure is defined by both the rules of good manufacturing practice and the requirements of ISO 9001:2015.

2. Control of the reference level of knowledge:

− requirements for the theoretical readiness of higher education students to perform practical classes (knowledge requirements, list of didactic units);

− questions (test tasks) to test basic knowledge on the topic of the lesson.

3. Knowledge requirements:

Higher education students should know the basic principles of conducting audits of pharmaceutical quality systems.

List of didactic units

1. Sequence of work for managing the audit program.
2. Sequence of work for conducting an audit.
3. Follow-up on audit results.

4. Test tasks

1. Is it possible to conduct an audit outside the audit object?

A) Yes.

C) This is impossible under any circumstances.

C) Yes, if provided for in the audit program.

2. Who determines the scope and resources of the audit program?

A) The person representing the audited entity

B) Group of auditors

C) Audit client

E) The person who manages the audit program

E) Technical expert

3. Who is responsible for conducting the audit?
A) Audit team leader
B) Escort
C) Audit client
E) The person who manages the audit program
E) Person representing the audited entity

4. Who sets the audit objectives?
A) Technical expert
B) Audit team leader
C) Audit client
E) The person who manages the audit program
E) Observer

5. During the audit, members of the audit team record the following supporting evidence as audit data:
A) compliance with audit criteria
C) non-compliance with audit criteria
C) All options are correct.

5. Formation of professional skills and abilities:
- content of tasks;
- recommendations (instructions) for completing tasks;
- requirements for work results, including design.

Task content

1. Describe the sequence of work for managing the audit program according to the stages of the PDCA cycle. Present the results in a table.

PLAN	
DO	
CHECK	
ACT	

Recommendations (instructions) for completing tasks

To complete the tasks, you must use the lecture material and sources from the list of recommended literature.

Requirements for work results, including design

During the task execution, all relevant rows and columns of the tables must be filled in.

Summing up. In the process of conducting the lesson, the goal of the lesson is achieved, namely: higher education applicants are monitored for the basic level of knowledge about audits of pharmaceutical quality systems and practical skills are formed for conducting audits at pharmaceutical enterprises.

List of recommended literature:

1. DSTU ISO 9001:2015 (ISO 9001:2015, IDT). Quality management systems. Requirements. Kyiv, SE "UkrNDNTS", 2016.

2. DSTU ISO 19011:2019 (ISO 19011:2018, IDT). Guidelines for conducting audits of management systems. Kyiv, State Enterprise "UkrNDNC".

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4. Lebedynets V. O., Karamavrova T. V. Analysis of the functioning of the internal audit process at domestic pharmaceutical enterprises. Social Pharmacy in Health Care. 2017. No. 03 (03). Pp. 58–65.

5. Karamavrova T. V., Lebedynets V. O., Plyaka L. V. Defining approaches to assessing the personal qualities of auditors of pharmaceutical systems. Social Pharmacy in Health Care. 2018. No. 4 (03). pp. 1–9.