MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY
Faculty of pharmaceutical technology and management
Department of management and quality assurance in pharmacy

GOOD PHARMACEUTICAL PRACTICES

(the name of educational component)

WORK PROGRAM
of educational component

training for Master
(Higher Educational Level Name)
field of knowledge 22 Healthcare
(Code and Knowledge Field Name)
in specialty 226 Pharmacy and industrial pharmacy
(Code and Specialty Name)
of educational program Pharmacy
(Educational Program Name)
specialization _____
(Specialization Name)

2023
year of creation

The work program of the educational componen Good Pharmaceutical Practices in specialty 226 Pharmacy, Industrial Pharmacy of educational program Pharmacy for applicants for higher education 5 year of study

Educational course team: Litvinova O.V., professor of Department of management and quality assurance in pharmacy, Doctor of Pharmacy, professor
Tkachenko O.V., assoc. professor of Department of management and quality assurance in pharmacy, PhD
(indicate the authors'full names, their positions, scientific and academic degrees)

Work program has been considered and approved at the Meeting of Department of management and quality assurance in pharmacy
Record from «__01__»__ September 2023 № _1__

Head of the Department _____ Prof.____Tatyana KRUTSKIKH____
(signature) (surname and initials)

Work program has been approved at the meeting of the Methodical Commission economics and management disciplines
Record from «__05__»__ September 2023 № _1__

Head of Specialized Committee _____ Prof.___Alla_NEMCHENKO___
(signature) (surname and initials)

1. The Description of the educational component

The language of the study: English

Status of the educational component: selective

Prerequisites for studying the educational component: "Industrial Technology of Drugs", "Organization and Economics of Pharmacy", "Pharmaceutical Marketing and Management", "Pharmaceutical Law and Legislation", "Medical and Pharmaceutical Commodity Research" and a number of others.

The subject of educational component «Good Pharmaceutical Practices» is quality management systems in pharmacy, approaches to its operation, regulation of pharmaceutical companies.

Information content of the educational component. 3 ECTS credit 90 hours are assigned to the study of the educational component.

2. Objectives and tasks of educational component

The purpose of teaching the educational component «Good Pharmaceutical Practices» is to train applicants for higher education for the pharmaceutical sector of the healthcare system who have a sufficient volume of theoretical knowledge and practical skills to plan and carry out work on the control, provision and quality management of processes that affect the quality of the pharmaceutical products at all stages of their life cycle: from development, research, registration and production to wholesale and retail sales.

Students will have knowledge of the structure and functions of government agencies operating in the quality assurance system of drugs, in particular the procedure for registration of drugs, licensing, certification, accreditation of pharmaceutical market entities, pharmacovigilance and state quality control of drugs and other general organizational aspects quality in the drug circulation system. Students must also master the relevant practical skills.

The main tasks of the educational component «Good Pharmaceutical Practices» is:

- formation of students' understanding of the role of quality assurance activities in the modern pharmaceutical industry and in non-manufacturing institutions and organizations of the pharmaceutical sector;
- formation of an idea of the basic principles and approaches underlying the rationing of activities related to the circulation of medicines (development, research, production, quality control, wholesale and retail sales of drugs);
- acquaintance with the European and national regulatory framework governing the circulation of medicines, in particular – with the provisions of the guidelines on good practices applicable at different stages of the life cycle of medicines;
- formation of system knowledge and practical skills regarding the work carried out during the life cycle of drugs, in particular the registration of drugs, pharmacovigilance, control of the pharmaceutical sector, etc .;
- providing theoretical knowledge and practical skills required for the development of pharmaceutical quality systems.

3. Competence and planned educational outcomes

Educational component «Good Pharmaceutical Practices» provides acquisition of competencies by applicants for higher education**:**

Integral competencies: The ability to solve typical and complex specialized problems and to critically consider and solve practical problems in professional pharmaceutical and/or research and innovation activities using the provisions, theories and methods of fundamental, chemical, technological, biomedical and socio-economic sciences; integrate knowledge and solve complex issues, formulate judgments based on insufficient or limited information; clearly and unambiguously convey one's own knowledge, conclusions and their validity to a professional and non-professional audience.

Soft- skills /General Competencies (GC)

GC 2. Ability to apply knowledge in practical situations and make informed decisions.

GC 6. Knowledge and understanding of the subject area and understanding of professional activity.

Hard-skills/ Professional competencies of the specialty (PC)

PC 7. Ability to ensure proper storage of medicines and other products of the pharmacy assortment in accordance with their physical and chemical properties and the rules of Good Storage Practice (GSP) in health care facilities.

PC 12. Ability to use knowledge of the regulatory and legislative acts of Ukraine and recommendations for good pharmaceutical practices in professional activity.

PC 18. Ability to develop and implement the quality management system of pharmaceutical enterprises in accordance with the requirements of current standards and to perform quality audits and risk management for the quality of pharmaceutical products.

Program learning outcomes (PLO)

PLO 24. Plan and implement professional activities on the basis of normative legal acts of Ukraine and recommendations of good pharmaceutical practices.

PLO 30. Ensure quality control of medicinal products and document its results. To carry out quality risk management at all stages of the life cycle of medicinal products

As a result of studying the educational component, the applicant for higher education will be able to

know:

- basic concepts, terms and definitions in the field of quality assurance of medicinal products;
- the history of world development of approaches to the control and quality assurance of pharmaceutical products;
- basic information on the activities of international, regional and national pharmaceutical organizations (International Conference on Harmonization of Technical Requirements for the Registration of Medicinal Products for Human Use (ICH), the International Pharmaceutical Inspection Cooperation Scheme (PIC / S), the European Network of Official Laboratories on drug control (OMCL - Official Medicine Control Laboratory) and others;
- Basic provisions of European and national regulations on good practices for national pharmaceutical control laboratories (GPCL), good laboratory practice (GLP), good pharmaceutical practice (GPP).
- basic order of state registration and re-registration of medicines in the European Union;
- basic order of development, implementation and support of pharmaceutical quality system at enterprise-producer/distributor of medicines;
- basics of proper functioning of document flow system of an organization at implementation and development of pharmaceutical quality system;
- the concept of integrated management systems of enterprises;
- approaches, methods and tools of managing risks for quality of medicines;
- the essence of corrective and preventive actions in the view of continuous quality improvement policy of the pharmaceutical sector organizations activities;
- basic provisions as for conducting internal audits (self-inspections) within pharmaceutical quality systems;

do:

- interpret the provisions and requirements of legislative and regulatory acts in the field of medicines circulation;
- determine processes required to form a pharmaceutical quality system at a pharmaceutical enterprise;
- compile a list of documents and forms of records (protocols) necessary for the functioning of a pharmaceutical quality system;
- develop standard documented procedures (including standard operating procedures, SOPs) for the regulation of pharmaceutical quality system processes;
- develop standard forms of protocols (records) applicable to register data on the functioning of the pharmaceutical quality system processes and the conformity of products with established requirements;

- develop programs and plans for carrying out internal audits (self-inspections) of a pharmaceutical quality system, as well as questionnaires, forms for registration of audit certificates, reports on the results of audits;
- develop corrective action plans to eliminate the consequences and causes of detected inconsistencies in the functioning of the pharmaceutical quality system;
- to formulate indicators and criteria for assessing the effectiveness of the processes of a pharmaceutical quality system, as well as to select the appropriate methods for carrying out such an assessment;
- develop the basic provisions of the "Quality Policy" of a pharmaceutical organization;
- formulate aims in the field of quality of a pharmaceutical organization;
- compile reports on the functioning of the pharmaceutical quality system and action plans for its continuous improvement;

have:

- skills of work with normative documents;
- skills of conducting internal audits.

4. Structure of the educational component

Names of content modules and topics	The amount of hours											
	full time study						part time study					
	the whole amount	including				self-study	the whole amount	including				self-study
		l	sem.	p.l.	lab.			sem.	p.l.	lab.	sem.	
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*
Content module 1. The quality assurance system of medicines – the structure, functions of regulatory agencies, regulatory framework. The concept of quality management system of enterprises - subjects of the pharmaceutical market (pharmaceutical quality systems)												
Topic 1. Introduction to the course "Good Pharmaceutical Practices". Chronology of world development of science on quality assurance and management. The concept of Good pharmaceutical practices (GXP) and their role in quality assurance at all stages of the life cycle of medicines. Regulatory framework for ensuring and quality control of medicines in the European Union.	12	1		4		7						
Topic 2. Activities of regulatory organizations in the field of medicines circulation: their functions and sphere of work. Analysis of the main elements of the state quality assurance system of medicines. The role of the International Pharmacopoeia. Certification and licensing of pharmaceutical market players	12	1		4		7						
Topic 3. The concept of quality management system of enterprises - subjects of the pharmaceutical market (pharmaceutical quality systems). Review of the	12	1		4		7						

requirements of ISO 9001 standard, universal and industry guidance ICH Q10 Pharmaceutical Quality System. Stages of construction of PQS.												
Topic 4. The concept of integrated management systems of enterprises – subjects of the pharmaceutical market. Overview of the requirements of ISO 14001, ISO standards 22000 HACCP, ISO 13485	11	1		4		6						
The whole amount of hours for the content module 1	47	4		16		27						
Content module 2. Applied aspects of formation, implementation, analysis and development of pharmaceutical quality systems												
Topic 5. Regulation and documentation processes PQS. Development of quality manual, documented implementation PQS processes and standard operating procedure	12	1		4		7						
Topic 6. Analysis and risk assessment for quality in pharmaceutical development, production and distribution of medicines. Methods for the determination analysis and risk assessment for drug quality	10	1		2		7						
Topic 7. The activities of the validation of manufacturing processes and qualification of equipment and auxiliary systems in enterprises, the subject of the pharmaceutical market	9,5	0,5		2		7						
Topic 8. Internal audits (self-inspections) of pharmaceutical quality systems: organization, documentary support, audit techniques, psychological and ethical aspects. Corrective and preventive actions (CAPA).	9,5	0,5		2		7						
The whole amount of hours for the content module 2	41	3		10		28						
Semester credit from module 1	2			2								
The whole amount of hours for the course	90	7		28		53						

5. Contents of the educational component

Content module 1. The quality assurance system of medicines – the structure, functions of regulatory agencies, regulatory framework. The concept of quality management system of enterprises – subjects of the pharmaceutical market (pharmaceutical quality systems)

Topic 1. Introduction to the course "Good Pharmaceutical Practices". Chronology of world

development of science on quality assurance and management. The concept of Good pharmaceutical practices (GXP) and their role in quality assurance at all stages of the life cycle of medicines. Regulatory framework for ensuring and quality control of medicines in the European Union. Introduction to Good Pharmaceutical Practices". Chronology of world development of science on quality assurance and management. The concept of Good pharmaceutical practices (GXP) and their role in quality assurance at all stages of the life cycle of medicines. Regulatory framework for ensuring and quality control of medicines in the European Union.

History of the development of the science of quality assurance and management. Life cycle of drugs. Implementation of the principles of quality assurance at the stages of the life cycle.

Topic 2. Activities of regulatory organizations in the field of medicines circulation: their functions and sphere of work. Analysis of the main elements of the state quality assurance system of medicines. The role of the International Pharmacopoeia. Certification and licensing of pharmaceutical market players

The structure of the state system for regulating the circulation of medicines. Registration of medicines as a mechanism for admission of drugs to use. Procedure for state registration (re-registration) of medicinal products in the European Union. Regulatory framework for pharmacovigilance. Licensing as a component of the permitting system in the field of economic activity. Stages of confirmation of compliance of conditions of production of medicines with GMP requirements. The role of the International Pharmacopoeia in the system of standardization and quality control of medicines.

Topic 3. The concept of quality management system of enterprises - subjects of the pharmaceutical market (pharmaceutical quality systems). Review of the requirements of ISO 9001 standard, universal and industry guidance ICH Q10 Pharmaceutical Quality System. Stages of construction of PQS.

Analysis of GMP requirements for pharmaceutical quality system. Analysis of the main provisions of the ICH Q10 guidelines. Analysis of the main requirements of the ISO 9001: 2015 standard. Determining the main stages of designing quality management systems for pharmaceutical companies.

Topic 4. The concept of integrated management systems of enterprises – subjects of the pharmaceutical market. Overview of the requirements of ISO 14001, ISO standards 22000 HACCP, ISO 13485

The concept of integrated management systems, environmental management, food safety systems, quality management systems for medical devices.

Content module 2. **Applied aspects of formation, implementation, analysis and development of pharmaceutical quality systems**

Topic 5. Regulation and documentation processes PQS. Development of quality manual, documented implementation PQS processes and standard operating procedure

Regulation and documentation of PQS processes, document management. Development of Quality Guidelines, documented procedures for the implementation of PQS processes and standard operating procedures (SOP). The role of PQS records (protocols) in data registration. Checking the compliance of the document of pharmaceutical quality systems.

Topic 6. Analysis and risk assessment for quality in pharmaceutical development, production and distribution of medicines. Methods for the determination analysis and risk assessment for drug quality

Risk classification. Risk identification. Aims and objectives of risk management. Basic principles of risk management for quality. Stages of the risk management process. Characteristics of the main methods and tools of risk analysis.

Topic 7. The activities of the validation of manufacturing processes and qualification of equipment and auxiliary systems in enterprises, the subject of the pharmaceutical market.

Basics of qualification and validation. Types of validation and qualification. Validation of analytical methods. Validation of cleaning.

Topic 8. Internal audits (self-inspections) of pharmaceutical quality systems: organization, documentary support, audit techniques, psychological and ethical aspects. Corrective and preventive actions (CAPA).

Basic components of modern models of quality management systems. The importance of audits in modern management systems. Classification of quality audits. Specifics of internal audits of quality management

systems. Approaches to audit process management and program. Basic principles of effective audit.
The final test

6. Topics of lectures

№	Name of topic	The amount of hours	
		full time study	part time study
1	**Topic 1.** Introduction to the course "Good Pharmaceutical Practices". Chronology of world development of science on quality assurance and management. The concept of Good pharmaceutical practices (GXP) and their role in quality assurance at all stages of the life cycle of medicines. Regulatory framework for ensuring and quality control of medicines in the European Union.	1	
2	**Topic 2.** Activities of regulatory organizations in the field of medicines circulation: their functions and sphere of work. Analysis of the main elements of the state quality assurance system of medicines. The role of the International Pharmacopoeia. Certification and licensing of pharmaceutical market players	1	
3	**Topic 3.** The concept of quality management system of enterprises - subjects of the pharmaceutical market (pharmaceutical quality systems). Review of the requirements of ISO 9001 standard, universal and industry guidance ICH Q10 Pharmaceutical Quality System. Stages of construction of PQS.	1	
4	**Topic 4.** The concept of integrated management systems of enterprises – subjects of the pharmaceutical market. Overview of the requirements of ISO 14001, ISO standards 22000 HACCP, ISO 13485	1	
5	**Topic 5.** Regulation and documentation processes PQS. Development of quality manual, documented implementation PQS processes and standard operating procedure	1	
6	**Topic 6.** Analysis and risk assessment for quality in pharmaceutical development, production and distribution of medicines. Methods for the determination analysis and risk assessment for drug quality	1	
7	**Topic 7.** The activities of the validation of manufacturing processes and qualification of equipment and auxiliary systems in enterprises, the subject of the pharmaceutical market	0,5	
8	**Topic 8**. Internal audits (self-inspections) of pharmaceutical quality systems: organization, documentary support, audit techniques, psychological and ethical aspects. Corrective and preventive actions (CAPA).	0,5	
	The whole amount of hours	**7**	

7. Topics of practical lessons

№	Name of topic	The amount of hours	
		full time study	part time study
1	**Topic 1.** Introduction to the course "Good Pharmaceutical Practices". Chronology of world development of science on quality assurance and management. The concept of Good pharmaceutical practices (GXP) and their role in quality assurance at all stages of the life cycle of medicines. Regulatory framework for ensuring and quality control of medicines in the European Union.	4	
2	**Topic 2.** Activities of regulatory organizations in the field of medicines circulation: their functions and sphere of work. Analysis of the main elements of the state quality assurance system of medicines. The role of the International Pharmacopoeia. Certification and licensing of pharmaceutical market players	4	
3	**Topic 3.** The concept of quality management system of enterprises - subjects of the pharmaceutical market (pharmaceutical quality systems). Review of the requirements of ISO 9001 standard, universal and industry guidance ICH Q10 Pharmaceutical Quality System. Stages of construction of PQS.	4	
4	**Topic 4.** The concept of integrated management systems of enterprises – subjects of the pharmaceutical market. Overview of the requirements of ISO 14001, ISO	4	

	standards 22000 HACCP, ISO 13485		
5	**Topic 5.** Regulation and documentation processes PQS. Development of quality manual, documented implementation PQS processes and standard operating procedure	4	
6	**Topic 6.** Analysis and risk assessment for quality in pharmaceutical development, production and distribution of medicines. Methods for the determination analysis and risk assessment for drug quality	2	
7	**Topic 7.** The activities of the validation of manufacturing processes and qualification of equipment and auxiliary systems in enterprises, the subject of the pharmaceutical market	2	
8	**Topic 8**. Internal audits (self-inspections) of pharmaceutical quality systems: organization, documentary support, audit techniques, psychological and ethical aspects. Corrective and preventive actions (CAPA).	2	
9	**The final test**	2	
	The whole amount of hours	**28**	

8. Topics of laboratorial lessons

Not provided by the curriculum

9. Self-study work

№	Name of topic	The amount of hours	
		full time study	**part time study**
1	**Topic 1.** Introduction to the course "Good Pharmaceutical Practices". Chronology of world development of science on quality assurance and management. The concept of Good pharmaceutical practices (GXP) and their role in quality assurance at all stages of the life cycle of medicines. Regulatory framework for ensuring and quality control of medicines in the European Union.	7	
2	**Topic 2.** Activities of regulatory organizations in the field of medicines circulation: their functions and sphere of work. Analysis of the main elements of the state quality assurance system of medicines. The role of the International Pharmacopoeia. Certification and licensing of pharmaceutical market players	7	
3	**Topic 3.** The concept of quality management system of enterprises - subjects of the pharmaceutical market (pharmaceutical quality systems). Review of the requirements of ISO 9001 standard, universal and industry guidance ICH Q10 Pharmaceutical Quality System. Stages of construction of PQS.	7	
4	**Topic 4.** The concept of integrated management systems of enterprises – subjects of the pharmaceutical market. Overview of the requirements of ISO 14001, ISO standards 22000 HACCP, ISO 13485	6	
5	**Topic 5.** Regulation and documentation processes PQS. Development of quality manual, documented implementation PQS processes and standard operating procedure	7	
6	**Topic 6.** Analysis and risk assessment for quality in pharmaceutical development, production and distribution of medicines. Methods for the determination analysis and risk assessment for drug quality	7	
7	**Topic 7.** The activities of the validation of manufacturing processes and qualification of equipment and auxiliary systems in enterprises, the subject of the pharmaceutical market	7	
8	**Topic 8**. Internal audits (self-inspections) of pharmaceutical quality systems: organization, documentary support, audit techniques, psychological and ethical aspects. Corrective and preventive actions (CAPA).	7	
	The whole amount of hours	**55**	

10. Tasks for self-study work

1. Prepare an abstract on the topic: «Good practices in pharmacy. Their importance for quality assurance of medicines».
2. Prepare an essay on the topic: «Functions of state regulatory authorities to control the circulation of medicines».
3. Prepare a presentation on the topic: «Registration Certificate. Rules of receipt».
4. Prepare an essay on the topic «Pharmacovigilance systems».

5. Prepare an essay on the topic: «Licensing conditions for business activities for the production of medicines, wholesale, retail trade in medicines».
6. Prepare a presentation on the topic: «Procedure for inspection for compliance with the conditions of production of drugs to GMP requirements».
7. Prepare an essay on the topic: «System of recall of drugs for wholesale and retail trade».
8. Prepare a presentation on the topic: «Basic principles of ISO 9001: 2015».
9. Prepare an essay on the topic: «The system of documenting the processes of PQS».
10. Prepare a presentation on the topic: «Theoretical and practical aspects of risk assessment at the stages of pharmaceutical development».
11. Prepare an essay on the topic: «Stages of qualification of equipment in enterprises - entities of the pharmaceutical market».

11. Criteria and evaluation order of educational outcomes

The evaluation of the educational component is determined taking into account the results of the current educational activity of the student of higher education and evaluations of his assimilation of individual modules.

The success of each applicant of higher education is evaluated on a 100-point scale.

A applicant of higher education can receive 60 points for the current educational activity within the module. The maximum number of points that a student of higher education can score during the completion of the final control, taking into account the points for independent work, is 40 points.

Assessment of current educational activity (carried out during each lesson) - control of theoretical knowledge, practical skills and abilities. When mastering each topic of content modules for the current educational activity, points for all types of activities are assigned to the applicants, which are added up at the end of studying the content module. Depending on the number of points scored, the applicant can receive a maximum of 60 points or a minimum of 6 points for studying the module in practical classes.

Distribution of marks

Current control and individual work								The final test	Total
Content module 1				Content module 2					
T1	T2	T3	T4	T5	T6	T7	T8	40	100
10	9	9	8	8	8	4	4		

T1, T2 ... T8 – topic.

GRADING SCALE

Rating marks	ECTS	National scale
		Module
90 – 100	**A**	excellent
82-89	**B**	good
74-81	**C**	
64-73	**D**	Fair
60-63	**E**	
35-59	**FX**	Unsatisfactorily
0-34	**F**	Unsatisfactorily (additional work is needed)

12. Forms of progress and semester supervision of academic achievements

Current control and semester supervision are used for control forms. The current control is carried out for each practical activity according to the specific goals of the topic, during the individual work of the teacher with the student for those topics that the student studies independently and they do not belong to the structure of the practical classes.

It is using the score scale for learning each practical lesson of the module for student current educational activity. At the end of the study of the content module, the score is summed up taking into account the individual independent work of the students.

Modular final control is carried out upon completion of module study. Students who completed all types of works provided for by the curriculum are admitted to the final control, and at the study of the module

they have scored a score of not less than the minimum. The form of final control is standardized and includes the control of theoretical and practical training.

Semester control is carried out in the form of a semester credit.

13. Methodological support

1. Work program of educational discipline.
2. Methodical materials of computer presentations of lectures.
3. Methodical recommendations for practical studies.
5. List of theoretical questions to the semester credit.
6. Test tasks.

14. Reading suggestions

The main reading suggestions

1. Good Pharmaceutical Practices: method. recommend. for practical studies for foreign students of the specialty Pharmacy / O. V. Tkachenko, E.V. Litvinova, S. M. Kovalenko _ Kharkiv: NUPh, 2021. _ 48 p.
2. Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version) URL: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:050:0044:0059:EN:PDF
3. EMA/541760/2011 «Guideline on good pharmacovigilance practices (GVP). Module I – Pharmacovigilance systems and their quality systems» («Настанова з належних практик фармаконагляду (ННПФ). Модуль I - Фармаконагляд та його система якості»)
4. EMA/CHMP/600958/2010/Corr.* "Appendix IV of the Guideline on the Investigation on Bioequivalence (CPMP/EWP/QWP/1401/98 Rev.1): Presentation of Biopharmaceutical and Bioanalytical Data in Module 2.7.1" URL: https://www.ema.europa.eu/en/documents/scientific-guideline/appendix-iv-guideline-investigation-bioequivalence-cpmp/ewp/qwp/1401/98-rev1-presentation-biopharmaceutical-bioanalytical-data-module-271_en.pdf
5. EMA/CHMP/CVMP/QWP/BWP/70278/2012-Rev 1 Guideline on process validation for finished products — information and data to be provided in regulatory submissions. URL : https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-process-validation-finished-products-information-data-be-provided-regulatory-submissions_en.pdf
6. EMA/CHMP/ICH/135/1995 Committee for Human Medicinal Products *ICH: E 6 (R2):* Guideline for good clinical practice - Step 5. December 2016. URL: https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-6-r2-guideline-good-clinical-practice-step-5_en.pdf
7. EMA/CHMP/ICH/167068/2004 - ICH. - Committee for Human Medicinal Products ICH guideline Q8 (R2) on pharmaceutical development. Step 5, June 2017 URL: https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use_en-11.pdf
8. EMA/INS/GMP/79766/2011 Quality Risk Management (ICH Q9). URL : https://www.inspiredpharma.com/wp-content/uploads/2012/03/ich-9.pdf
9. EMA/INS/GMP/79818/2011 Pharmaceutical Quality System (ICH Q10). URL : https://www.inspiredpharma.com/wp-content/uploads/2012/03/ich-10.pdf

10. EudraLex. – The Rules Governing Medicinal Products in the European Union. – Volume 4. EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use. URL: https://ec.europa.eu/health/documents/eudralex/vol-4_en
11. EudraLex. – The Rules Governing Medicinal Products in the European Union. – Volume 4. – Other documents related to GMP. – Guidelines of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01) (OJ C 95, 21.3.2015, p. 1 URL: http://academy.gmp-compliance.org/guidemgr/files/GDP%20for%20APIs.pdf https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-i-pharmacovigilance-systems-their-quality-systems_en.pdf
12. International Pharmacopoeia. 2019. URL : https://apps.who.int/phint/en/p/docf/.
13. ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes. URL : https://www.iso.org/standard/59752.html
14. ISO 14001:2015 Environmental management systems — Requirements with guidance for use. URL : https://www.iso.org/standard/60857.html
15. ISO 19011:2018 Guidelines for auditing management systems. URL : https://www.iso.org/obp/ui/#iso:std:70017:en
16. ISO 22000:2018 Food safety management systems — Requirements for any organization in the food chain. URL : https://www.iso.org/obp/ui/#iso:std:iso:22000:ed-2:v1:en
17. ISO 9001:2015 Quality management systems — Requirements. URL : https://www.iso.org/standard/62085.html
18. Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services from the WHO technical report series, No. 961, 45th report of the WHO Expert Committee on specifications for pharmaceutical preparations © World Health Organization 2011 URL: https://www.who.int/medicines/areas/quality_safety/quality_assurance/FIPWHOGuidelinesGoodPharmacyPracticeTRS961Annex8.pdf
19. The Rules Governing Medicinal Products in the European Union. Notice to Applicants - V. 2B. - Common Technical Document. - May 2008. - European Commission. Enterprise and Industry Directorate-General URL: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/b/update_200805/ctd_05-2008_en.pdf
20. The Rules Governing Medicinal Products in the European Union. Notice to Applicants - V. 2B. - Common Technical Document. - May 2008. - European Commission. Enterprise and Industry Directorate-General URL : https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/b/update_200805/ctd_05-2008_en.pdf
21. World Health Organization. (2011). Marketing authorization of pharmaceutical products with special reference to multisource (generic) products : a manual for National Medicines Regulatory Authorities (NMRAs), 2nd ed. World Health Organization. https://apps.who.int/iris/handle/10665/44576

Supplementary reading suggestions

1. Chen, Hsinjung, Shinlun Liu, Yijyuan Chen, Chinshuh Chen, Huiting Yang, and Yuhshuen Chen. Food Safety Management Systems Based on ISO 22000:2018 Methodology of Hazard Analysis Compared to ISO 22000:2005. *Accreditation and Quality Assurance*. 2020. V. 25. N 1. P. 23–37. https://doi.org/10.1007/s00769-019-01409-4.
2. CPMP/QWP/EWP/1401/98 Rev.1/Corr** "Guideline on the Investigation of Bioequivalence" URL: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-investigation-bioequivalence-rev1_en.pdf

3. EMA/CHMP/ICH/493213/2018 «ICH M9 guideline on biopharmaceutics classification system-based biowaivers» https://www.ema.europa.eu/en/documents/scientific-guideline/ich-m9-biopharmaceutics-classification-system-based-biowaivers-step-5_en.pdf
4. Ferrón-Vílchez, Vera. Does Symbolism Benefit Environmental and Business Performance in the Adoption of ISO 14001? *Journal of Environmental Management.* 2016. V. 183, N. Pt 3. P. 882–94. https://doi.org/10.1016/j.jenvman.2016.09.047.
5. Good Manufacturing Practice for Manufacturers of Food Supplements. URL : https://foodsupplementseurope.org/wp-content/themes/fse-theme/documents/publications-and-guidelines/good-manufacturing-practice-for-manufacturers-of-food-supplements.pdf
6. Ikram, Muhammad, Amin Mahmoudi, Syed Zulfiqar Ali Shah, and Muhammad Mohsin. Forecasting Number of ISO 14001 Certifications of Selected Countries: Application of Even GM (1,1), DGM, and NDGM Models. *Environmental Science and Pollution Research International*. 2017. V. 26, N. 12. P. 12505–21. https://doi.org/10.1007/s11356-019-04534-2.
7. Linders, Peter W.J. *Setting Standards* : ISO 13485: Challenges in Achieving High-Level Structure Compliance. *Biomedical Instrumentation & Technology*. 2020. V. 54. N 1. P. 68–70. https://doi.org/10.2345/0899-8205-54.1.68.
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16. Electronic resources

1. Кафедра управління, економіки та забезпечення якості у фармації НФаУ: http://yep.nuph.edu.ua/uk/
2. Бібліотека НФаУ: e-mail library@nuph.edu.ua
3. Центр дистанційних технологій навчання НФаУ [Електронний ресурс]. - Режим доступу: http://www.pharmel.kharkiv.edu
4. World Health Organization – WHO. URL : https://www.who.int/home
5. The International Council for Harmonisation – ICH. URL : https://www.ich.org/
6. Pharmaceutical Inspection Co-operation Scheme - PIC/S. URL : https://picscheme.org/
7. The European Directorate for the Quality of Medicines & HealthCare – EDQM. URL : https://www.edqm.eu/
8. European Medicines Agency – EMA. URL : https://www.ema.europa.eu/en
9. EudraGMDP. URL : http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do
10. Food and Drug Administration – FDA. URL : https://www.fda.gov/
11. United Kingdom's Medicines and Healthcare Products Regulatory Agency – MHRA. URL : https://www.gov.uk