THE COURSE SCHEDULE OF LECTURES

in Good pharmaceutical practices for __5__ year

(name of the educational component)

speciality _226 Pharmacy, industrial pharmacy, master (full-time) English

(autumn semester, 2024-2025)

№	Date	The topic of the lecture	Volume, hour	Lecturer
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)				
1	18.10.2024	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	Prof. Litvinova O.V.
2	18.10.2024	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	Prof. Litvinova O.V.
3	01.11.2024	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	Prof. Litvinova O.V.
4	01.11.2024	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	Prof. Litvinova O.V.
***Content module 2.* Applied aspects of formation, implementation, analysis and development of pharmaceutical quality systems**				
5	15.11.2024	Topic 5. Regulation and documentation processes PQS. Development of quality manual, documented implementation PQS processes and standard operating procedure	1	Prof. Litvinova O.V.
6	15.11.2024	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	Prof. Litvinova O.V.
7	29.11.2024	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	Prof. Litvinova O.V.
8	29.11.2024	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	Prof. Litvinova O.V.
		Total:	**7**	

Note: the lecture is available online

Head of the Department of management, marketing, and quality assurance in pharmacy, Prof. Volodymyr MALIY

THE COURSE SCHEDULE OF PRACTICAL CLASSES

in Good pharmaceutical practices for __5__ year

(name of the educational component)

speciality _226 Pharmacy, industrial pharmacy, master (full-time) English

(autumn semester, 2024-2025)

№	Date	The topic of the practical lesson	Volume, hour	Evaluation system knowledge, points	
				min	max
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)					
1	21.10.2024* 22.10.2024** 24.10.2024***	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	6	10
2	28.10.2024* 29.10.2024** 31.10.2024***	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	6	8
3	04.11.2024* 05.11.2024** 07.11.2024***	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	6	8
4	11.11.2024* 12.11.2024** 14.11.2024***	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 Content module control	4	6 12	6 20
		TOTAL FOR CM 1:		36	52
Content module 2. Applied aspects of formation, implementation, analysis and development of pharmaceutical quality systems					
5	18.11.2024* 19.11.2024** 21.11.2024***	Topic 5. Regulation and documentation processes PQS. Development of quality manual, documented implementation PQS processes and standard operating procedure	2	4	7
6	18.11.2024* 19.11.2024** 21.11.2024***	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	4	7
7	25.11.2024* 26.11.2024** 28.11.2024***	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	2	7
8	25.11.2024* 26.11.2024** 28.11.2024***	Topic 8. Internal audits (self-inspections) of pharmaceutical quality systems: organization, documentary support, audit techniques, psychological and ethical aspects. Corrective and preventive actions (CAPA). Content module control	2	2	7
		TOTAL FOR CM 2:		12	28
9	02.12.2024* 03.12.2024** 05.12.2024***	***Semester credit test in the module: "Good pharmaceutical practices"***	4	12	20
		TOTAL FOR STUDYING MODULE 1	**28**	**60**	**100**

* Groups 1, 2, ** - Groups 3,4, *** - Group 5

Head of the Department of management,
marketing, and quality assurance in pharmacy,
Prof. Volodymyr MALIY