

“QUALITY SYSTEM IN PHARMACY”

The plan of lectures, practical classes and independent work for foreign students of the 5th course group № 1 of pharmaceutical department for IX semester 2023/2024

№	Lecture subject	Quantity of hours	Date
1	The evolution of the global development of quality management science and its role in pharmacy	2	05.09
2	Regulatory bodies of Ukraine in the field of quality management of medicinal products	2	19.09
3	Risk assessment for the quality of the medicinal product at the stages of its life cycle	2	03.10
4	Organization of activities for validation of production processes and qualification of equipment and auxiliary systems in organizations - subjects of the pharmaceutical market	2	17.10
<i>Total</i>		8	

№	Practical class subject	Quantity of hours	Date
1	The evolution of the global development of quality management science and its role in pharmacy	2	06.09
2		2	13.09
3	Regulatory framework for quality management of medicinal products	2	20.09
4		2	27.09
5	Regulatory bodies of Ukraine in the field of quality management of medicinal products	2	04.10
6		2	11.10
7	Statistical methods of quality control	2	18.10
8	Regulation and documentation of pharmaceutical quality system processes	2	25.10
9		2	01.11
10	Risk assessment for the quality of the medicinal product at the stages of its life cycle	2	08.11
11		2	15.11
12	Organization of activities for validation of production processes and qualification of equipment and auxiliary systems in organizations - subjects of the pharmaceutical market	2	22.11
13		2	29.11
14	Internal audits (self-inspections) of pharmaceutical quality systems	2	06.12
15		2	13.12
	Всього	30	

№	Independent students` work subject	Quantity of hours	Date
1	The evolution of the global development of quality management science and its role in pharmacy	4	06.09 – 12.09
2		4	13.09 – 19.09
3	Regulatory framework for quality management of medicinal products	4	20.09 – 26.09
4		4	27.09 – 03.10
5	Regulatory bodies of Ukraine in the field of quality management of medicinal products	3	04.10 – 10.10
6		3	11.10 –

			17.10	
7	Statistical methods of quality control	6	18.10 24.10	–
8	Regulation and documentation of pharmaceutical quality system processes	3	25.10 31.10	–
9		3	01.11 07.11	–
10	Risk assessment for the quality of the medicinal product at the stages of its life cycle	3	08.11 14.11	–
11		3	15.11 21.11	–
12	Organization of activities for validation of production processes and qualification of equipment and auxiliary systems in organizations - subjects of the pharmaceutical market	3	22.11 28.11	–
13		3	29.11 05.12	–
14	Internal audits (self-inspections) of pharmaceutical quality systems	3	06.12 12.12	–
15		3	13.12 21.12	–
	Всього	52		