Approved at the department meeting
of 29.08.2024, minutes nr. _1,
Head of Department of Pharmaceutical and
toxicological chemistry
Dr.habilitated in pharm., professor,

_____ ***Vladimir Valica***

Calendar Plan
of the lectures at the discipline «Introduction to Good Pharmaceuticals Practices», IInd year, IIIrd semester, 2024-2025 academic year

Nr.	*Date*	*Hours*	*Theme*
1-2.	02-13.09.2024	2	Good Pharmaceutical Practice (GxP). General considerations. The importance of good pharmaceutical practice in obtaining safe and harmless quality medicines. RM and international legislation in the field of good pharmaceutical practices.
3-4.	16-27.09.2024	2	Notions of Quality Management. The peculiarities of GxP compared to ISO. Documentation system in good pharmaceutical practices. The basic principles of the development of Standard Operating Procedures. The advantages of using them.
5-6.	30.09-11.10.2024	2	Guide of Good Laboratory Practices (GLP). Introduction and terminology. Definitions and deciphering of the most important terms used in preclinical studies. The requirements against personnel, rooms, equipment, test systems, animals.
7-8.	14-25.10.2024	2	Guide to Good Practice in Clinical Trials. Introduction and terminology. Ethical principles in conducting clinical trials. The essential documents for carrying out a clinical trial.
9-10.	28.10-08.11.2024	2	Basic GMP criteria. Guide to Good Manufacturing Practice for Medicines. The structure, the definition of the most important terms in the rules of good manufacturing practice of medicines.
11-12.	11-22.11.2024	2	Manufacturing and quality control requirements described in GMP. Equipment and process requirements. Sampling of raw materials and packaging materials. Reference samples and counter samples. Qualification and validation. Certification by a Qualified Person and issuance of the series.
13.	25-29.11.2024	1	Guide to good pharmaceutical storage practice (GSP), Principles, concepts, requirements for the storage of pharmaceutical products. Particularities of storage of different groups of products.
14.	02-06.12.2024	1	Guide to Good Practice for the Distribution of Medicinal Products for Human Use (GDP). Basic principles, terms, premises and equipment, documentation, personnel, transport.
15 .	09-13.12.2024	1	Guide on good pharmacovigilance practice (GVP). Basic principles, terms, definitions. Classification of adverse drug reactions. Improving the pharmacovigilance system.

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Calendar Plan
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1.	02-06.09.2024	2	Good Pharmaceutical Practice (GxP). General considerations. The importance of good pharmaceutical practice in obtaining safe and harmless quality medicines. RM and international legislation in the field of good pharmaceutical practices.
2.	09-13.09.2024	2	Notions of Quality Management. The peculiarities of GxP compared to ISO. Documentation system in good pharmaceutical practices. The basic principles of the development of Standard Operating Procedures. The advantages of using them.
3.	16-20.09.2024	2	guide good Laboratory practices (LPG) . Introduction and terminology. Basic concepts, key definitions.
4.	23-27.09.2024	2	The organization and CONDUCT studied preclinical . documents vital for achievement A study preclinical . The requirements against personnel, rooms , equipment , test systems , animals .
5.	30.09-04.10.2024	2	guide for Good PRACTICE in Clinical Study . Introduction and terminology . principles ETHICAL in CONDUCT studied clinics . documents vital for achievement A study clinical .
6.	07-11.10.2024	2	*Totalization practical work*
7.	14-18.10.2024	2	Basic GMP criteria . guide good Drug Manufacturing Practices . Structure , definition THE May leading terms from RBPFM.
8.	21-25.10.2024	2	Manufacturing requirements and control quality described in GMP. requirement against the equipment and processes .
9-10 .	28.10-08.11.2024	4	taking raw materials and packaging materials . Reference samples and counter evidence . Qualification and validation. Certification by a Person Qualified and release the series .
11-12.	11-22.11.2024	4	Guide for good storage practice for pharmaceutical products (GSP), Principles, concepts, requirements for the storage of pharmaceutical products . Particularities of storage of different groups of products .
13.	25-29.11.2024	2	guide for Good Practices of distribution of drugs for use human (GDP). Basic principles, terms, premises and equipment, documentation, personnel, transport.
1 4 .	02-06.12.2024	2	Guide on good pharmacovigilance practice (GVP). Basic principles, terms, definitions . classification SIDE EFFECTS TO medicines . improve Sistema of pharmacovigilance .
15 .	09-13.09.2024	2	*Totalization practical work*

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