**THEMATIC PLAN OF LECTURES**
**ON GOOD PRACTICES IN PHARMACEUTICS**
*for the 5th year students of the Faculty of Pharmacy*
*IX semester 2023 - 2024 academic year*

Approved at Department meeting
Protocol №1, 31.08.2023

| № | Date | Topic | Lector |
|---|---|---|---|
| 1. | 07.09 | General principles of pharmaceutical development. The features of the pharmaceutical development of liquid, semi-solid, solid and sterile dosage forms | Assoc. prof. Oksana VASHCHENKO |
| 2. | 21.09 | Generic drug products and biosimilars. The requirements for the assessment of the equivalence of generic preparations. The principles and criteria for referring generic drug products to the waiver category. Bioequivalence | Assoc. prof. Oksana VASHCHENKO |
| 3. | 05.10 | Good Manufacturing Practice (GMP) as a basis of quality assurance of drug products. The requirements of GMP for production. The types of documents, their form, content, general principles of writing | Assoc. prof. Oksana VASHCHENKO |
| 4. | 19.10 | The requirements of Good pharmacy practice (GPP) for the preparation of drug products in pharmacies. Interconnection of Good Distribution Practice (GDP), Good Distribution Practice (GDP), Good practice of pharmacovigilance and GPP | Assoc. prof. Oksana VASHCHENKO |

**THEMATIC PLAN OF PRACTICAL CLASSES ON GOOD PRACTICES IN PHARMACEUTICS**

| № | Date | Topic | Hours |
|---|---|---|---|
| 1. | 01.09 | Quality Assurance of drug products at all phases of their lifecycle. Standards of Good practices | 2 |
| 2. | 08.09 | General approaches to the pharmaceutical development. The requirements for the research on pharmaceutical development of liquid and semi-solid dosage forms | 2 |
| 3. | 15.09 | The requirements for the research on the pharmaceutical development of solid dosage forms, transdermal patches, pressurized metered-dose preparations for inhalation and dry powders for inhalation | 2 |
| 4. | 22.09 | The requirements for the conduct of preclinical studies of medicinal products. The rules of Good laboratory practice (GLP). Clinical trials of drug products. Good Clinical Practice (GCP). The purpose, basic principles and requirements of GCP | 2 |
| 5. | 29.09 | The requirements for the assessment of generic preparations equivalence. The principles and criteria for referring generic drug products to the waiver category. Bioequivalence. Biosimilars | 2 |
| 6. | 06.10 | Good Regulatory Practice. Normative documents regulating the authorization of drug products in Europe. The structure of registration dossier | 2 |
| 7. | 13.10 | The requirements of Good Manufacturing Practices (GMP) for quality management and personnel, premises and equipment | 2 |
| 8. | 20.10 | The requirements of GMP for production. The types of documentation. The form and content of standard operating procedures, Manufacturing Formulae, Processing, Packaging and Testing Instructions | 2 |
| 9. | 27.10 | The requirements of GMP for contract manufacture and analysis, complaints and product recall. Changes in registration documents, classification of changes, their expertise | 2 |
| 10. | 03.11 | The requirements of GMP for biological medicinal products | 2 |
| 11. | 10.11 | The requirements of GMP for herbal medicinal products | 2 |
| 12. | 17.11 | The requirements of Good Storage Practice (GSP) | 2 |
| 13. | 24.11 | The requirements of Good Distribution Practice (GDP) | 2 |
| 14. | 01.12 | The regulations and principles of Good Pharmacy Practice (GPP) | 2 |
| 15. | 08.12 | The requirements of GPP for the preparation of drug products in pharmacies | 2 |
| | | **Total:** | **30** |

**QUESTIONS FOR SELF-EDUCATION ON GOOD PRACTICES IN PHARMACEUTICS**

| № | Topic | Hours |
|---|---|---|
| 1. | Acquaintance with the basic terms of guidelines: ICH Harmonised Tripartite Guideline Pharmaceutical Development Q8, Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001, Guide to Good Manufacturing Practice for Medicinal Products of Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme | 6 |
| 2. | The requirements for the research on pharmaceutical development of sterile dosage forms | 6 |
| 3. | The requirement for the research on pharmaceutical development of drug products for oral administration | 6 |
| 4. | Acquaintance with the structure of registration file in the format of Common Technical Document. The requirements for the chemical, pharmaceutical and biological documentation in format of Common Technical Document | 6 |
| 5. | Acquaintance with the nomenclature of excipients used for production and preparation of drug products. General requirements for excipients | 6 |
| 6. | The requirements for the manufacture of sterile medicinal products | 6 |
| 7. | The requirements for the manufacture of radiopharmaceuticals and medicinal gases | 6 |
| 8. | The current requirements for distribution and retailing of medicinal products | 6 |
| 9. | The requirements for the production of drug products in pharmacies in The European Union | 4 |
| | **Total:** | **52** |

Head of the Department