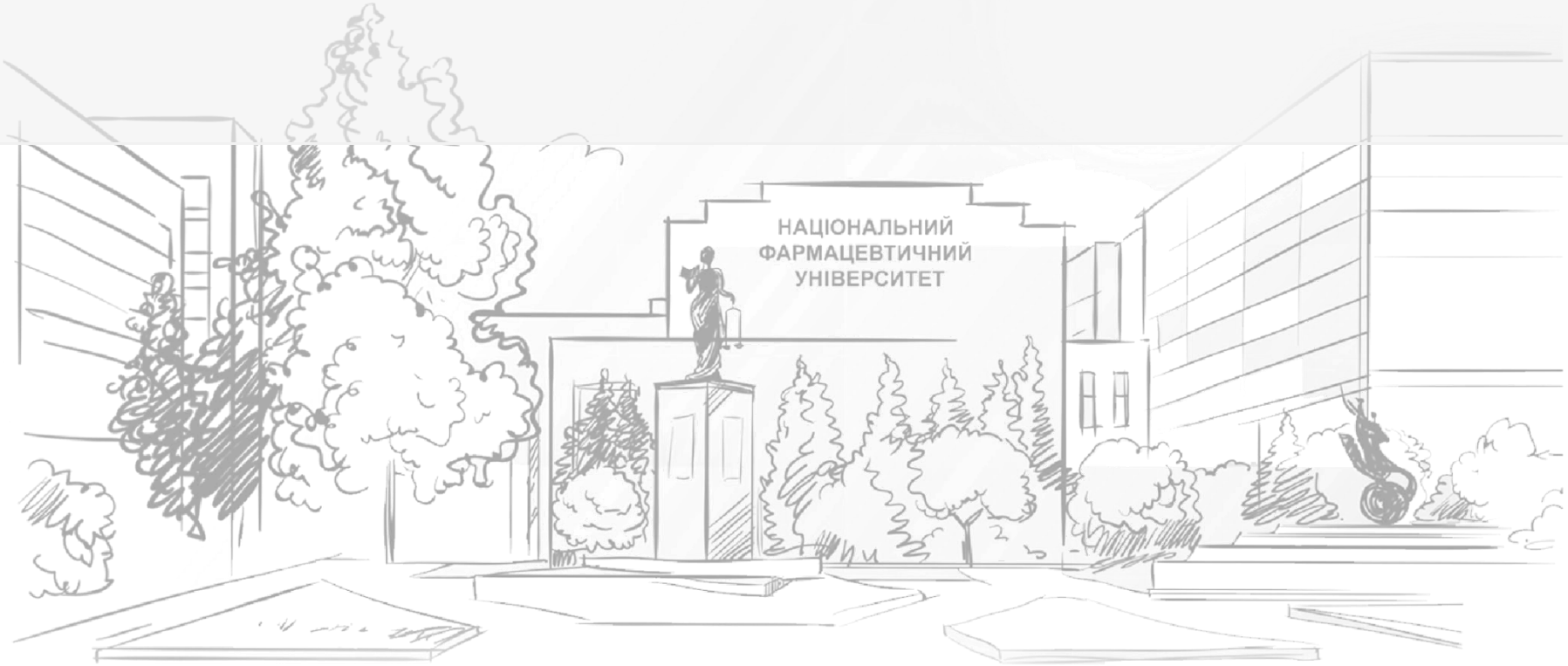
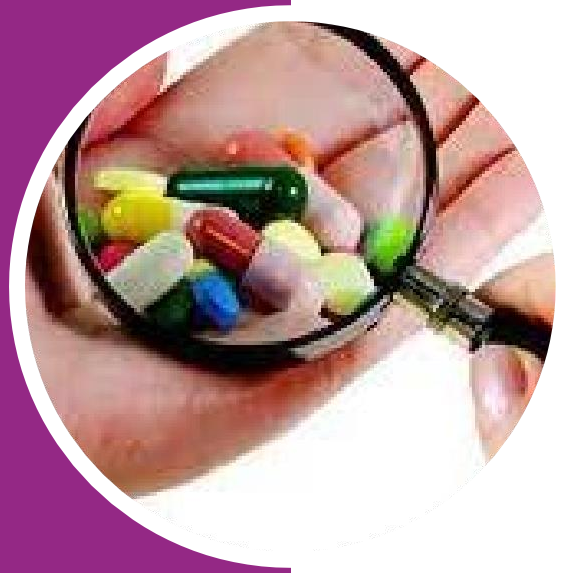
MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY
DEPARTMENT OF MANAGEMENT, MARKETING AND QUALITY ASSURANCE IN PHARMACY

GOOD PHARMACEUTICAL PRACTICES



GOOD PHARMACEUTICAL PRACTICES

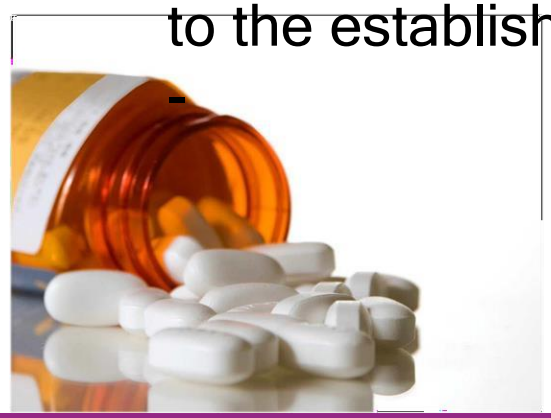


Brief annotation: the discipline is elective in the master's program in 226 Pharmacy, industrial pharmacy. The subject of educational component is the study of general principles of good practice in pharmacy, the requirements of which are used to ensure the quality of drugs during the stages of their life cycle, from development to implementation (good laboratory practice GLP, good clinical practice GCP, good manufacturing practice GMP), good distribution practice (GDP), good pharmaceutical practice (GPP), etc.).

The purpose of the discipline: is to prepare applicants for higher education in specialty “Pharmacy” for the pharmaceutical sector of health care, who have sufficient theoretical knowledge and practical skills to plan and implement work to control, ensure and manage the quality of processes affecting quality of pharmaceutical products at all stages of its life cycle: from development, research, registration and production to wholesale and retail sales.

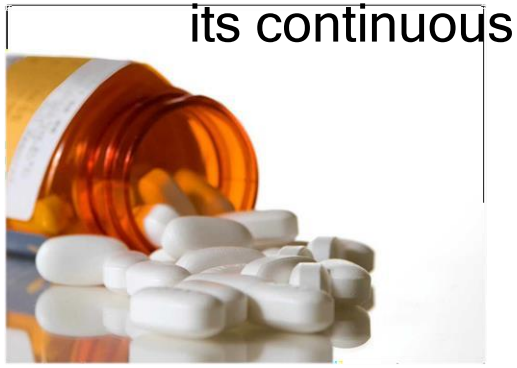
GOOD PHARMACEUTICAL PRACTICES

According to the results of training, applicants for higher education will be able to:
- interpret the provisions and requirements of laws and regulations in the field of circulation of medicines;
-to determine the processes necessary for the formation of the quality management system of the pharmaceutical industry;
- compile a list of documents and forms of records (protocols) required for the functioning of the pharmaceutical quality system;
-develop standard documented procedures (including standard operating procedures, SOPs) to regulate the processes of the pharmaceutical quality system;
-to develop standard forms of protocols (records), applicable for registration of data on functioning of processes of pharmaceutical quality system and conformity of production to the established requirements;



GOOD PHARMACEUTICAL PRACTICES

According to the results of training, applicants for higher education will be able to:
-develop programs and plans for internal audits (self-inspections) of the pharmaceutical quality system, as well as questionnaires, forms (forms) for registration of audit certificates, reports on the results of audits;
-develop corrective action plans to eliminate the consequences and causes of identified inconsistencies in the functioning of the pharmaceutical quality system;
- to formulate indicators and criteria for evaluating the effectiveness of the processes of the pharmaceutical quality system, as well as to choose appropriate methods for such evaluation;
-develop the main provisions of the “Quality Policy” of the organization of the pharmaceutical profile;
- to formulate aims in the field of quality of the organization of the pharmaceutical profile;
- prepare reports on the functioning of the pharmaceutical quality system and action plans for its continuous improvement.



The scheme of the course

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.

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

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.

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 scheme of the course

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

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

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

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

TEACHER

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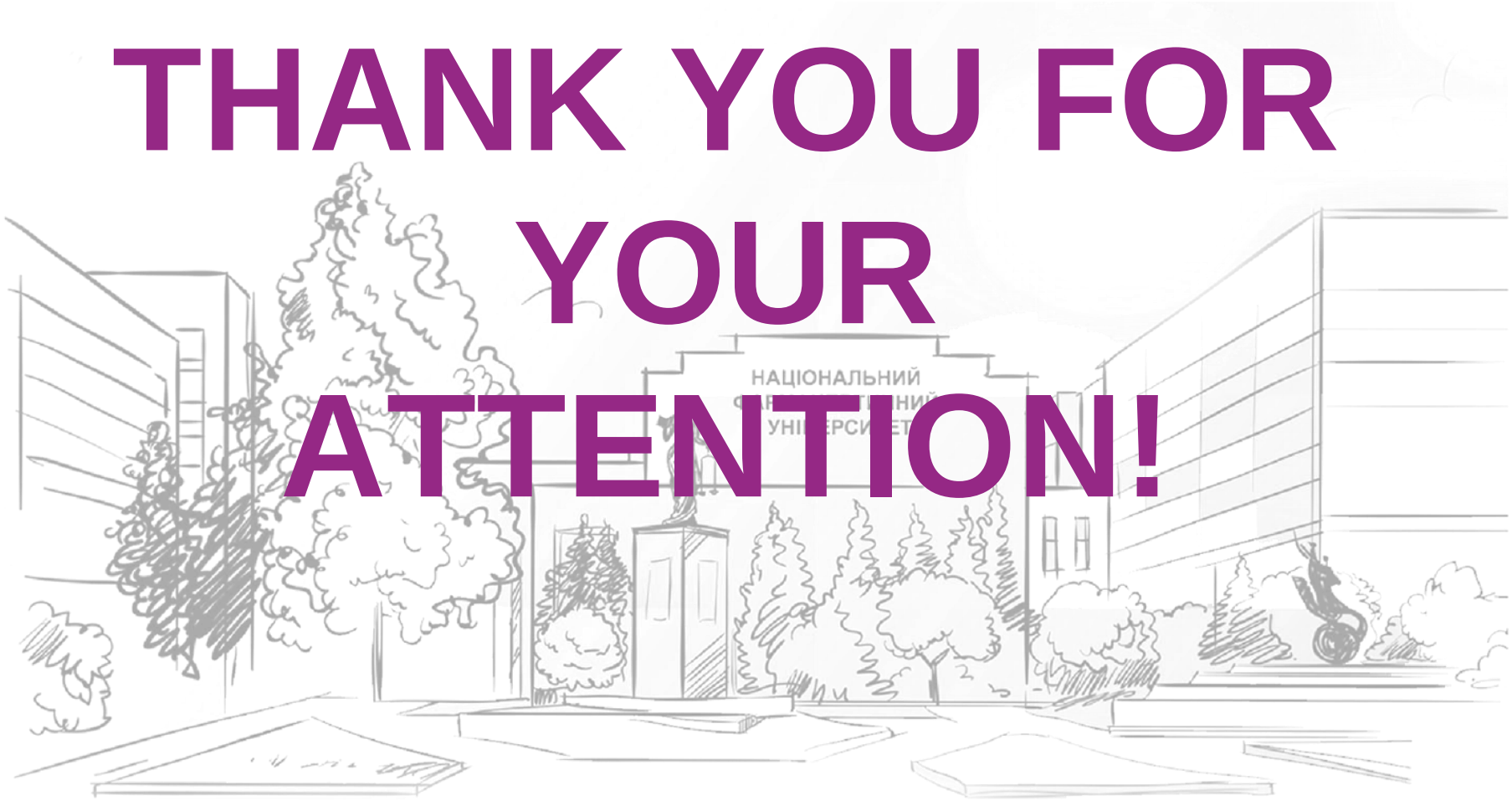
THANK YOU FOR YOUR ATTENTION!



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