

SUMMARY OF DISCIPLINE

Management of laboratory activity

The purpose of the course is to master the algorithms of grading technologies and the efficiency of laboratory methods as a component of the diagnostic process.

The task of the discipline - mastering a set of standards for modern laboratory diagnostics; defining rules for sample preparation of biological material for modern and objective directions of laboratory research; implementation of modern laboratory testing procedures in accordance with international rules of good laboratory practice (GLP).

As a result of studying the discipline, the graduate student should know:

- The concept of quality management system in medical laboratories of Ukraine in accordance with the requirements of international standards and the Plan of measures for its implementation;

- DSTU EN ISO 15189: 2015 approved at the state level, which has set specific requirements for the quality and competence of medical laboratories;

- principles of good laboratory practice;

- how the state system of external evaluation of the quality of clinical laboratory investigations works by implementing Programs of interlaboratory comparisons of measurement results.

be able:

- to apply in practice the rules of international standards on good laboratory practice;

- apply the special skills of modern laboratory research defined by the Standard using modern equipment;

- Determine the tactics of complex laboratory research in accordance with the rules of good laboratory practice;

- Analyze the results of laboratory tests according to standard operating procedures.

The program of the discipline

Topic 1. The rules of biomedical and legal ethics in laboratory research

Topic 2. International standards of good laboratory practice in conducting laboratory-instrumental research, principles of creation of laboratories with the use of modern equipment, the latest medical technologies and scientific developments

Topic 3. Creating standard operating procedures, laboratory test protocols, analysis rules, generalizations, and validation of current laboratory test results

Topic 4. Building an effective laboratory management system.

Topic 5. Internal audits. Performing internal audits in accordance with ISO 19011: 2018

Topic 6. Assessment of risks and opportunities in laboratory activities.