PRECLINICAL STUDIES

Course Workload		Assessment form (examination/ graded test/ ungraded test)
ECTS	Hours	
3	108	Ungraded test

Students will know how to formulate the basic principles of preclinical studies, the basic principles of GLP, GCP; to justify the studied pharmacokinetic parameters; to describe the phases of clinical trials; to formulate the basis for the organization of joint project activities and joint preclinical studies of pharmaceuticals; to substantiate research methods of acute and chronic toxicity, specific toxicity (reproductive toxicity, mutagenic and carcinogenic effects, immunotoxicity, allergenicity); to reproduce the laws, standards governing the conduct of preclinical studies; to describe a test system to study the medicines effectiveness.

Course structure:

1. SUBJECT OF PRECLINICAL RESEARCH STUDY
    - 1.1. History of the issue. Stages of drug development.
    - 1.2. The main directions and principles of preclinical research.
    - 1.3. Test systems used.

2. GLP PRINCIPLES AS A BASIS FOR CONDUCTING PRECLINICAL RESEARCH
    - 2.1. Laboratory practice rules.
    - 2.2. Quality assurance system for preclinical studies.
    - 2.3. Investigational and comparative medicines.
    - 2.4. Planning and conducting a preclinical study.
    - 2.5. Primary data. Preclinical study report.

3. STUDY OF DRUG SAFETY
    - 3.1. Acute and chronic toxicity.
    - 3.2. Specific types of toxicity: reproductive toxicity, mutagenic and carcinogenic effects, immunotoxicity, allergenicity.

4. STUDY OF PHARMACOKINETICS
    - 4.1. Subject of pharmacokinetics study.
    - 4.2. Scheme of the pharmacokinetic experiment, the main studied parameters.
    - 4.3. Linear and nonlinear pharmacokinetics.
    - 4.4. Pharmacokinetic parameters: half-life, mean residence time in the body — MRT, total clearance, stationary volume of distribution, absolute degree of absorption and rate of absorption
    - 4.5. Characterization of drug excretion.

5. STUDY OF THE DRUGS EFFECTIVENESS

5.1. Modeling diseases as a basis for studying the specific pharmacological activity of drugs.

5.2. Examples of test systems for the study of cardiovascular, oncological diseases, as well as for studying the effectiveness of antidotes.

6. BIOMEDICAL STATISTICS

6.1. The need for adequate statistical processing of experimental data.

6.2. The concept of the general population, sample.

6.3. Normal distribution.

6.4. Parametric and nonparametric tests.

7. CLINICAL RESEARCHES

7.1. Good clinical practice (GCP), history and reasons for occurrence, basic principles.

7.2. Legal framework for conducting clinical trials in the Russian Federation.

7.3. Types and phases of clinical trials.

7.4. Study planning and design.