Drug Development

I.M. Sechenov First Moscow State Medical University

Degree or qualification is awarded: **Certificate of Accreditation**

Language of study:
Mode of study: **full-time, distance learning**
Duration: **216 hours**
Availability of free education: **no**
Price:

Programme curator: **Natalia V. Pyatigorskaya**
Tel.: **+74991285755**
E-mail: osipova-mma@bk.ru

The program allows individuals with higher or secondary professional pharmaceutical, chemical, chemical and technological, biological, biotechnological, medical or veterinary education, and those who have completed an educational program of professional retraining of specialists in Industrial Pharmacy.

The purpose of the Program is to form competences on justification of pharmacological (therapeutic) criteria for clinical studies of the I-IV phase, and on assessment of a concept of development of new drugs and generics and the impact of pharmacokinetic, pharmacodynamic, and biopharmaceutical parameters on clinical development.

- Medicines administration routes. Development of a dosage forms (tablets, modified release tablets). Stability studies of adosage form: factors affecting the stability, types of stability studies, ICH guidelines on stability study. Study of biological products. Branding and Marketing. Selection of animals for preclinical research. Carcinogenicity studies. Studies of ontogenetic toxicity. Studies of specific toxicity. Evaluation of reliability of results of toxicological studies. Biopharmaceutical research. Study of metabolism: specificity of the I and II phases, the cytochrome P450 system. Study of absorption: factors affecting the absorption, distribution, excretion. Single-chamber model. Two-chamber model. Intravenous and extravascular administration. Non-linear kinetics and therapeutic drug monitoring. Endpoints of a clinical study. Surrogate endpoints and biomarkers. Definition endpoints. Regulatory and resource issues in the planning of clinical studies.
- Drug search and development stages: disease selection, target cells and target receptors, screening, development strategies, post authorization studies. Clinical studies of the I - IV phases. Adverse drug reactions, special risk groups. Good Manufacturing Practice standards for medicinal products (GMP): legislation and guidelines, the main sections, production processes, scaling and validation of a technological process, packaging.
- Antimicrobial drugs. Antiviral drugs. Anti-inflammatory drugs. Public health and the factors that influence it. Noncommunicable diseases: Parkinson's disease, asthma and COPD, depression, schizophrenia. Pharmaceutical research in the developing countries. Vulnerable subjects of clinical studies.

Specializations within this programme