Good Regulatory Practices

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: **144 hours**
Availability of free education: **no**
Price:

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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 a view of regulatory systems in different countries, regulatory approaches and their practical implementation, current questions of regulatory science.

- Leading regulatory agencies: FDA, EMA and other European agencies, agencies from other countries and international cooperation. Interaction with regulatory agencies during the development. Types of registration dossiers and regulatory procedures for registration. International Conference on Harmonization (ICH). Guidelines of ICH. Common Technical Document. Dossiers regional formats. The pharmaceutical part of a dossier: content, requirements, regulatory, industrial and laboratory analytical aspects. Planned quality. Post-marketing regulatory issues: maintenance of a registration dossier, amendments to a registration dossier in the US, EU and Japan. Intellectual property and its protection throughout the lifecycle of a drug. Principles and Good Practices of drug promotion, marketing strategies and medical marketing. Medical and pharmaceutical information. Regulation of advertising and promotion of drugs. Other interactions with healthcare professionals and patients. Regulatory Affairs Department of a pharmaceutical company. New regulatory aspects, new approaches to assessing the safety of drugs, biosimilars, quality economy and other.

Specializations within this programme