MINPROMTORG RUSSIA

EAEU Eurasian Economic Union

State Institute of Drugs and Good Practices

EURASIAN ACADEMY OF GOOD PRACTICES

MOSCOW
2022

OFFICIAL SUPPORT

"By creating the Eurasian Academy of Good Practices we take an important step in fostering cooperation within the Eurasian Economic Union. Designed to provide advanced training to EAEU pharmaceutical specialists and optimize cooperation with pharmaceutical inspectors from other countries, it shall also help develop export potential of the EAEU pharmaceutical companies".

Denis Manturov
Minister of Industry and Trade of the Russian Federation

"It is crucial to bring together all our countries' forward-looking and qualified forces to promote proper development of good practice within the EAEU.
We are transitioning to a common market of medicines and expect the Academy to provide the most qualified and up-to-date consulting assistance. We are looking forward to close and successful cooperation with everyone who joins the Academy".

Viktor Nazarenko
Minister for Technical Regulation of the Eurasian Economic Commission

ACADEMY LEADERSHIP

"I hope that the Eurasian Academy of Good Practices will become *the* professional platform for the development of universal standards and approaches to good practice in pharmaceutical production. The GMP inspection experience we have accumulated, the expertise that draws on the world's best practices and the insight knowledge of domestic markets allow us to form a curriculum that meets today's demands as much as possible and takes into account current EAEU trends".

Vladislav Shestakov
President
Eurasian Academy of Good Practices
Director
State Institute of Drugs and Good Practices

"Promoting an open dialog between regulators and pharmaceutical market players, the Eurasian Academy of Good Practices serves as an expert decision-making platform for the development of respective regulatory documents together with the EAEU states. The Academy's teaching potential and considerable pharmaceutical inspection experience contribute to the creation and implementation of relevant programs with a focus on hands-on training and the use of innovative learning solutions such as VR".

Professor Irina Spichak
Doctor of Pharmacy
Executive Director
Eurasian Academy of Good Practices

ABOUT THE ACADEMY

A new, multi-faceted learning, research and expert platform, the Eurasian Academy of Good Practices fosters the development of the pharmaceutical industry.

The Academy was established upon the initiative of the EAEU pharmaceutical inspectorates with the support of Russia's Ministry of Industry and Trade on February 27, 2021.

The Academy's Board of Trustees includes representatives of the EAEU regulatory authorities, associations of Russian and international pharmaceutical manufacturers, and leading pharmaceutical companies.

The Chairman of the Academy's Board of Trustees is Prof. Ramil Khabriev, Doctor of Pharmaceutical Sciences, Doctor of Medical Sciences, member of the Russian Academy of Medical Sciences and the Russian Academy of Sciences

KEY OBJECTIVES:

- Assisting the EAEU authorized bodies, their subordinate organizations and other pharmaceutical organizations in hiring qualified workforce.
- Appraisal and consulting on good pharmaceutical practice and on inspection of medicines circulation entities.
- Helping pharmaceutical companies boost their export potential.

ABOUT THE ACADEMY

WHAT WE DO

- **Training**
- **Research & consulting**
- **Appraisal**
- **Outreach activities**

THE ACADEMY TODAY

- An open dialog platform: discussing industry's issues with Russia's and EAEU regulators
- An expert platform: developing solutions for relevant regulatory documents, including for the EAEU
- High research, consulting and expert potential in development and registration of medicines and medical devices
- Top research and teaching staff, own school for GxP inspectors
- Hands-on training with the use of innovative learning technologies such as VR; own simulation center
- Innovative projects supporting R&D in the pharmaceutical industry, including the Pharma-2030 program
- Events creating a positive image of Russia's pharmaceutical industry and promoting its achievements with both the professional community and the population

EXPERT COUNCIL

The Expert Council of the Eurasian Academy of Good Practices features the industry's leading experts, high-skilled specialists, and the EAEU regulators.

THE COUNCIL'S MAIN RESPONSIBILITIES:

- Drafting proposals in top-priority research areas, developing standards, recommendations, teaching guidelines and other regulatory documents
- Aligning the EAEU and the EU GxP guidelines and regulations
- Representing the Academy in authorized agencies and organizations in Russia, the EAEU and abroad
- Contributing to the Academy's curriculum, strategy and development plan
- Drafting proposals for the development of international cooperation in the Academy's research and technical areas

EXPERT COUNCIL MEMBERS

Madina Sottaeva

Deputy Head
Inspection of Pharmaceutical Manufacturers & Appraisal Bureau,
State Institute of Drugs & Good Practices
Expert Council Chair

Nazi Abdyrasulova

Head of GxP
Department of Medicine Provision & Medical Equipment,
Ministry of Health of the Kyrgyz Republic

Aizhamal Batralieva

Pharmaceutical Affairs Coordinator
National Center for Expertise of Medicines & Medical Devices,
Republic of Kazakhstan

Vladimir Gegechkori

Lead GxP specialist
State Institute of Drugs & Good Practices

Gelena Grosheva

Head of Licensing of Pharmaceutical Manufacturers
Department for Development of Pharmaceutical & Medical Industry,
Ministry of Industry & Trade of the Russian Federation

Dinara Dautova

Head of Inspection Department
National Center for Expertise of Medicines & Medical Devices,
Republic of Kazakhstan

EXPERT COUNCIL

Elena Denisova

Deputy Director
Department for Development of Pharmaceutical & Medical Industry,
Ministry of Industry & Trade of the Russian Federation

Aziz Dusmatov

Director
State Center of Expertise and Standardization of Medicines, Medical Devices & Medical Equipment,
Pharmaceutical Industry Development Agency,
Ministry of Health of the Republic of Uzbekistan

Elena Kudryavtseva

Head of Department of State Quality Control of Medical Products
Federal Service for Surveillance in Healthcare,
Russian Federation

Elena Lavnik

Head of Pharmaceutical Inspectorate,
Ministry of Healthcare of the Republic of Belarus

Chinara Mambetalieva

Deputy Director of Technical Regulation & Accreditation Department,
Eurasian Economic Commission

Andrey Meshkovsky

GxP expert

Elena Popova

Senior Director
Regulatory Affairs & Healthcare Policy,
Association of International Pharmaceutical Manufacturers

Irina Pshenichnaya

Head of Legal Department
State Institute of Drugs & Good Practices

Tatyana Tumelya

Head of Good Pharmaceutical Practice Bureau
Center for Examinations & Tests in Health Service,
Ministry of Healthcare of the Republic of Belarus

Mkrtych Shakaryan

Head of Inspection Department
Scientific Center of Drug & Medical Technology Expertise,
Republic of Armenia

TRAINING

The Academy provides continuing professional education courses towards state-recognized certificates. License No. 041627 issued by the Moscow Department of Education.

ПРАВИТЕЛЬСТВО МОСКВЫ

ДЕПАРТАМЕНТ ОБРАЗОВАНИЯ И НАУКИ ГОРОДА МОСКВЫ

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11.08.2021 № 02-14-4574121

на № _____ от _____

Автономная некоммерческая организация «Евразийская академия надлежащих практик»

ул. Земляной Вал, д. 1/4, стр. 2, этаж 1, помещ. III ком. 2, офис 1, вн. тер. г. муниципальный округ Басманный, г. Москва, 105064

Уведомление о предоставлении лицензии

В соответствии с частью 5 статьи 14 Федерального закона от 04.05.2011 г. № 99-ФЗ «О лицензировании отдельных видов деятельности», пунктами 92 и 93 Административного регламента предоставления органами государственной власти субъектов Российской Федерации, осуществляющими переданные полномочия Российской Федерации в области образования, государственной услуги по лицензированию образовательной деятельности, утвержденного приказом Рособрнадзора от 23.12.2020 г. № 1276, Управление государственного надзора и контроля в сфере образования Департамента образования и науки города Москвы уведомляет, что по заявлению о предоставлении лицензии № 000954 от 15.06.2021 г. принято положительное решение (приказ Департамента образования и науки города Москвы от 10.08.2021 г. № 692Л).

Приложение: выписка из реестра лицензий в форме электронного документа в 1 экз.

Начальник Управления государственного надзора и контроля в сфере образования И.В. Гуськов

Е.С. Самуйлова
8-499-444-34-82

Specialists involved in circulation of medicines are offered relevant upskilling programs, professional retraining and webinars.

The Academy's programs meet all the current requirements, keeping abreast with industry trends within the EAEU.

30+ training events per year

Select a program & apply online

WHY STUDY AT THE ACADEMY:

- In-demand training for industry specialists, including tailor-made programs for pharma companies
- Highly skilled teaching staff featuring industry's leading experts, top lecturers and practitioners, representatives of regulatory authorities, and pharmaceutical inspectors from around the world
- Programs with a particular focus on hands-on training drawing on the inspectorate's experience accumulated during inspections of pharma companies, both domestic and international
- A high proportion of practical sessions in a course, including those held at the Academy's simulation centers
- Innovative learning solutions such as simulation, VR, modular training, etc.

VR Factory is the Academy's state-of-the-art pharmaceutical simulation center. The unique VR learning facility allows to hone the skills of GMP inspection.

VR FACTORY ALLOWS TO:

- Boost the quality of training and mastering of complex technological processes
- Organize distance learning – no need to travel to a real production site
- Automate training and skills assessment
- Build a convenient training infrastructure with rapid deployment, detailed statistics and network updates of training materials

RESEARCH & CONSULTING

Research and consulting are carried out at the Academy's Research & Expert Center for the Development and Registration of Medicines.

The Center provides scientific consulting at all stages of development of medicines: from creating regulatory strategies, planning preclinical and clinical research programs, producing reports and drafting instructions for use, to investment consulting upon purchase, registration or phasing in of innovative medicines.

The Center hosts a permanent expert council and special expert commissions featuring leading specialists – developers of technological and production processes, researchers, clinicians, scientists and practitioners.

The team provides assistance to pharma companies in a wide range of issues related to development and launch of medicines in the EAEU and other countries, thus helping the domestic pharmaceutical industry boost its export potential.

Andrey Vasilyev

Doctor of Biological Sciences
Head of Scientific Consulting
30+ years in regulatory system

Dmitry Romodanovsky

Doctor of Biological Sciences
Head of Generic & Biosimilar Medicines
14+ years in regulatory system

Margarita Dranitsyna

PhD in Medicine
Lead specialist
150+ successful registration cases (biostatistics) over the last 5 years

Alexandr Mashutin

PhD in Pharmaceutical Sciences
Lead specialist
20+ years in development & registration of medicines

Elena Gavrishina

Head of Original Medicines
200+ successful registration cases over the last 5 years

Anastasia Shestakova

Lead specialist
6+ years in regulatory system

The Center's main objective is to set up expert work to produce a profile on the EAEU regulations on registration of medicines within the EAEU and abroad, in line with the requirements of leading regulators such as EMA and FDA, in order to launch Russian medicines internationally.

In view of establishing a common pharmaceutical space, the EAEU states consider scientific consulting as a priority.

For Russia, adopting a systematic approach to scientific consulting seems particularly pertinent in the light of the Pharma-2030 program and state funding of development and registration of medicines.

LEGAL APPRAISAL & CONSULTING CENTER

The Legal Appraisal and Consulting Center provides support in pharmaceutical and antitrust regulation cases, i.e. litigation, undergoing checks, developing new regulatory acts and evaluating their potential to maintain legal compliance in the future.
Our unique experience in working with the largest Russian and international pharma companies enables us to carry out assignments of all degrees of complexity at short notice.

THE CENTER OFFERS THE FOLLOWING ONE-STOP SERVICES:

- development and comprehensive assessment of draft regulations of the Russian Federation and of the EAEU acts on medicines and medical devices
- litigation support and representation of interests in pharma litigations
- support in matters of antitrust law, including representation of pharmaceutical manufacturers and distributors during investigations and antitrust infringement trials
- full support in conducting public procurement of medicines, including documentation
- comprehensive due diligence risk assessment, including appraisal and recommendations to mitigate critical risks
- drawing up of individual employment agreements for the industry, development of internal policies, standard procedures and processes
- consulting and legal opinion on specific points of pharmaceutical legislation

Timur Grigoryev
PhD in Law
Head of Legal Appraisal & Consulting

Over 12 years in consulting and representation of Russian and international companies in Russian courts and before antitrust authorities. Specializes in contractual relationship claims, has extensive experience in legal support before the state regulators, and in drafting federal laws and other regulatory acts.

BUSINESS DEVELOPMENT APPRAISAL & CONSULTING CENTER

The Business Development Appraisal & Consulting Center was established to help pharma companies improve their competitiveness. The Center offers consulting on pricing strategies for medicines, including vital and essential medicines (VED), advising on contract manufacturing organizations, as well as data collection and analytics in pharma.

The Center's expertise helps create an optimal development strategy and shape a well-balanced product portfolio.

BUSINESS DEVELOPMENT APPRAISAL & CONSULTING CENTER PROVIDES:

- medicine pricing consulting and appraisal:
  - calculation of maximum sale prices for VEDs and verification of documents submitted for (re-)registration under Resolutions Nos. 865 and 1771
  - compilation of a registration dossier
- matching of contract and licensed manufacturing organizations with the criteria set by customers
- appraisal of medicine's potential to be launched internationally
- expert decisions on business development and product portfolio advising

The Center's highly-skilled team has extensive experience in business analytics, strategic and operational marketing, BD, R&D, promotion and advertising in medicine. The team's mastery of regulatory acts and insights into industry and market dynamics help evaluate business development models and give advice on current product portfolio.

An understanding of international pharmaceutical market trends combined with the support of foreign trade missions provide a clearer picture of export opportunities.

Raziya Solodova

Head of the BD A&C Center

OUTREACH ACTIVITIES

The Eurasian Academy of Good Practices is actively involved in outreach activities.

The Academy traditionally holds the following annual events:

- The International Student Festival GxP Fest
- The International Professional Excellence Awards GxP-Profi (for industry specialists)

THE INTERNATIONAL STUDENT FESTIVAL GxP FEST

GxP Fest is one of the key events in the EAEU pharmaceutical industry. Each year, the festival brings together students, postgrads and teachers from respective universities across Russia and the EAEU, representatives of domestic and international regulators and pharmaceutical companies, and experts in professional education.

Pharma's future is my future...

GxP FEST'S MAIN GOALS:

- Fostering aspiring specialists' involvement in the development of pharma
- Scouting young talents in pharma
- Forming a talent pool able to come up with disruptive strategies for the industry's future

GxP Fest
for university students:

- an insight into future profession through the interactive GxP-battle and the hands-on GxP-quest
- getting to know leading pharma companies and experts, domestic and international
- taking part in the Job Fair, showcasing portfolio to companies, etc.

GxP Fest
for pharma companies:

- introducing the company and its offers to aspiring specialists
- attracting top students, etc.

THE INTERNATIONAL STUDENT FESTIVAL GxP FEST 2022

GxP Fest 2022 was held from February 22 to April 21, 2022. The two-round competition was open to both students and teachers for the first time.

GxP FEST 2022 IN NUMBERS:

- **780** students
- **92** student teams
- & **41** teacher teams, representing **61** universities
- from **7** countries: Russia, Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyz Republic and Uzbekistan.

To get through qualification, students took part in a pharma-battle or a multidisciplinary quiz. The final round consisted of the interactive GxP-quest, where teams had to solve field-specific problems and overcome various obstacles, as assigned on a special play area. The unique software for this game has been developed at the Academy.

The busy online program for students featured professional contests by pharmaceutical companies, workshops and meetings with the business community, a webinar on how to write a successful CV by HeadHunter, and a job fair with over 40 pharma companies.

- Students were able to browse through job openings and internships at the top pharma companies, and learn more about prerequisites and employment opportunities
- Employers participating in the fair got access to portfolios of 150 top students who qualified for the professional contest
- Pharma companies were able to share their presentations and job openings with universities and student unions across Russia and the EAEU

The GxP Fest 2022 business program featured leading pharma experts, representatives of Russia's Ministry of Industry and Trade and Ministry of Science and Higher Education, Belarus's Ministry of Healthcare and the Eurasian Economic Commission, top managers of 40 pharma companies, as well as leadership and teachers of universities from across Russia and the EAEU.

During the plenary session, experts identified current challenges in pharmaceutical training and offered a comprehensive overview of the critical areas in the skill gap, as seen by educators, the industry and regulators.

At the end of the discussion, a resolution was adopted to be shared with Russia's regulators such as the Ministry of Industry and Trade, the Ministry of Science and Higher Education and the Ministry of Health.

GxP-PROFI AWARDS

GxP-Profi is international professional excellence awards held with the support of Russia's Ministry of Industry and Trade.

GOALS OF GxP-PROFI:

- identifying leaders of GxP innovation in pharma
- showcasing the best initiatives for product quality improvement
- sharing GxP leaders' experience

GxP-Profi is open to pharma manufacturers who strive for continuous product quality improvement and have completed successful GMP, GDP and GSP projects.

SUBMISSION REQUIREMENTS:

- Relevance of the quality improvement solution
- Focus on innovation
- Proven efficiency and economic benefits

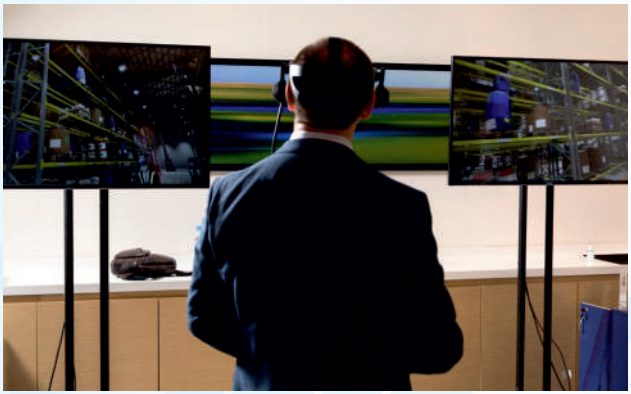
SUBMIT YOUR PROJECT

Quality leaders and game changers...

The innovative project should help improve and optimize processes, products, technologies and techniques in GMP and GSP – from streamlining engineering systems to digital transformation.

Submitted projects are reviewed by an expert committee featuring leading Russian and international pharma experts, representatives of regulators, professional associations and communities, company leadership and top pharma specialists.

Pharma companies presenting the best projects are honored with the GxP-Profi title and a prestigious professional award.



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