

№ 02
2019

~ Ministry
for economic development
of Kaluga Region

VESTNIK

EVENTS
SOCIETY
ECONOMY
TECHNOLOGIES

INDUSTRY
BUSINESS
RATINGS
IDEAS

PROJECTS
FORECASTS
ANALYTICS
COMPETENCES





LOANS
FOR SMALL AND MEDIUM
ENTERPRISES

from **8.5%**



BANK GUARANTEES ON INDIVIDUAL TERMS*

* Including bank guarantees specified by Federal Law **No.44-FZ** dd.05.04.2013 On Contractual System in Purchase of Goods, Work, Services for State and Municipal Needs

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Russian Pharmaceutical Market

RESULTS-2018

RUR 1.28 Trillion

- volume of pharmaceutical market

3%

- growth of Russian pharmaceutical market

*The Ministry for Industry and Trade of the Russian Federation

RUR 26.1 bln

- volume of export of drugs (excluding EAEU countries)

19.3%

- growth of drug export volume (excluding EAEU countries)

*RNC Pharma®

RUR 991.9 bln

- revenue from sales of drugs

4.6%

- growth of sales of drugs in physical terms

RUR 5.3 bln

value of drug packs sold through pharmacies

4.9%

- growth of sales of drugs in monetary terms

IMPORTED / RUSSIAN-MADE DRUGS IN 2018

59%

- share of Russian-made drugs in physical terms

29.2%

- share of Russian-made drugs in money terms

5.3%

- growth of sales of Russian-made drugs in physical terms

6.2%

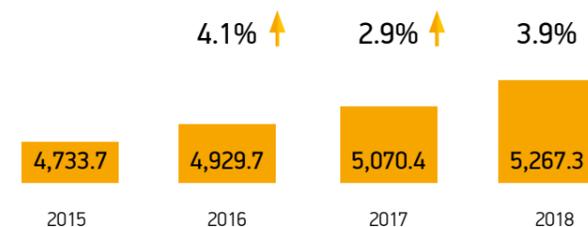
- growth of sales of Russian-made drugs in monetary terms

5.2%

- growth of cashflow from import of finished drugs



DYNAMICS OF DRUGS SALES IN PHARMACIES



Kaluga Pharmaceutical Cluster – Leading Cluster in the Russian Federation



Anatoly SOTNIKOV,
Director General,
OAO Agency for Innovative
Development – Center for Cluster
Development of Kaluga Region



What, in your opinion, distinguishes Kaluga pharmaceutical cluster from similar clusters in other regions? What are advantages of the region for localization of pharmaceutical production?

The main difference, I believe, is the following. Today our cluster is a comprehensive structure balanced in all senses. There is industrial manufacturing of finished dosage forms developing in parallel with research and development of original pharmaceutical substances, also there are training programs for specialists. Advantages of Kaluga Region for localization of pharmaceutical production are attributed to global investment attractiveness of the region, which is based on well-designed

investment policy of the regional Government. Strong infrastructure of support for innovative activities has been formed in the region. It has been continuously developing over the last 15 years. Already now, it is has positive effect on the dynamics of project implementation. In other words, the period from making decision to the release of first products is substantially reduced. Number of cluster participant is constantly growing. Active work is under way practically at all plants of the cluster to expand volume of production, including production of drugs under import replacement program. Kaluga pharmaceutical cluster is a leading cluster in the Russian Federation by many parameters. In 2013, it was the winner of the tender held by the Government of the Russian

Federation, and it was among first 14 pilot innovative clusters of Russia. In 2016, it was qualified and became participant of priority project of the Ministry of Economic Development of the Russian Federation 'Formation of clusters – leaders of world-level investment attractiveness'. These are not merely statuses, but priority access for participants of our cluster to various mechanisms of state support: free training of specialists, privileged access to financing programs of Industrial Development Fund (IDF), to support programs of Russian Export Center and to other regional and federal support tools. I consider as important advantage the opportunities, which are offered by Kaluga Pharmaceutical Cluster Association as a communication venue. Here, many joint projects are

born, problems of its participants are discussed and ways to resolve them are found, which are of interest for many other enterprises. Thus, once, a problem to localize treatment of pharmaceutical waste was solved, excellent logistics system was created to store and ship pharmaceutical substances.

Apart from that, the issue of personnel training for pharmaceutical production sites is efficiently solved: practical training center, created on the basis of Medical Faculty of Obninsk Institute for Nuclear Power Engineering (OINPE) NRNU MEPhI, performs both retraining and training of specialists (holders of bachelor's, master's degrees, and post-graduates) for pharmaceutical enterprises and research institutes in the areas of pharmaceutical and medical chemistry, competent in developing, manufacturing and quality control of pharmaceutical and radio-pharmaceutical preparations. The Center was the first in the practice of higher education to be equipped with a module of clean premises and it offers the most efficient dual training system (parallel training in NRNU MEPhI and practical training at the enterprises of employers of Kaluga pharmaceutical cluster: AstraZeneca, Hemofarm, Berlin-Pharma, Mirpharm, Bion, Khimpharmkomplekt, Nearmedic Pharma, AO SSC RF IPPE, A. Tsyb MRRC, Karpov Institute of Physical Chemistry, etc.



Pharmaceutical enterprises of Kaluga Region enjoy entire range of tax benefits and privileges established by federal and regional legislation.

There was a unique project in 2019, when OOO Hemofarm launched scholarship program to incentivize students, who study in the interests of Kaluga pharmaceutical cluster and who demonstrate big achievements in their studies and scientific research. The Company identified 9 winners, who will receive monthly scholarship in the amount of RUR 20,000. High efficiency of the cluster, its balanced management system was confirmed during on-site audit and expert assessment, carried out by the European Secretariat for Cluster Analysis (ESCA) in 2017. Kaluga pharmaceutical cluster became first Russian winner of Silver Cluster Excellence Certificate awarded by the European Secretariat for Cluster Analysis (ESCA).

You have already mentioned that manufacturing of innovative products requires presence of smoothly-running chain: from search of ideas to release of market product. Specialists say that one of important links in this chain is the availability of government support. On which support can rely Kaluga companies specialized in their own developments?

In fact, more than 70% of products from the cluster enterprises and majority of member companies of the cluster are innovative ones, hence, in this context we can speak about support of new innovative projects initiated by the participants of the cluster. In 2015, thanks to federal and regional financing, a regional engineering pharmaceutical center was created and equipped with the most modern equipment, where project teams obtain services on privileged terms. Our Agency, as a representative of Federal Fund for Support of Innovations in Kaluga Region, provides support in priority order in preparing applications for grants under programs of the Fund. Amount of grants ranges from RUR 2 mln to RUR 25 mln. The Fund supports innovators at various stages: from financing studies and R&D to commercialization and market launch of new products. The very structure and composition of participants form beneficial environment and additional

Structure and composition of participants form beneficial environment and additional opportunities for development of innovative production.

opportunities for development of innovative production: from cooperation at new development stage and preparation of required dossier to manufacturing of pharmaceutical substances and finished dosage forms, modern packaging and disposal of pharmaceutical waste. There is a very interesting opportunity among tools of federal support, to which participants in our cluster have priority access - obtaining loan up to RUR 500 mln from the Industrial Development Fund to create innovative production site at 1% annual rate for 5 years.

What other additional measures of support are available today for pharmaceutical manufacturers of Kaluga Region?

In their role of investors, pharmaceutical enterprises of Kaluga Region use the entire range of tax benefits and privileges established by federal and regional legislation. Active position of the regional Government and the Governor personally is not less important in lobbying interests of pharmaceutical manufacturers of Kaluga Region at the federal authorities. There are plenty of examples. Thus, in 2017 with direct regional support, federal Special Investment Contract (SpIC) was concluded between AstraZeneca Industries, the Ministry of Industry and Trade of the Russian Federation and the Government of Kaluga Region. And AstraZeneca became the first pharmaceutical company not only in our region but also the first one in Russia, which obtained privileged conditions for its business

guaranteed by SpIC. In 2018, Novamedica Company concluded its first SpIC in the industry for support of creation of major pharmaceutical production site from scratch. Novamedica will additionally invest more than RUR 3 bln within the contract frame in modernizing its Russian enterprise and in ensuring technology transfer for production of drugs for treatment of socially-significant diseases. I know that currently the company works on creation of a number of own pharmaceutical products. R&D department of the company plans to develop about 15 innovative drugs before 2022. Nine of them are already at various development stages. Under terms of SpIC Novamedica will get main incentives for development of pharmaceutical production in

Russia. These are status of local manufacturer, entitlement for status of sole supplier of wide range of vital medicines allowing participation in state purchase system. I am confident that these measures, as well as other ones, will guarantee successful development of Novamedica project, and also a stimulus for other companies to use more actively the support. Which is now offered both at federal and regional levels.

Opening new modern production sites, further development of pharmaceutical cluster are aiming at resolving critical issues of Russian pharmaceutical industry. First of all, it means high-quality and affordable domestic drugs launched to the Russian market. How Kaluga pharmaceutical cluster is coping with this task today?

In my opinion, it is excellent in coping with the task. All recent years, the cluster demonstrates unprecedented growth of sales volume and number of manufactured finished dosage forms (FDF): from RUR 5.2 bln in 2012 to RUR 52.7 bln now, and 154 names of FDF in 2018. Moreover, another 30 FDF are now at registration stage, 26 medicines



are undergoing clinical tests and are at prospective development stage. The quality of drugs manufactured in the region is confirmed by the fact that all our production sites are certified under GMP standards. New high-tech enterprises and new production lines are put in operation on a regular basis. In 2017, Palladio BNM plant manufacturing packaging for pharmaceutical and cosmetic products was opened. OOO Sanatmetal SNG started operations in 2018; it is a plant manufacturing implants for traumatology, surgery of vertebral column, dental surgery, animal health, and also joint implants. Also, last year, two leading enterprises of the cluster expanded their production capacity. Novo Nordisk launched full cycle production of insulin in Grabtsevo Industrial Park; also, a new shop for the assembly of injection pens was opened there. Nearmedic Pharma opened full cycle production of reactants for genetic person's identification at the site of its plant in Obninsk. Test kits is a proprietary and unique product, which differs significantly from similar products offered by Western companies. Thus, the company intends to lower dependence of Russian laboratories from foreign suppliers from 98% to 50%.

What are today's prospects of the cluster development and further enhancing of competitiveness of products, their quality and affordability?

Prospects of Kaluga pharmaceutical cluster development are related first of all to its continued growth and development of its existing participants, with coming of new investors, development of infrastructure and ecosystem of the cluster, including development of all services needed for developing and manufacturing of FDF. In 2021, the commissioning of OOO Novamedica plant is planned (joint project with AO ROSNANO); more than 35 drugs will be manufactured there under contract with Pfizer. Planned capacity of the plant exceeds 38.5 mln items per year. In October 2018, an agreement was signed between the Government of Kaluga Region and AO Miraxbiopharma concerning construction of the plant to manufacture non-sterile medicines and substances designed to treat pre-cancer pathologies and to prevent oncology diseases of reproduction system.

There are already several other pharmaceutical projects in the investment portfolio of the region. We also make efforts to localize R&D divisions of pharmaceutical companies in Kaluga Region, because today it is a key to long and successful life of the cluster enterprises and it will enhance their global competitiveness. Creation of innovative research and technology center (IRTC) on the basis of NRNU

All recent years, the cluster demonstrates unprecedented growth of sales volume and number of manufactured finished dosage forms

MEPhI Obninsk site will become an important factor in solving this issue. It will be sort of technology valley in the area of nuclear medicine and pharmaceuticals; its future residents will obtain substantial tax privileges and preferences completely analogous to Skolkovo Project. Work on forming a package of documents for the IRTC for the Russian Government is well under way, and the region is actively involved in this work.



Cluster of Pharmaceuticals, Biotechnology and Biomedicine 2018-2019

64
enterprises and entities included in the cluster

10
full cycle plants meeting GMP standards

38
small innovative and project companies

>70%
– share of innovative companies

>75%
of the cluster products are finished dosage forms

9,840
persons
– number of employees in cluster participants, including

4,670
employees at pharmaceutical production facilities

3,790
specialists employed by research and development centers



PRODUCTION OF DRUGS:

50 names of FDF in 2012	158 names of FDF in 2018
30 names of drugs at registration stage	26 drugs undergo clinical tests

>20 pharma substances and >50 drugs among import replacement substances and drugs

2019
10%
– pharmaceutical production volume growth

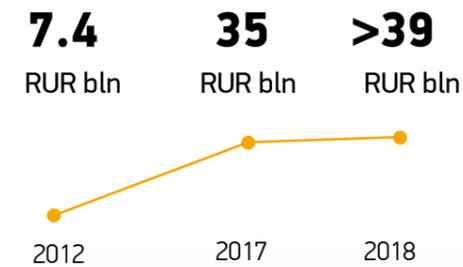
102%
– industrial production index for pharmaceutical products

RUR 5.8 bln
– private investments in pharmaceutical sector

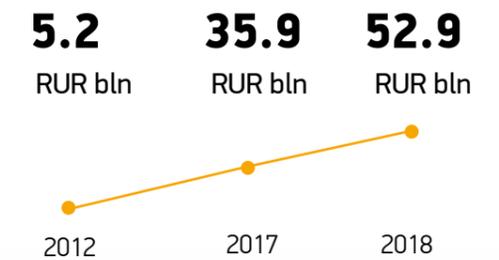
RUR 3.3 bln
– R&D expenses

\$ 65.388 mln
– Consolidated revenue from export sales of pharmaceutical products

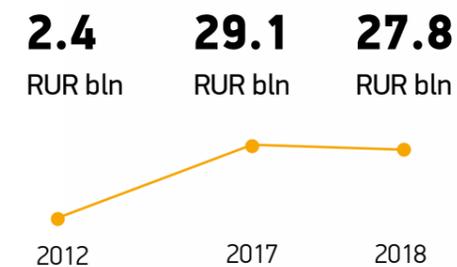
VOLUME OF MANUFACTURED PHARMACEUTICAL PRODUCTS:



VOLUME OF REVENUE FROM SALES:



VOLUME OF SHIPPED PHARMACEUTICAL PRODUCTS:



We Are Ready to Become Competence Development Center for Pharmaceutical Industry



Igor POZHARNOV,
Chairman of
the Management Board,
Kaluga Pharmaceutical
Cluster (PCK) Association,
GR Director,
OOO AstraZeneca Industries



What evolution stage of Kaluga pharmaceutical cluster can we speak about today? Which new companies joined it in 2018? Are there any plans to commission new production sites in 2019?

Kaluga pharmaceutical cluster is constantly developing in all directions – in industrial production, in R&D and in personnel training. In 2018, OOO Palladio BNM, manufacturer of modern pharmaceutical packaging, and OOO B-Pharm Production, supplier of vaccines and domestic and imported drugs, joined the cluster. There are currently 64 companies in the cluster. They all intend to increase production volumes. All preconditions are created in the cluster to attract investors, and it brings results. For example, in 2018, volume of investments from extra-budgetary sources amounted to RUR 2.6 bln. Commissioning of two new production

AstraZeneca bio-pharmaceutical company, signed a memorandum of cooperation in research and education activities with NRNU MEPhI in 2018. We welcome such initiatives, and we are ready to become competence development center for the industry participants. Great attention is paid to creation of competent team; this is why we implemented four programs of re-training and further training for employees of the cluster enterprises. One of them was organized in partnership with Obninsk Institute for Nuclear Power Engineering (OINPE) NRNU MEPhI. We also organized several workshops for participants of pharmaceutical market with engagement of industry experts. We see growing interest in our activities by foreign partners. Last year only, a number of foreign delegations visited the cluster. For example, in April we had a delegation from Sweden headed by Peter

Favorable conditions are created in Russia to expand export of medicinal products to foreign countries

facilities, Pharm-Syntez and Sphera-Pharm, is scheduled for 2019; they will manufacture finished dosage forms. Interaction is developing in all lines. Last year, 13 industry-specific events were held, more than 800 specialists took part. Number of agreements is signed with research institutes and industry-specific clusters, for example, agreement with Prombiocluster, Kirov Region. The cluster actively cooperates with pharmaceutical companies, scientific and professional communities; it participates in industry-specific events and organizes its own events, in particular, those engaging youth in research studies. One of pharmaceutical cluster participants,

Ericson, Ambassador of Sweden to Russia.

Within the frame of Marking National Program, the Center for Development of Advanced Technologies and Kaluga Pharmaceutical Cluster Association signed an agreement to create consultancy center in order to implement labeling systems on the basis of pharmaceutical cluster. Why is it necessary to implement tracking system for drugs?

Advantages from implementation of drugs marking system are

evident for the industry. The state will be able to better control taxes and lower percentage of counterfeit drugs; manufacturers will be able to mitigate damage to their image due to counterfeiting; they will also receive free of charge information on series and batches of drugs that they manufacture and being in circulation contained in the system of drugs tracking. These measures will allow enhancing efficiency of the system of drugs distribution, and, ultimately, will be beneficial for patients, who will know for sure that they buy qualitative medicine; and if they identify non-compliance, for example, a medicine, which is past its sell-by, date, or there are suspicions about forfeiting, they will be able to inform on that via mobile application. Maintaining uniform register of drugs will also have positive influence on the development of export: manufacturers will be able to plan their production capacity to meet needs, and the state will know exactly volumes of exported

of the development of regional pharmaceutical market and Kaluga pharmaceutical cluster within the frame of new strategy?

Taking into account that the strategy will determine the industry development for the coming 10 years, it should be oriented to relevant needs of the pharmaceutical sector. It concerns support for future medical pharmaceutical technologies, adoption of measures to incentivize local innovations, to protect intellectual rights of pharmaceutical companies. We also expect extension of already existing subsidies for financing clinical tests and creation of production not of specific substances, but process lines. All these measures will allow ensuring a step change for health care system; patients will be ultimate beneficiaries of such a change. They will get access to advanced efficient technologies. Now, favorable conditions and prospects are created in Russia

Commissioning of two new production facilities, Pharm-Syntez and Sphera-Pharm, is scheduled for 2019

drugs. For that, in order to support export, it is necessary to harmonize Russian standards with international ones. Those modifications that were introduced may prevent implementation of system operation requirements by all subdivisions by 2020. In order to ensure efficient operation of the system, it is necessary to consolidate efforts of all participants of the pharmaceutical market, state authorities regulating circulation of drugs, pharmaceutical companies and the system operator.

Official approval of Pharma 2030 Strategy is expected in 2019. How do you evaluate prospects

allowing participants of Kaluga pharmaceutical cluster ramping up production, expanding their presence in the market and increasing export of finished dosage forms. This is why we hope that the strategy will include measures for export support. In the longer term, pharmaceutical will grow continuously; already now we feel immense development potential, both at the Russian market in whole, and within the frame of its regional cluster.



Competences



DEVELOPMENT AND SYNTHESIS OF PHARMACEUTICAL SUBSTANCES

Manufacturing and registration of pharmaceutical substances

Development of production technologies in fine organic synthesis and author's supervision

- 000 Mir-Pharm
- ZAO Obninskaya Khimiko-Pharmatsevticheskaya Kompanya (ZAO Obninsk Chemical and Pharmaceutical Company)

Development of analysis methods for chemical substances

Chemical purification of substances and bringing their quality to high level of purity

- GC Medbiopharm
- 000 BION
- 000 Hemopharm
- AO Pharm-Syntez
- 000 Berakhim
- 000 Khimfarmkomplekt



DEVELOPMENT, MANUFACTURING AND APPLICATION OF RADIO PHARMA MEDICINES, RADIO ISOTOPES

Manufacturing of wide range of diagnostics and therapy radiopharmaceuticals (RP), radio isotopes, radiation sources, highly-enriched stable isotopes

Improving radio chemical technology of radiopharmaceuticals manufacturing

- A. Tsyb MRRC
- AO SSC RF IPPE

Creating radiation-modified, radiation-crosslinked substances and materials and technologies of their manufacturing

Provision of radiation treatment services based on electron accelerators and isotope units

- AO Karpov Institute of Physical Chemistry



MANUFACTURING OF FINISHED DOSAGE FORMS

Contracted manufacturing of active pharmaceutical ingredients (API), new formulations and finished forms under GMP standards

Certification and pre-sale preparation of finished dosage forms

- 000 Hemopharm (STADA CIS)
- 000 Berlin-Pharma (Berlin-Chemie/ Menarini Group)
- 000 Novo Nordisk (Novo Nordisk Group)
- 000 AstraZeneca Industries (AstraZeneca Inc.)
- 000 Mir-Pharm

Full production cycles for finished dosage forms under GMP standards
Packing of finished dosage forms under GMP standards

Process transfer of production of finished dosage forms

- 000 Obninskaya Khimiko-Pharmatsevticheskaya Kompanya (ZAO Obninsk Chemical and Pharmaceutical Company)
- 000 Nearmedic Pharma
- 000 Sphera-Pharm
- AO Pharm-Syntez
- 000 NPO PharmVILAR
- 000 Novamedica



PROCESS ENGINEERING

Development of laboratory and experiment-industrial technologies of industrial manufacturing of pharma substances by chemical methods

Development of laboratory and experiment-industrial regulations

Testing of experiment-

- NP AC PAM
- 000 Mir-Pharm
- 000 Life Science OKhFC
- 000 Institut Technologicheskogo

industrial technologies

Manufacturing of pilot batches of synthetic pharma substances under GMP requirements

Quality control and structure identification

Development of registration documents

Inzhiniringa (GC Medbiopharm) (Institute for Technology Engineering)



BIOTECHNOLOGIES

Development and manufacturing of texturized products

Development and manufacturing of complex food and bioactive additives

- ZAO Partner-M
- 000 Produkty Funktsionalnogo Pitanya (000 Functional Nutrition)
- AO Biotechnologichesky Komplex Rosva (Rosva

Manufacturing of phosphates, proteins, starches

Advanced processing of grain: production of gluten, dextrose-fructose syrup, dextrose monohydrate, sorbate and ascorbic acid

- Biotechnology Complex)
- 000 Institut Lechebnogo Pitanya (000 Institute for Clinical Nutrition)
- 000 Portsiionnye Produkty (000 Batch Food)



MANUFACTURING OF HEALTHCARE PRODUCTS

Development and manufacturing of prosthetic implants and tools for intramedullary fixation

Development and manufacturing of medicinal equipment: centrifuges, distillation devices, bactericidal chambers, needle destructors

Development and manufacturing of test kits for

- 000 Sanatmetal SNG
- 000 NPP Omitex
- 000 Magnitodomennye Tehnologiyi (000 Magnetic Domain Technologies)
- 000 Nauchno-Proizvodstvennoye

person's identification, test systems for early individual express diagnostics of acute myocardial infarction

Development, manufacturing and implementation in healthcare practice of advanced high-quality diagnostics test kits for laboratory diagnostics of the most significant human infection diseases

- Predpriyatie Eco-Filter (000 Eco-Filter Science and Production Company)
- 000 Liston
- 000 Nearmedic Pharma
- 000 Endzhentics
- 000 OFC-Cardio



DISPOSAL OF PHARMACEUTICAL AND MEDICAL WASTE OF ALL HAZARD CLASSES (EXCLUDING MERCURY)

Deactivation of pharmaceutical and medical waste

Disposal of chemical and other hazardous waste

- 000 ECOPharm

- 000 NPP OMITEX



MANUFACTURING OF PHARMA PACKAGING, PACK INSERTS, INSTRUCTIONS

- 000 Palladio Obninsk

- 000 ILOX



MANUFACTURING OF INFUSION SOLUTIONS

Manufacturing of a wide range of infusion solutions

- 000 Sphera-Pharm

30 Years of Leadership



Roman BOLGARIN
Head, Project Development
Department
NEARMEDIC 000



NEARMEDIC



NEARMEDIC PHARMA Pharmaceutical Plant (Nearmedic Group) has operated in Obninsk industrial park since 2015. The plant has the area of 22,000 sq.m. Its capacity enables it to manufacture up to 100 mln packages of medicines per year. The enterprise performs full-cycle manufacture: from synthesis of starting materials to manufacture of finished products. The line of products consists exclusively of in-house original developments of the company.

This year Nearmedic Group is celebrating its 30th anniversary. It is the fourth year that the manufacturing site of the company – Nearmedic-Pharma – has operated in Kaluga pharmaceutical cluster. How is the project progressing? Which key figures of 2018 could you mention?

The year 2018 has been extremely important for the entire Nearmedic Group. As of the year end Kagocel was once again recognized as product No. 1 in the antiviral product group according to DSM Group. It is the sixth year in succession that the high level of our work and trust of patients and doctors have been demonstrated.

Opening in the territory of the Nearmedic Pharma plant of the Russia's first fully-cycle manufacture of molecular and genetic kits for identification of the personality and establishment of kinship has become an important event. These kits are used in criminalistics and forensic medical examinations. This manufacturing process is unique not only for Russia, but also for the CIS and Eastern Europe countries, it has been certified by an international company as compliant with the special global quality standard ISO 18385. This standard combines GMP requirements and specific requirements to reagents,

which guarantees the proper level of the products quality. Last year this project became the winner of Patriot national award in the area of import substitution in the Efficient Manufacture nomination. This is an absolute recognition of our achievements, as the Award is annually given to companies taking the Russia's industry to a new level. As regards the existing line of products and medical devices, we carry out continuous post-marketing clinical studies confirming the efficacy and safety of our products in line with regulatory requirements and recommendations. Every study is held according to global standards with participation of the leading Russian clinical centers. For example, last year we completed large-scale studies of use of the Collost cosmetic complex for correction of age-related changes of the facial skin. The Institute of Plastic Surgery and Cosmetology became the basic clinical center of the study. During the studies our injection collagen product once more demonstrated a high acceptability and safety profile, along with high efficacy compared with the leading Western brands available in the market. The level of the studies is also confirmed by a publication about them on the largest specialized international web-site "Clinical Trials" effecting regular monitoring of clinical studies all over the world.

In which therapeutic areas are new medicinal products being developed?

At the moment we are actively developing our regeneration area including a line of medical devices for regeneration of the bony tissue. The manufacture of such devices is based on the technology of production of a native non-reconstructed collagen. Within the framework of the regeneration we are also developing a unique system for treatment of the human fat tissue helping isolate the "stromal and vascular fraction". This fraction is widely used to treat a number of diseases and injuries of human tissues requiring stimulation of the organism's regeneration potential.

We keep on implementing the project for release on an innovative anti-tuberculosis product for medicine-resistant forms of tuberculosis. Last year we completed a pilot clinical study in patients with newly



At the Russian Investment Forum in Sochi the Chairman of the Government of the Russian Federation, Dmitry Medvedev, highly praised Kagocel antiviral product and reminded the forum participants of the need to timely prevent and treat acute respiratory viral infections and flu during the period of the increased infection rate.

diagnosed forms of tuberculosis. Its high safety profile and strong bactericidal action were demonstrated. We are currently completing full-cycle manufacture of the product at our site and preparing for the next stage of clinical studies in patients with multiple and wide medicine resistance to tuberculosis. Last year our anti-tuberculosis product was assigned the official INN approved by the WHO – Makozinon. It is of great importance that the uniqueness of our products is confirmed by Russian and international patents.

of consumers to receive modern innovative medicines, medical devices and diagnostic systems. Secondly, the majority of our products are our in-house developments being a product of the efficient use of the company's scientific and technological potential. So another main priority of Nearmedic is our HR. These are the people working in our company celebrating its 30th anniversary this year who have made us the market leader helping us build and implement even more challenging plans.

According to the company's internal forecasts, what will be the priorities of Nearmedic in 2019?

Our company has stable leading positions in numerous areas of the pharmaceutical and biomedical market due to our priorities that remain unchanged for years. First of all, this is our commitment to enabling a wide range

Russia to Join 80+ Club of Countries through Innovations



The healthcare industry has been set a goal – to increase the average duration of life and to ensure admission of Russia to the 80+ club of countries. This goal cannot be achieved, unless the existing system is modernized. For this purpose the competitive ability of the Russian economy through digital technologies and the quality of the medical aid need to be enhanced and expenses need to be optimized. These measures are to promote implementation of the Healthcare national project.

Irina PANARINA,
CEO
AstraZeneca
Russia and Eurasia
Business Ambassador of
Delovaya Rossiya in the Kingdom of
Sweden

Why is it becoming more difficult to save lives amidst growing innovations?

Currently the medical aid in Russia is assessed through analysis of ratios important of the administration of medical and preventive treatment facilities (death rate, number of treated patients, financial and economic ratios, absence of fines, administrative sanctions, etc.), rather than for a particular patient and his physician. The access to the market is formed by health professionals

primarily based on the product price, cost of the treatment course, and the preference is most often given to less expensive procedures with view to the targeted nature, efficacy, safety of the therapy and its long-term results.

Therefore though innovations and efficient treatment methods all over the world are created, the quality of the therapy is not enhanced for patients. Such innovations and methods cannot be introduced using the traditional assessment

procedures, since innovations have no analogues or comparable groups – this is the foundation of the national system.

How can the treatment quality be enhanced along with substantial reduction of expenses?

Given that cost optimization and greater efficiency of spending on healthcare are pressing issues in foreign countries (Sweden,

UK, Holland, Italy), a new approach – Value-Based Healthcare aimed at optimization of expenses and treatment results is being created. The Value-Based Healthcare (VBH) provides for the quantitative assessment of clinical results (outcomes) and for their comparison with other parameters, such as the economic and social benefit.

Introduction of the VBH takes into account interests of all participants of the healthcare area and is an example of the win-win strategy when each stakeholder receives benefits. For patients VBH means the best level of health at the least expense. Health professionals and service suppliers achieve greater efficacy and increased level of the patient satisfaction. Payers are able to better control their spendings and to promote their insurance against risks and suppliers can offer more economically efficient solutions through comparison of prices with treatment results. The main advantage of VBH is the overall improvement of the public health along with reduction of the state expenses for healthcare.

What should be done to optimize costs and improve treatment results in Russia?

VBH provides for a model where the payment for medical services is effected depending on the treatment results, assessment of treatment outcomes.

However there are some difficulties with introduction of this concept. As a rule, the greatest difficulty is getting access to personalized data about therapy efficacy (outcomes) and related costs. These data sets are the key source of data for decision makers, however they are hard to obtain in the required amount and with

the required quality. Patent registers – organized systems for collection of information about patients with a similar disease – are the most efficient tool for collection and storage data about prospect observation and remote outcomes at the personalized level. Such registers are used for analysis of the real practice of the patient treatment and to objectively assess treatment investments. That is why development and introduction of such registers is one of the steps towards the result-oriented healthcare.

Digitalization of all management processes will also contribute to better healthcare efficiency. Digital developments will enable provision of more personalized aid to patients, establishment of closer relations between patients and their physicians, improvement of inter-physician interactions, promote telemedicine and evidentiary medicine. Besides, systems helping physicians take decisions, and diagnostic systems based on the artificial intellect, e.g. during an endoscopic examination, are of great interest.

Foreign pharmaceutical companies have experience of introduction of new technologies and solutions and have in practice built patient-oriented ecosystems in various countries and are ready to support the Ministry of Healthcare during introduction of the digital framework in Russia and integration of the best solutions into the healthcare system.

One of the examples of the efficient introduction of digital tools in healthcare is the Center of Innovations in Healthcare and Internet of Things in Wuxi in China. It is a platform open for any manufacturers uniting isolated software, technical and pharmaceutical solutions in healthcare into a single complex and demonstrating

its efficiency in the simulation mode based on the Center of Innovations. Solutions are selected and arranged by a commission of chief clinical specialists, and their efficacy is assessed in the real conditions at cooperating hospital complexes of the city.

Another example is the Babylon application about health and for health demonstrating the efficiency of telemedicine for solution of healthcare tasks in England. Essentially the application is a primary appointment cabinet where a patient can get answers to any simple questions, receive online consultation of a physician and make a personal appointment. Receipts are also issued electronically, information is transferred to the pharmacy where a patient can get the prescribed drug. All these functions reduce the waiting time and decrease the load on the healthcare system, and the remote mode provides round-the-clock access to the healthcare services.

Besides, the risk sharing programs actively introduced all over the world are an important step of the transition to this model, as in this case payment for a drug depends on the treatment result. Due to the schemes like this innovative products can be bought despite limited budgets and patients can get access to the most efficient treatment technologies.

The harmonious union of innovations and digital technologies will help people live a longer healthy life, and enable the government to ensure more efficient treatment of people and to achieve the goals set.

AstraZeneca Project Launched in Russia

The PRECISION program for improvement of the clinical practice, promotion of quality and speed of the medical aid for patients with severe bronchial asthma (SBA).

The PRECISION program is a main project of AstraZeneca deeming acceleration of access for patients to innovative solutions in healthcare one of its main priorities. The implementation of this initiative started with training of specialists: in 2018 the national supervisory committee for implementation of the PRECISION program in Russia and AstraZeneca have held some training events for 200 pulmonologists and allergists all over Russia.



AstraZeneca is the Russia's best employer according to Top Employers Institute

According to Top Employers Institute AstraZeneca is the Russia's best employer due to its highest HR standards. TEI annually holds an international study to identify the best employers. Over 25 years of the global certification program existence, more than 1,300 best employers in 115 countries on five continents have been identified. The assessment based on ten parameters, including: overall HR strategy, HR planning, performance assessment, career management, development of leadership programs, corporate culture, etc.



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OCPC: We follow high standards



Vladimir PUCHNIN,
CEO,
OCPC ZAO
Ph.D. in Pharmacy



Obninsk Chemical and Pharmaceutical Company (OCPC) has been engaged in manufacture of pharmaceutical substances for products (diazolin, ethylmethylhydroxypyridine succinate, methylethylpyridinol hydrochloride) since 2002. In 2003 the company set up a shop for manufacture of finished dosage forms in the form of tablets. OCPC successfully implements the import substitution program for medicinal products.

What are the current priorities of the OCPC activity? What does the product portfolio look like and what project will be developed in the near future?

OCPC manufactures pharmaceutical substances and medicinal products. At the same time the company develops pharmaceutical products using the efficient and safe manufacture technology. We follow high standards of the products quality using modern innovative technologies. The company has several lines of manufacture. First of all, this is synthesis of substances with further manufacture of film-coated tablets, e.g antioxidant Mexiprim. We also sell the starting substance to manufacturers of injection products. The pharmaceutical substances manufactured by OCPC are used for manufacture of such products as Miropristone, Gynestril, Gynepriston, Bezak, etc. Secondly, there are substances manufactured exclusively for sale to other manufacturers of medicinal products. One of them is Vitaglutam used by Valenta Pharma AO for manufacture of the antiviral product Ingavirin. Thirdly, there are products manufactured by us using purchased substances. For example, the hepatoprotector Maxar, the substance for which is manufactured by E.B. Elyakov Pacific Institute of Bioorganic Chemistry (Russian Academy of Sciences) from the herbal raw material, Maackia amurensis ligni extract. As you can see the company effects practically a full manufacturing cycle: from synthesis of substances to manufacture of medicinal products. Today the company's manufacturing portfolio includes 22 pharmaceutical substances and 24 medicinal products with different therapeutic effect.

We annually register 5-7 medicinal products. Thus in 2017 our company registered a selective



immunologic depressant Femorix, a nootropic drug Fonturacetam, antiulcer drugs Famotidine and Omeprazole, antiallergic Cromoglicic acid and long acting anticonvulsant Valproic acid. In 2018 Fenazalgin (for urology), the antiviral product Normomed, the antimicrobial drug Prostolor protalgor, the antibiotic Levomycetin in tablets, the vein toning and vein protecting drug Stimulven and product for treatment of sexual disorders Dapoxetine. At the moment over 50 new medicines for use in such therapeutic categories as gastroenterology, gynecology, urology, critical care medicine, neurology and oncology are under development at the registration stage.

Does your company take part in the import substitution program?

Yes, it does. Femorix (INN - teriflunomide) included into the list of



vital and essential drugs of "twelve nosologies" can be mentioned as a good example of the import substitution. It is manufactured under a contract with Tekhnologiya Lekarstv OOO and is a generic of Aubagio manufactured in France. Our company manufactures not only Femorix itself, but also the substance teriflunomide for it.

Who is the main consumer of OCPC products? Does your company effect export supplies?

The majority of our products are manufactured under contract agreements with large Russian companies, such as Nizhpharm OAO, Valenta Pharm AO. Some products are supplied to the pharmaceutical warehouse of Mir-Pharm OOO and then to pharmacies via distributors. At the same time products manufactured by OCPC are distributed not only in Russia, but also in some CIS countries, such as Belarus, Ukraine, Moldova, Kazakhstan, Kyrgyzstan. Since our company is small-sized, to ensure the presence in the market we concentrate on manufacture of products that are important from the pharmacological point of view, but that are not required in large amounts.

Your company is a member of Kaluga Pharmaceutical Cluster association. The cooperation with large companies evidences recognition of prospective innovative capabilities of small and medium enterprises. How does OCPC develop cooperative connections within the cluster and what is the essence of the partnership?

Within the KPC we are first of all partners of the STADA group. In particular we closely cooperate with Nizhpharm OAO. We have a contract for manufacture of Miropristone, Gynepriston, Gynestril, Mirolut, Mexiprim and Tranexam. Besides, we have long-standing



scientific and business relations with A.F. Tsyb Medical Radiological Scientific Center. We rent premises there and have carried out a joint research development of an antishock drug. We also cooperated with the National Research Nuclear University MEPhI (Moscow Engineering Physics Institute). Some specialists of OCPC have completed Master's programme at the department of pharmaceutical and radiopharmaceutical chemistry specially set up for resolution of the staff issue of the region's pharmaceutical industry. However our interaction is mutual, so employees of our company in the turn trained and train students at the Obninsk National Research Nuclear University MEPhI. Specialists are trained using the dual education system. This helps form the HR reserve of particular enterprises, since a part of the training is delivered on site and after its completion specialists have clear understanding of their future place of work.

MRCs: Development of Modern Nuclear Medicine



Andrey KAPRIN,
General Director of Federal State Budgetary Institution "National Medical Research Radiological Center" of the Ministry of Health of the Russian Federation, full member of the Russian Academy of Science, chief non-staff oncologist at the Ministry of Health of the Russian Federation



A.F. Tsyb MRSC was founded in 1962 for development of X-ray therapy methods, prevention and treatment of radiation injuries, study of the biological and medical effects of the ionizing radiation. MRSC is the Russia's leading institution in the area of radiology and radiation medicine, development and application of high-tech radiological methods of diagnostic and treatment of patients with oncologic and other diseases.

What is the direction of the modern nuclear medicine development, in particular development of radiopharmaceuticals?

Development of radiopharmaceuticals is an integral part of the nuclear medicine. The nuclear medicine is impossible without radiopharmaceuticals. There are two types of radiopharmaceuticals: diagnostic and therapeutic. The first type is used for radionuclide diagnostics, and the second type is used for treatment of oncologic and other diseases. They differ by the type of radiation: the diagnostic radiopharmaceuticals contain radionuclides radiating photons, while therapeutic radiopharmaceuticals contain radionuclides whose spectrum includes beta-particles or alpha-particles. Currently development of radiopharmaceuticals for the positron emission tomography (PET) is the most rapidly evolving line of development of diagnostic radiopharmaceuticals. During the recent years radiopharmaceuticals, both diagnostic, and therapeutic ones, have been developed based on biotechnological drugs: monoclonal antibodies, peptides, DNA fragments. The interest to radionuclides of ittrium-90 and lutetium-177 has increased recently. This could substantially promote the possibility of creation of the new generation radiopharmaceuticals for the radionuclide therapy.

What does MRSC do in this area and are there any positive results?

A.F. Tsyb MRSC has an experimental nuclear medicine laboratory developing innovative radiopharmaceuticals for radionuclide diagnostics and therapy of oncologic and other diseases, and holding pre-clinical studies of such drugs. We develop radiopharmaceuticals on the basis of generator-produced radionuclides of technetium-99m, rhenium-188 and gallium-68. Today these are

the most promising radionuclides due to their optimal nuclear and physical properties for use in diagnostics and therapy. Besides, generators of technetium-99m, rhenium-188 and gallium-68 make it possible to repeatedly during 8 months produce radionuclides from them in clinic and synthesize radiopharmaceuticals immediately before injection. This is a great advantage compared with "hot" radiopharmaceuticals produced at plant and supplied to clinics on the centralized basis. Over four recent years employees of the experimental nuclear medicine laboratory have developed an osteotropic drug based on the phosphonic acid and rhenium-188 for treatment of bone diseases, and three drugs based on microspheres of the human blood albumen and radionuclides of rhenium-188 and ittrium-90 for treatment of inoperable cancer and joint synovitis. All of the above radiopharmaceuticals have passed pre-clinical studies, there are experimental-industrial regulations for their manufacture.



What is the future of your developments?

It is a good question. We quickly carried out pre-clinical studies of four radiopharmaceuticals jointly with the Medradiopreparat plant (a branch of FSUE Federal Center of Nuclear Medicine Projects Design and Development) and State Scientific Center of the Russian Federation – A.I. Leypunsky Institute of Physics and Power Engineering (IPPE) at the expense of financing under Pharma 2020 program. While there is no financing program like this for clinical studies, which substantially prevents clinical studies of radiopharmaceuticals. I hope this will become possible within the framework of the future Pharma 2030 program.

Tsyb MRSC Creates Portable Neutron Generator for Cancer Treatment



A team of scientists from A.F. Tsyb MRSC and All-Russia Research Institute of Automatics named after N.L. Dukhov is developing a portable unit for treatment of malignant neoplasms using neutron radiation. The portable generator unlike stationary units has small dimensions (25 x 120 cm) and weighs no more than 270 kg, so it can be placed in multiprofile clinics to increase the number of patients. The new technology has been patented. The prototype of the device has been tested on small household animals taking into account neutron and photon radiation combined use of which decreases the total dose of radiation. The medical cluster will use this portable source of neutrons for the boron neutron capture therapy.

Joint Studies of Liver Cancer Treatment of IPPE and Tsyb MRSC

Specialists of Leypunsky IPPE on the basis of Tsyb MRSC are completing pre-clinical studies of the Russian radiopharmaceutical based on the radioactive isotope ⁹⁰Y for treatment of the liver cancer. Within the framework of the cooperation specialists of Leypunsky IPPE produce a radioactive isotope, and employees of Tsyb MRSC produce its carrier. About 7 thou cases of primary liver cancer and about 130 thou cases of metastatic liver cancer are annually diagnosed in Russia. Due to the short shelf life for foreign radiopharmaceuticals (64.1 hour) it was offered to create a domestic product based on microspheres of the serum albumen with ⁹⁰Y. The clinical phase of the study is to be launched in 2020.



The Sky is the Limit



Andrey GOVERDOVSKY,
CEO, IPPE
Doctor of Physics and Mathematics



The State Scientific Center of the Russian Federation – A.I. Leypunsky Institute of Physics and Power Engineering (IPPE) is one of the leading research and scientific centers of Rosatom SC. Under the scientific guidance of IPPE the idea of creation of reactors based on fast neutrons and reactors with direct transformation of nuclear power into the electrical power has been implemented. The works of IPPE in the area of nuclear physics, nuclear power technologies and nuclear safety are recognized all over the world. IPPE holds experimental studies in the area of nuclear and laser physics and plasma physics, radiation material study, radiochemistry and new science-driven technologies, including nano technologies, hydrogen energy and nuclear medicine technologies.

IPPE is one of the Russia's leading research centers known for its experimental leader studies in various areas of application. In which areas of the nuclear medicine does your institute cooperate with medical centers? What products do you plan to develop?

First of all, this is brachytherapy. Today we go to health professionals and get an assignment from them – they know better what is needed, what for and in what amount. They specify parameters, and we create a product. Micro sources have different activity. Depending on the patient various sources of power are needed. This is a whole line of activity and we have mastered it. A physician independently selects the sources from those offered by us. We are not going to stop where we are – today these are micro sources with iodine, and tomorrow a new thing in line with physicians' recommendations will be developed – another method or another isotope, i.e. another texture. Developments of IPPE in the area of the nuclear medicine include generator of rhenium W-188/ Re-188 for therapy of oncologic diseases, ophthalmic applicators for contact X-ray therapy of malignant neoplasms of visual organs, generator of technetium $^{99}\text{Mo}/^{99}\text{Tc}$, as well as micro sources with I-125 for brachytherapy. Manufacture of domestic micro sources that have had no alternatives until now, will support Russian clinics and materially reduce the cost of operations. We plan to develop the issue of the big triad "iodine – itrium – radium". Micro sources with iodine-125 have been used in a hundred of brachytherapy operations so far, but we need tens of thousands operations, not hundreds. As regards itrium-90 used for treatment of the liver cancer, we jointly with A.F. Tsyb MRSC have already achieved the stage of pre-clinical studies. We are to launch

clinical studies in a couple of years. We also plan to proceed to the practical part of implementation of the third component of the big triad – radium-223 – in the near future. It is accumulated in bones and called the killer of metastases. It is very difficult to produce radium. Power reactors are needed, and we plan to resolve this issued together with L.Ya. Karpov Research and Scientific Physical and Chemical Institute (RSPCI). We are going to create a generator of radium-223 in the near future. It is another powerful project with MRSC. I think it will take 5-7 years to launch clinical studies of radium.

To what extent is the issue of the import substitution for the nuclear medicine pressing in Russia? What is the role of IPPE in this project?

Given the technologies developed in Russia, micro sources are extremely important. Due to the prices currently charged by western countries operations have become almost impossible. We provide all the required things to physicians. Our technologies allow us to produce micro sources that are 4-5 times cheaper. This means the opportunity to perform a huge number of operations all over the country. The manufacture is focused first of all on our country. The first operation in brachytherapy of the malignant tumour of the prostate gland using Russian micro sources of the isotope iodine-125 was performed on October 9, 2015 at the A.F. Tsyb MRSC. Actually we have created a purely domestic product within the framework of the import substitution project. The "seeds", i.e. micro sources, developed by IPPE are much cheaper than foreign ones, which enables performance of vital operations at the expense of the funds allocated by the state.

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Facts about BelAseptika

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- ✓ In-house accredited laboratory for scientific studies and 2 control and analytical laboratories procuring new manufacture and quality control technologies.
- ✓ In-house site manufacturing of more than 100 professional products with the annual release of more than 10 new types of products.
- ✓ Its own raw materials base of medicinal herbs at one of the most beautiful and ecological places of Belarus – Myadzel District.
- ✓ Apterkarsky Sad, an excursion and tourism complex – a unique landscape object with botanic collections of medicinal herbs and flowers presented as theme compositions, plant art objects.

“To serve people, protect them against dangerous diseases”.

A.A. Krasilnikov, founder of the company

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PAM creates Research Environment

Park of Active Molecules Alliance of Competences is an association of organizations (based on Medbiopharm Group) operating in the area of the innovative biopharmacy. The main task of the association is implementation of innovative ideas of Russian scientists in the area of biopharmacy, improvement of the quality public life and health. The alliance is located in Obninsk, the first Russian Science Town. Being an official partner of the Skolkovo Foundation, the alliance provides a technological site for implementation of projects by residents of the innovative center.



Rakhimdzhan ROZIEV,
Director
Part of Active Molecules AC

The scientific and education sector is one of the strongest in the structure of Kaluga pharmaceutical cluster. Park of Active Molecules Alliance of Competences is one of the key divisions of the sector. How is interaction within the sector, cluster built today? What partnership programs and other forms of interaction do you deem most promising?

The cooperation of PAM AC with Innovative Biopharmacy Scientific and Education Center (EDC) set up at K.E. Tshiolkovskiy Kaluga State University in 2013, and with the National Research Nuclear University MEPhI and other education institutions of Kaluga Region (e.g. Pilgrim BioSchool) is primarily aimed at promotion of the research and scientific business activity of students and pupils, future scientists.

Small companies focused on development of original medicines experience lack of highly qualified personnel knowing modern technologies of studies, diagnostics and manufacture of innovative products. At the same time graduates having profile education often have problems with employment due to the lack of experience of work and practical skills. The cooperation of PAM AC with universities



is to resolve this issue.

Today by agreement with enterprises within PAM seniors of the KSU and other universities can participate in particular innovative products. For students this is not just further studies, but immersion into the science and real business. This is an opportunity already during studies at the university to change the way of thinking from student to innovative, business, to discover a variety of specialists and specialties required for implementation of this project, and to understand who you are: researcher, manufacturer or businessman. This way young people have a chance to find an interesting job immediately after graduation, in their region; the region resolves the issue of outflow of young specialists, while small enterprises can find highly qualified personnel.

But university is not just a source of manpower for the region, it is also a generator of the creative intellectual and research environment. So due to the EDC and Park of Active Molecules, the KSU that has never had any special technological equipment before, now has access to research laboratories and all competences available with PAM. This is an innovative base for the university making it possible not only to advance the level of students' education, but also to commercialize their own scientific projects. PAM members in their turn are now able to fully equip laboratories and to receive additional grants of the university. The education block is located in universities, and PAM houses the research part, the cooperation is beneficial both for universities and for us. Regional authorities also support this idea. In 2018, eleven students have passed training and practice at PAM AC on the equipment of the Regional Engineering Center (REC), six postgraduate and Master's theses have been prepared under the supervision of the PAM AC employees and six students of the KSU have been engaged in the scientific activity. Besides, winners of the UMNIIK competition of youth innovative scientific and technical projects have prepared their projects on the basis of PAM using the REC equipment.

Could you tell about the most interesting projects of 2018 characterizing innovative achievements of the Alliance.

In 2018 the clinical III phase study of the patented medicinal product Octagam for



restoration of the reproductive function has been carried out. 125 patients took part in the study, 120 of which were randomized. Octagam is a non-hormonal drug with a unique action mechanism. It can be recommended for treatment of the male infertility caused by sluggishness and small amount of male germ cells or change of their functional properties.

Last year a clinical II phase study of the universal blood substitute Krunidon with the function of the oxygen delivery to tissues was initiated. The drug also secures blood mobilization from the pool in case of blood loss, stimulation of blood formation in case of inadequate blood supply. It can fully replace donor red blood cells in urgent and emergency situations accompanied by blood loss and shock. During the study Krunidon was first administered to patients with intraoperative blood loss. The drug has been administered to 20 patients so far. Physicians note that already after a first infusion the pressure of patients normalizes, oxygen deprivation reduces. It should be noted that unlike donor blood Krunidon is compatible with any blood group and does not expose the patient to the risk of get infected with viral or bacterial infections. Krunidon will be infused to another 40 patients before the study is completed and another stage is launched.

In 2018 pre-clinical studies of the new medicinal product for treatment of mental deficiency of different etiology have been completed. The studies were held during the period 2016 – 2018 with the support of the Skolkovo

Foundation (grant No. Г51/16 dated July 28, 2016). Comparative studies of the product efficacy for various models with disorders caused by various exposures using a range of various tests have demonstrated high neuroprotective and cognitive stimulating activity of molecule in small doses.



RSPCI – Reliable Supplier of Radiopharmaceutical Products



Vladimir DUFLOT,
Innovation Director of
JSC Karpov Research and
Scientific Physical and
Chemical Institute (RSPCI),
D.Sc. of Chemistry



L.Ya. Karpov RSPCI was set up in 1957. Its main tasks include development and implementation of radiochemical, nuclear physical and radiation chemical technologies, study of the interaction of nuclear and ionizing radiation with substances and materials. The main line of business is creation of a range of diagnostic and therapeutic radiopharmaceuticals; study of the mechanism of interaction of the ionizing radiation with a substance, development of technologies of the radiation synthesis and modification of chemical compounds, provision of services for radiation of various types of materials, products, etc.

What new projects is the institute currently developing in the area of radiopharmacy and nuclear medicine?

L.Ya. Karpov Research and Scientific Physical and Chemical Institute remains a reliable supplier of radiopharmaceutical products to the Russian market: generators of technetium-99m in three modifications, lines of radiopharmaceuticals based on iodine-131, samarium-113, carbon-14. Medical radionuclides, such as molybdenum-99, iodine-131, samarium-153 are regularly supplied abroad via the unified operator, Isotope JSC. The enterprise has the following significant achievements in the area of manufacture. This year it has completed organization of the manufacture and released a new modification of generators of technetium-99m – a double-needle generator ГТ-5К meeting international standards and having some advantages compared with the existing models. A section for charging generators of technetium-99m meeting GMP requirements has been commissioned. Organization and commissioning of the section for separation of xenon-133 – a pharmaceutical substance new for our company – have been effected. This year we plan to perform test supplies of this product to foreign consumers, and if tests show good results, organize regular supplies. Modernization of the technological line for manufacture of molybdenum-99 located in hot chambers to ensure stable shipments of the increased volume (up to 350 Ci per week) has been completed. At the moment the enterprise has successfully completed development of three radiopharmaceuticals that have passed pre-clinical studies under state contracts within the framework of the Federal Target Program "Development of the Pharmaceutical and Medical Industry of the Russian Federation up to 2020 and further". These developments are protected by patent and know-how.

Developments related to production of two more promising radionuclides – yttrium-90 and holmium-116 and medical devices based thereon are at the initial phase. There are customers of these products both in Russia, and abroad. The high level of the developments is confirmed by the fact that two employees of L.Ya. Karpov RSPCI, V.S. Ermakov and E.I. Lobanova, have won (receive main awards) the competition, Innovative Leader of the Nuclear Industry – 2018, held by Rosatom State Corporation within the framework of I Youth Congress of Rosatom in St. Petersburg; besides V.S. Ermakov and V.M. Boiko have received an award of the competition of young scientists of the nuclear industry in 2018 held by Rosatom for their work.

In which areas does RSPCI interact with Kaluga cluster of pharmacy, biotechnologies and biomedicine?

The interaction with Kaluga cluster of pharmacy, biotechnologies and biomedicine is diversified. Our products are used at the A.F. Tsyb Medical Radiological Scientific Center for diagnostics and treatment of severe oncologic diseases. We supply molybdenum-99 for charging generators of technetium to IPPE. One of the pre-clinical studies of the radiopharmaceutical developed by our enterprise has been carried out in cooperation with employees of the A.F. Tsyb MRSC. We effect radiation sterilization of packaging materials for some enterprises of the pharmaceutical cluster. Bachelors and masters of the National Research Nuclear University MEPhI (Moscow Engineering Physics Institute) pass practice at our enterprise and prepare various qualification papers. We are really grateful to the cluster for organization of the training for our employees in various area of pharmacy.

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MEPhI is Anchor University of Kaluga Pharmaceutical Cluster

Center of Practical Training of Specialists in the Pharmaceutical Industry in Obninsk is based on MEPhI. The personnel are trained using a dual scheme: the theory is taught at the center, and practice is passed at the pharmaceutical enterprises of the KPC. The center has a model of the target training of specialists for particular pharmaceutical manufactures, basic departments at “anchor” enterprises of the cluster are organized, professional standards of the “industrial pharmacy” are developed. The university implements programs for advanced qualification and professional retraining of employees of the pharmaceutical industry, including practice at the Pharmaceutical Center of Practical Training and Competences of MEPhI with preparation of a qualification paper.

As the cluster of pharmacy, biotechnologies and biomedicine develops, the need for training of highly qualified personnel arises. Please, tell about participation of MEPhI in formation of the workforce capacity for the pharmaceutical industry.

Kaluga pilot innovative cluster of pharmacy, biotechnologies and biomedicine (KPC) is a Russia’s major cluster in life sciences uniting all stages from development of new innovative pharmaceutical substances, finished dosage forms, new biomedical technologies to practical release of medicinal products and application of new technologies in the real high-tech medicine. KPC will become a global leader in development, manufacture and use of radiopharmaceuticals, will ensure the global level of technologies of the X-ray, including proton and neutron, therapy. MEPhI annually proving its leadership in the education, scientific and innovative activity at the global level is the anchor university of Kaluga pharmaceutical cluster. One of the main lines of the education, scientific and innovative activity of MEPhI is the area of life sciences that is primarily developed

personnel for the pharmaceutical industry of the Russian Federation. The center has unique equipment and technologies, including the “clean room” for training of specialists in the conditions that fully correspond to the real manufacturing processes.

What is required for training of the specialists that are in demand?

We think that employers themselves should be engaged in the personnel training. MEPhI has become the center of knowledge transfer from pharmaceutical manufacturers, research and scientific institutes being residents of the KPC. The best professionals of enterprises and research and scientific institutes develop and teach unique disciplines required for training of specialists in the pharmacy industry and high-tech nuclear medicine centers. We use various approaches for this purpose: traditional, “dual”, modular, master classes, training and manufacturing practice at enterprises and at the Center of Practical Training and Competences of the KPC. Such partnership creates a special ecosystem securing intellectual

MEPhI annually proves its leadership in the education, scientific and innovative activity at the global level.

at the Obninsk site of the university. The Pharmaceutical Center of Practical Training and Competences in Pharmacy of MEPhI in Obninsk substantially contributes to training, retraining and advanced qualification of the

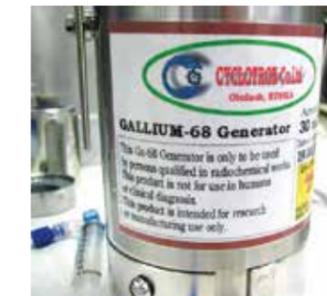
investments into the human capital. It helps implement the principle of diversification in training, engaged external specialists for teaching and allows going beyond particular disciplines. Such cooperation



Tatyana LEONOVA,
Vice Rector MEPhI,
acting director MEPhI



MEPhI Studies Radiopharmaceutical Oncomarker Synthesis Technology



MEPhI specialists have completed the first stage of applied scientific studies of development of the radiopharmaceutical oncomarker synthesis technology based on the generator radionuclide Ga-68. Following study results, the radiopharmaceutical with the best radioactive chemical properties has been selected (Tetraphosphate EDTMP, gallium-68) and technology of its

manufactured based on the generator radionuclide Ga-68 for diagnostics of oncologic diseases using positron emission tomography has been developed. Development of the method of synthesis of the radiopharmaceutical – analog of glucose marked with isotope Ga-68, has no analogs in the world and represents a promising area for introduction in the practical medicine.

makes it possible to personalize training, to deepen and develop existing practices and capabilities to build an individual education program with the possibility to gain additional skills.

Where else dose MEPhI interact with Kaluga pharmaceutical cluster?

First of all MEPhI trains specialists in the industrial pharmacy for the KPC: study of medicines, validation (qualification) of the pharmaceutical manufacture, quality control of medicines, manufacture of medicines. As the KPC association also includes high-tech nuclear medicine centers, the university trains physicians for them, radiopharmacists, medical physicists, radiological biologists, designers of nuclear reactors, radiation supervisors, specialists in IT-technologies, etc. The Russian pharmaceutical industry will be developed by those students who are receiving profile education now. Besides, to train specialists in pharmacy, concentration of the current needs of the industry is not enough, prospects of development of technologies, development methods should be taken into account. And here the expert opinion of companies, their requirements to graduates’ competences are essential. The KPC association has become an excellent communication platform for the direct dialogue between manufacturing companies and universities: MEPhI, leading profile universities, first of all St. Petersburg Chemical and Pharmaceutical University. Conferences and round tables are held regularly to reconcile the position universities, pharmaceutical companies, profile associations, authorities on the quality of graduates training, taking requirements of professional qualification boards into account. Such events help engaged the maximum number of participants of the cluster into the expert work and adjust profile training programs.

MEPhI’s Universal Development for Reading Muscle Signals



Engineers and scientists from MEPhI have developed a Mio-interface device able to read the electrical activity of muscles and to transform it into signals. The development is proposed to be used for creation of rehabilitation trainers, smart clothes for sportsmen reading ECG and other parameters, systems for control of the arm bionic prosthesis, as well as for remote control of the smart phone and “smart

house” system. Mio-interface is a project of the man-machine interface reading the electrical activity of the arm muscles, recognizes gestures and transforms them into the commands from devices. In 2018 this project has won in the Chinese and Russian Innovation Awards.

Future Belongs to Innovative Clusters

K.E. Tsiolkovsky Kaluga State University was established in 1948. Currently, the University trains personnel in a wide range of areas, including Medical Care. Based on the University, the Russian fifth simulation center has been created, where future specialists pass primary accreditation and medical professionals of the region can improve their skills. The simulation center was equipped as a part of the program to develop an innovative cluster of pharmaceuticals and biomedicine in Kaluga Region.



Maxim KAZAK,
Rector of K.E. Tsiolkovsky Kaluga
State University



Kaluga State University is the oldest education institution of Kaluga Region that trains specialists for many industries of the economy. Please tell about your interaction with the pharmaceutical cluster.

We train professionals in many areas taking efforts to improve efficiency of the education system and develop cooperation with industrial clusters of Kaluga Region. I am sure that the future, which is directly connected with innovations and economic development of the region, belongs to them. That is why we closely cooperate with the clusters. In particular, scientists of Kaluga State University are members of the Coordination Council of the Governor of Kaluga Region for development of the pharmaceutical cluster. At present, our University participates in the Alliance of Competencies "Park of Active Molecules". Our science and education center works together with the alliance that allows involving students in research activities and ensures preparing highly skilled personnel for companies of Kaluga pharmaceutical cluster. The University has created Biopharmaceutics innovative scientific and education center that actively cooperates with pharmaceutical and biotechnological companies of Kaluga Region (for example, LLC NPK Medbiopharm, JSC Biotechnology Complex – Rosva) in personnel training and skills-raising and when organizing scientific and

research activities of students. Kaluga State University is among TOP10 Russian universities financed by the Ministry of Science and Higher Education of the Russian Federation under the strategic development program. It obtained licenses for new specialties: pharmaceutical chemistry, bioengineering, microbiology, and genetics. We opened the Master's program in Biotechnology. In the future, it is planned to extend cooperation with Kaluga pharmaceutical cluster and obtain the status of a national research center in the field of biopharmaceutics

Maxim Anatolievich, your University has the Russian fifth simulation center for students and medical professionals. Please tell about results of its operation.

In the medical education system, simulations are the basis for a number of techniques intended to reproduce clinical situations for training, repetition, evaluation and research. The essence of this training is using instead of training machines, simulators and simulating robots instead that a future doctor examines and carries out various manipulations. Future doctors are trained in such centers under the supervision of experienced specialists. It is much more convenient to master patient treatment skills in practice using training machines where it is possible to model any treatment



situation. Each doctor is obliged to pass skills-raising courses every 5 years. Since 2016, the right for medical and pharmaceutical activities in Russia is provided only to specialists who have higher education in accordance with the Federal Education Standard of the Russian Federation and have specialist accreditation certificates. The accreditation procedure includes such appraisal measures as testing, assessment of practical skills and competencies in standardized simulated conditions, and accomplishment of situational tasks. Therefore, a simulation center should be a part of every education institution as a precondition for advanced medical education. Creation of Virtual and Simulation Technologies in Medical Education innovative science and education center at Kaluga State University in 2016 is a transitional stage from traditional learning methods to more advanced perfect trainings that allow improving the quality of medical education and medical care. Key stations of the center are equipped not only with devices applied in urgent situations (respiratory apparatuses, defibrillators, infusion pumps, intensive care and trauma units, etc.), but also with a simulation system for various purposes to master initial skills and simulate elementary medical situations. Computer systems simulate physiologic conditions of the mannikin robot as

realistically as possible: breathing, heartbeats, lungs noises and heart tones, pulsation, blood pressure increase and decrease, heartbeat disorders. At the same time, the training system is built on the method of learning from simple manipulations to polishing actions in clinical situation in a team. The simulation center has equipment that allows recording in real time and further replaying and discussing. Recording is carried out by several cameras, and readings of the simulator monitors are registered simultaneously. Using such programs to record and reproduce actions of students increases the efficiency of further discussion. This



helps a teacher to obtain information what students need most of all and contributes to updates of curriculums. Creating and commissioning of the center is important not only for Kaluga State University, but also for Kaluga Region as a whole, as one of its purposes is satisfying needs of the region for training of highly skilled medical professionals. The center is capable to train doctors using advanced medical education technologies and subject to state-of-the-art science achievement. Certainly, this will increase the quality of medical care in Kaluga Region. Besides, the final attestation applying an impartial structured clinical exam using simulation equipment reduces the probability of improper, formal passing of improvement programs and mitigates corruption risks. For the period of its existence, employees of the Virtual and Simulation Technologies in Medical Education together with clinical hospitals of Kaluga and Kaluga Region held education trainings and video conferences to raise skills of around 100 nurses and doctors. In addition, the center trained around 250 students of Kaluga State University in the Medical Care. In the future, it is planned to create additional stations of the simulation center and open a university student polyclinic.

Marking of Drug Products in the Russian Federation



START OF THE COMPULSORY MARKING

The experiment has been conducted since February 1, 2017

13,660
participants of the experiment

19,106,456
packages marked

2,002
drug products

Key legislative acts regulating the Experiment for marking of drug products in the Russian Federation:

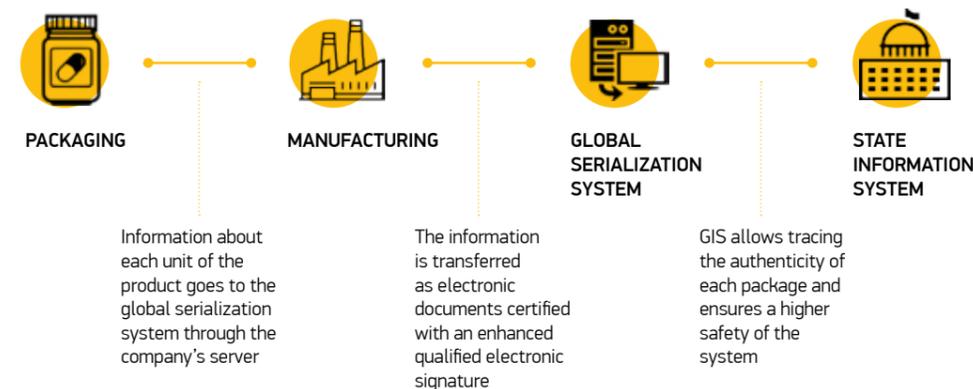
- Resolution of the Government of the Russian Federation No 62 dated January 24, 2017 "On the experiment for marking with control (identification) signs and monitoring the turnover of certain types of drug products for medical application";
- Federal Law No 425-FZ dated December 28, 2017 "On amendments to the Federal Law "On Circulation of Drug Products";
- Resolution of the Government of the Russian Federation No 791-r dated April 28, 2018 "On approving the operation model for the system of product marking with identification means in the Russian Federation";
- Resolution of the Government of the Russian Federation No 1556 dated December 14, 2018 "On approving the Regulation on the medical application drug product monitoring system"

Drug Marking Consulting Center of Kaluga Pharmaceutical Cluster

The Advanced Technology Development Center and Kaluga Pharmaceutical Cluster Association created a consulting and training center to implement the marking system based on the pharmaceutical cluster. As part of the cooperation, the Advanced Technology Development Center provides discounts for equipment and software to participants of the cluster and assistance in

documenting and raising short-term financing. The drug product marking project was started in 2017. Now, each package of drug products contains a DataMatrix digital code with information about the manufacturer and the product. All data on the product movements is entered into the unified state information system.

Creation of the drug product marking database



IDF Approves a Loan for Kaluga Region Pharmaceutical Companies for Drug Product Marking



The Expert Council of the Industry Development Fund (IDF) approved projects in certain regions of the Russian Federation for the total loan amount of RUB 772 mln. The total value of these projects will exceed RUB 1.5 bln. The approved projects of Kaluga Region include a loan of Nearmedic Pharma

and OCPC for the total amount of RUB 79 mln under the Drug Product Marking program. The Drug Product Marking program is intended to enable pharmaceutical manufacturers to install equipment for traceability of their products.



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- built-to-suit

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0%

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- property tax during 10 years

TPSED

2 single-industry towns

0%

- profit tax for 5 years
- property tax for the first 5 fiscal periods
- land tax

Obninsk Technology Park

2 sites

Biotechnologies, radio medicine, nuclear technologies, IT, new materials

- 01 JSC Agency for Innovative Development – Center for Cluster Development of Kaluga Region
- 02 Regional Engineering Center (REC) in the Pharmaceuticals Area
- 03 Equipment Sharing Center (ESC) in the Pharmaceuticals Area
- 04 Russian Technology Transfer Network (RTTN)
- 05 ANPO Business Incubator of the Obninsk Science and Technology Center
- 06 Youth Innovative Creativity Center
- 07 Kaluga Laster Innovation & Technology Center
- 08 Foundation for Assistance to Small Innovative Enterprises in Science and Technology (FASIE)

Governmental Support to Industry

AT THE FEDERAL LEVEL



- 01 Assistance in obtaining federal tax benefits by companies that carry out capital expenditures in the implementation of investment projects
- 02 Assistance in obtaining support within governmental programs of the Russian Federation, federal target programs, IDF programs
- 03 Assistance in entering into special investment contracts

AT THE REGION LEVEL



- 03 Regional special investment contract with Kaluga Region
- 04 Priority social and economic development area
- 05 Kaluga Special Economic Zone
- 01 Register of investment projects
- 02 Federal special investment contract on behalf of the Russian Federation
- 06 Register of renovation and upgrading programs
- 07 Register of regional investment projects

Trust of People to Sberbank Grows



Sergey LUKIYAN,
Manager
of Kaluga Branch
No 8609,
Sberbank PJSC

In late March, the central office of Kaluga Branch of Sberbank held a press conference of Sergey Lukiyan, Manager of the local branch. The meeting was devoted to the 2018 results and presentation of new banking products.



“The year of 2018 was successful for us. There are positive trends in the retail segment. We provided RUB 13.8 bln of consumer loans and their amount increased by 68%. The same trends (56%) are observed in the housing lending, where the amount of mortgage loans came close to almost RUB 13 bln. The bank actively develops in the field of salary projects. For example, the share of Sberbank

increased by more than 10% in the past year and is currently 78%, so over 2/3 of residents in the region receive salaries through Sberbank.”

Based on the market demand, Sberbank actively develops its ecosystem. In the conditions when a client is focused not only on receiving a financial service, but

also on solving related problems, Sberbank is aimed at providing demanded services. The ecosystem includes many brands represented at the bank's website: DocDoc, a popular telemedicine service; Beru implemented together with Yandex; Sberbank-mobile providing mobile communication services and other services. According to Manager Sergey Lukiyan, the bank develops a system

of services for individuals that is focused on faster processes of services and legal transactions.

For example, the DomClick internet platform, where any buyer can choose a real estate, file an application for a mortgage loan and register the real estate. Order a real estate evaluation service without engaging external evaluators. Using the Legal Expertise, track the transaction status, so that the bank can warn clients of the reputational nature of the transaction in accordance with the documents. In the Safe Settlement Service, calculate the risks of both a mortgage loan and a sale contract, which is successfully used by clients who do not deal with mortgage loans.

For the convenience of clients, the bank develops electronic payments for housing and utility services.

service terminals due to complicated security issues. Therefore, we are moving towards mobile offices that can service 5-6 settlements per tour.”

In 2019, innovations addressed Federal Law No 214-FZ “On Participation in Shares Construction”. To ensure financial security of shared construction participants, escrow accounts were introduced: a buyer of an apartment deposits money to an escrow account as a lump-sum or by installments. The bank blocks the funds until the construction is completed and transfers them to the developer only after the apartment is delivered. When construction of the real estate is completed, funds from the escrow account are paid to the developer.

“85% of utility bills in the region are paid through online services. Together with the Ministry of Construction and the Unified Information and Settlement Center, we discuss introducing a single payment document, so that people conveniently pay utility bills. Besides, for the convenience purposes, today payment documents have a two-dimensional barcode. We offer a list of services for automatic payments that allows clients not to come to the bank's office in principle and not to look for service providers, doing this automatically through the entry of a five-digit code.”

Today, the retail segment of Kaluga Region comprises 88 fixed offices and 2 mobile outlets that service settlements with population of less than 1,000 people. Besides, Kaluga Region has a pilot project – a multiservice smart-office that has onboard a cash machine, a shop van with food products, an Internet kiosk, and online connection with an operator. The smart-office is equipped with a telemedicine service that allows consulting with specialists from Moscow; it is the most popular among clients. At present, such smart-offices serve the Maloyaroslavets, Ferzikovo and Peremyshl Districts.

“Smart-offices are a good alternative when it is impossible to install fixed

“This is the world's practice that is usually applied in real estate transactions. Using escrow accounts enables all participants of the transaction to secure performance of the obligations and minimize their risks of the transaction failure and probable fraud of either party.”

Financial instruments for business development continuously evolve meeting demands and needs of clients. In the past year, the bank raised 4.6 thou. small business clients and provided loans for RUB 900 mln. The bank expanded the presence of branches that currently serve not only individuals, but also the small business segment that should contribute to a wider client base in the small and medium enterprise (SME) segment. For the convenience of SME clients, the service of new technologies was also expanded. Now, the account opening procedure takes just 30 minutes that considerably reduces the time of both client waiting and collecting the package of documents. So, the implementation of new technologies and the Smart-Loan program allow documenting a loan in a short time and without a large package of documents. For beginning companies and entrepreneurs, there is the Easy Start service package, where the serviced are almost free-of-charge at the initial stage and new rates are added, which allows choosing a set of convenient services at your own discretion, as the business develops, many payment

documents appear and it becomes required to withdraw cash in the bank's cashier's office.

In addition, the time required to provide bank guarantees was significantly reduced – now the bank can provide any bank guarantees for SMEs for up to RUB 15 bln in three days that is convenient for companies participating in tenders.

This year, Kaluga Region together with Google starts the Business Class pilot project. The government will give recommendations on promotion of the project. Entrepreneurs will be able to take part in free-of-charge online contests intended to train them in chosen modules during five month. Entrepreneurs will receive certificate following the training and successful examination.

In the online service development areas, the bank launched a service to transfer documents to the Federal Customs Service for exporters and importers.

“We provide a high level of services to clients, who do not have enough time for a visit to the bank, through online services and try to ensure that our client can receive all services in one place, so we placed a multipurpose center in our premises at ul. Kirova, 21-A to serve legal entities and will soon open a tax inspectorate office, where entrepreneurs will be able to be consulted, file documents and solve all their problems during one visit to Sberbank.

The trust of people to Sberbank grows that demonstrates the stability and success of its operation. We have earned such trust not using a large-scale structure or reputation related to the long soviet period, but applying high technologies, higher quality and safety of our services, in which large money is being invested. The upward trends in the client base and usage of services speak for themselves, so it is pleasant that client vote with their feet.”



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Life Sciences Development Based on Kaluga Pharmaceutical Cluster



Kaluga Pharmaceutical Cluster Association and Merck, a science and technology company, signed a cooperation agreement to develop Life Science technologies in Kaluga Region.

Merck is a world's leading science and technology company in the field of healthcare, Life Sciences and high-tech materials.

The priority cooperation areas include creating joint infrastructural projects, training laboratories and competence centers; creating partner projects with participants of the pharmaceutical cluster based on advanced technology solutions of Merck; implementing projects in scientific and research activities.



The Volume of Pharmaceutical Substances Imported by Novo Nordisk Increased 241-Fold in Monetary Terms

In 2018, the value of active pharmaceutical ingredients (API) imported into Russia amounted to around RUB 87 bln. The growth of supplies in monetary terms was 29.3%. The natural growth decreased by 5% in 2018. The key contribution to the ruble trends is still made by suppliers of pharmacopoeial APIs (+29.5%). Novo Nordisk accounts for the maximum increase in the TOP-15 of corporations leading in the monetary volume of imports – the volumes increased 241-fold for the year. The company imported into Russia 4 products; the main volume of supplies accrues to insulin detemirum (64% of the total volume in rubles) and insulin aspartum (35%). The production of both drug products is localized in full cycle at Kaluga facilities.



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Implementation of a New CRM System in Stada

The project of implementing the "field" personnel management system Navicon Pharma CRM in Stada, an international pharmaceutical company, won the "Project of the Year" award of Global CIO in the "Medicine and Pharmaceuticals" industry. The project was implemented by the IT company Navicon which has a high expertise in automation of pharmaceutical sector companies. The project enabled automating business processes of over 500 medical representatives and regional managers of Stada that made their work even more efficient and convenient.

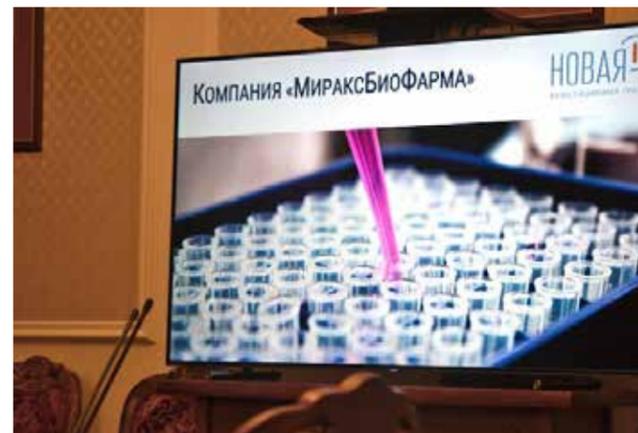


Hemofarm is Called a Socially Responsible Employer of Kaluga Region

Hemofarm production company (Stada AG holding) won the contest "Socially Responsible Employer of Kaluga Region" for the fourth time. This year, the company was awarded in the category "For Development of Talent Pool in the Organization". The contest is held by the Ministry of Labour and Social Protection of Kaluga Region based on its evaluation of working conditions, efficiency of social partnership, implementation of social development programs in the organization with a view to attract skilled personnel, etc. Every year, Hemofarm demonstrates high indicators of social responsibility in the personnel hiring and development area.



MiraxBioPharma Builds a Plant in Maloyaroslavets District



ОАО MiraxBioPharma, a Russian pharmaceutical company, and the Representative Office of Kaluga Region signed an agreement for construction of a plant in Maloyaroslavets District to manufacture non-sterile drug products and substances. The new production facility based on GMP standards will manufacture drug products for treating pre-cancer pathologies and preventing oncological diseases of the reproductive system.

*Investments exceed RUR 800 mln.
Commissioning of the pharmaceutical plant is scheduled for 2020.*



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Digest

The Obninsk Clinical Hospital will Become a Part of the Nuclear Skolkovo



The Federal Medical and Biological Agency of Russia (FMBA) supported a project based on R&D Nuclear Institute MEPhi to expand the Nuclear Skolkovo. It is proposed to include Clinical Hospital No 8 in the Innovative Science and Technology Center and use its potential for education programs and development of new pharmaceutical products. The hospital holds a license for clinical studies of new drug products together with FSBI National Medical Research Center of Radiology. Leading experts of FMBA will give consultations and hold skills-raising trainings within the telemedicine project. It is also planned to create two research laboratories – for “smart” radio pharmaceutical products and regenerative technologies.

Implementation of the Health National Project in Kaluga Region



The Government of Kaluga Region has developed seven regional projects as part of the Health national project. They are intended to develop the primary medical and sanitary aid system, struggle against cardiovascular and oncological diseases, improve the healthcare for children, human resourcing and digitization of the industry. In a three- year period, it is planned to upgrade the network of medical and obstetrical stations in the region. In 2019, mobile medical stations were launched to provide aid to residents of villages with population of up to 100 people. Besides, it is planned to construct a multifunctional polyclinic in Kaluga (Right Bank district) and a new building for the regional oncological center.



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