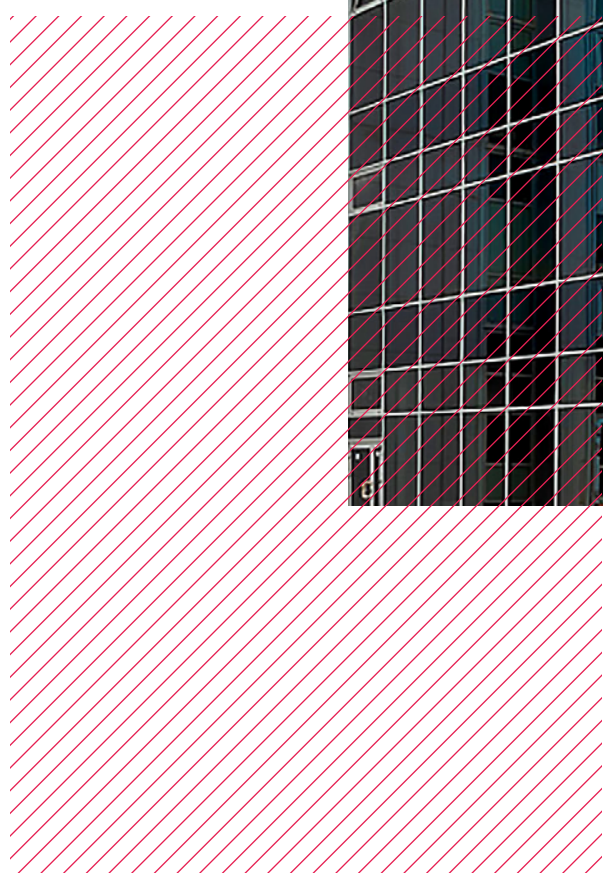
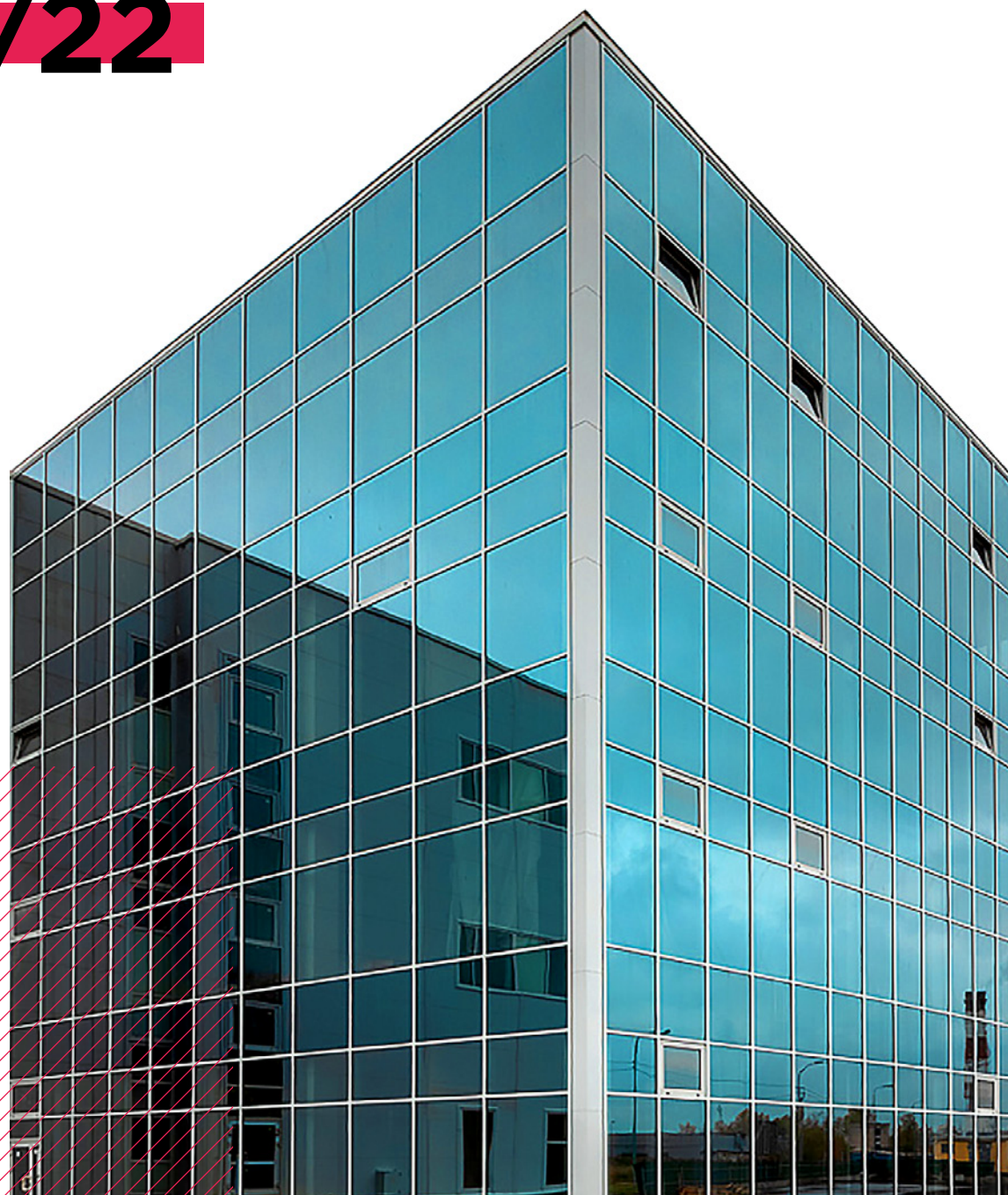




partnership 2021/22



SAMSON-MED

BIOPHARMACEUTICAL COMPANY
SINCE 1937

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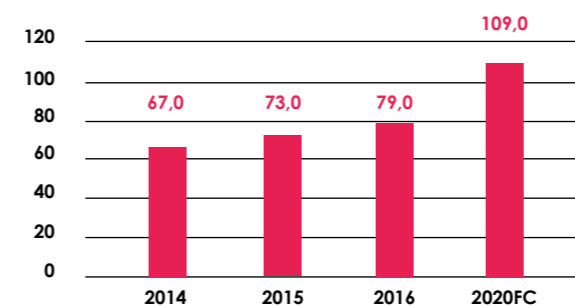


WORLDWIDE MARKET OF CONTRACT MANUFACTURING. PHARMACEUTICAL MARKET OF RUSSIA

According to analytical agencies, drug production associated costs account for an average of 20-25% of the total pharmaceutical company cost structure. Contract manufacturing service can significantly reduce production costs. According to Frost & Sullivan, the global contract manufacturing market (CMO – contract manufacturing organization) amounted to \$72.7 billion in 2015. Growth rates exceed 8% per year, and the CMO market is expected to break the \$100 billion bar by 2020.

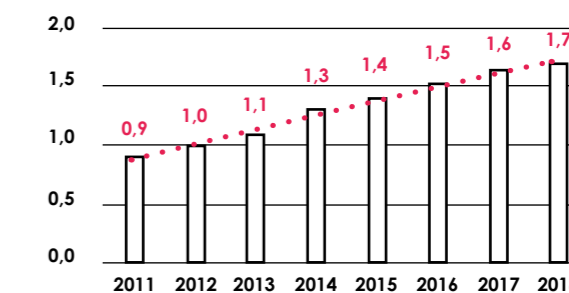
The Russian pharmaceutical market has shown steady growth over the past 8 years, and in 2018 reached a value of 1,682 billion rubles (\$27 billion). Until 2017, the volume of drug consumption grew by at least 8% annually. A strong positive trend continued despite a slowdown in 2018.

Global pharmaceutical contract manufacturing market 2014-2020, billion dollars



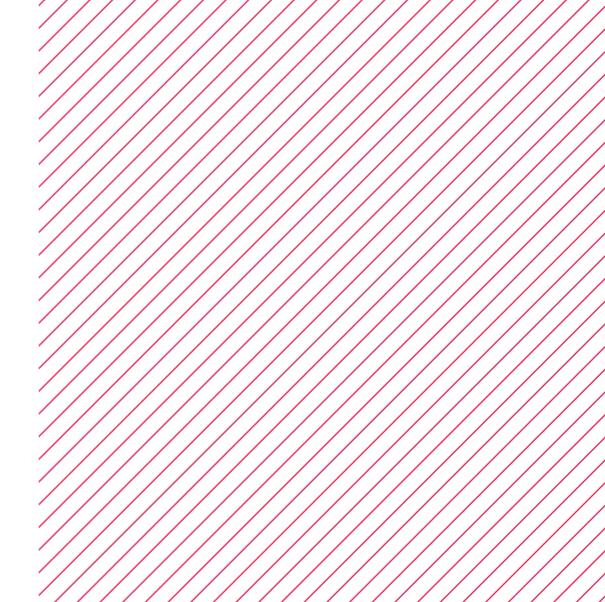
Source: Frost & Sullivan data
<https://frprf.ru/file/Farm.pdf>

Russian pharmaceutical market 2011-2018, billion rubles



Source: DSM data
https://dsm.ru/docs/analytics/Annual_report_2018_DSM.pdf

MARKET ACCESS. STATE PREFERENCES FOR THE EAEU PRODUCED MEDICINES



The Russian Federation Government Decree No. 1289 dated November 30, 2015 “On the restrictions and terms of sale of medicines originating in foreign states and included in the list of vital and most important ones for the purposes of purchase for state and municipal needs” (“Third is a Crowd”).

The Russian Federation Government Decree No. 572 dated May 12, 2018 “On Amending the Russian Federation Government Decree No. 1289 dated November 30, 2015”.

The Russian Federation Ministry of Finance Order No. 126n dated 04.06.2018 “On the conditions for the admission of foreign states origin goods for the purposes of purchase for state and municipal needs (entered into force on 05.11.2018).

In addition, according to the Russian Federation Ministry of Finance Order No. 126n dated 04.06.2018 participants whose orders contain goods manufactured by the EAEU countries receive a 15% advantage of the contract price they have proposed.

In accordance with the decree, when 2 or more applications for the tender auction are submitted by EAEU members, all the other foreign applications for participation must be rejected.

The document clarifies that in accordance with paragraph 1 of Government Decision No. 1289 of 30.11.2015, if foreign drugs suppliers' applications were rejected during the tender, preference is made to the participant that offers locally EAEU produced medicines, including all the stages from active substance synthesis to finished drug packaging .

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The benefits allocation procedure depends on the supplier choosing method . In case of proposals or quotations tender, the price of the EAEU participant is reduced by 15%, which gives a competitive advantage for local producers. The contract with the winner is concluded at the price offered in the application.

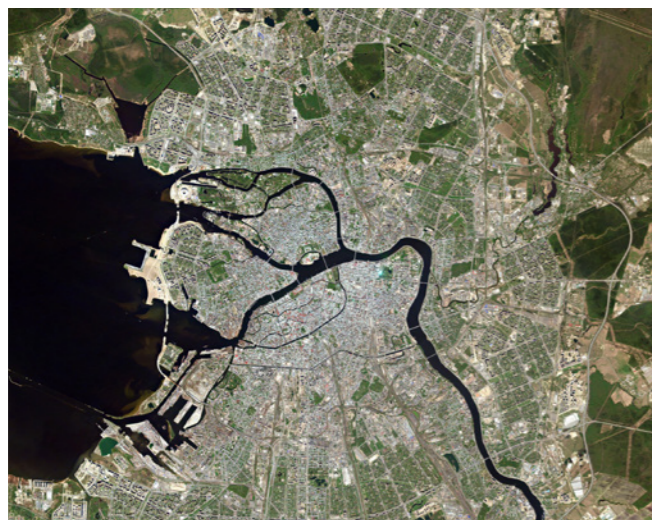
In the case of the only such application, the contract price may be 25% higher than the lowest price of the participants with only the finished dosage stage implemented on the EAEU territory. If there are more applications, then the one who has offered the lowest price wins.

The order is different in auctions. The contract is concluded at a price 15% lower than the one proposed by the winner, if there is at least one product of foreign origin in his application. The winner from the EAEU eventually gets the opportunity to conclude a contract at the price indicated in his application.



GEOGRAPHIC PROFILE

why st. petersburg?



St. Petersburg is one of the three largest cities in Europe both in terms of population (5.3 million people) and territory (1.4 thousand km²).

Convenient transport and logistics hub: all types of communications - sea, rail, air and road transport.

A city with a stable economy - the average annual GRP growth rate amounted to 9.5% over the past 5 years, which exceeds the average annual GRP growth rate in Russia (6.5%).

Favorable business environment: a wide range of government support measures, international business events, the positive dynamics of St. Petersburg in the world ratings position.

High level of employees' qualification : the share of qualified specialists in the total number of people employed in the economy is 68.4%. The proportion of people with higher education from the total number of people employed in the economy is 42.3%.

In addition to Samson-Med, the following companies are building factories in the pharmaceutical cluster in the Pushkinskaya (Vostochnaya) production zone: Geropharm, Biocad, Active component.

Easy external relations of the city due to its location. The distance to Estonia, Finland, Latvia, Belarus, Lithuania is less than 500 km.

St. Petersburg has the unofficial status of Russia's pharmaceutical capital. The pharmaceutical production is one of the drivers of economic growth in the city:

18% of total Russian pharmaceutical production is located in St. Petersburg

the average annual industrial production index for the pharmaceutical industry in St. Petersburg is 107.4%

Saint-Petersburg Chemical and Pharmaceutical University is the leading university for providing specialists for the pharmaceutical industry. The city has specialized pharmaceutical research and development centers

over 7200 people are employed at pharmaceutical enterprises in the city



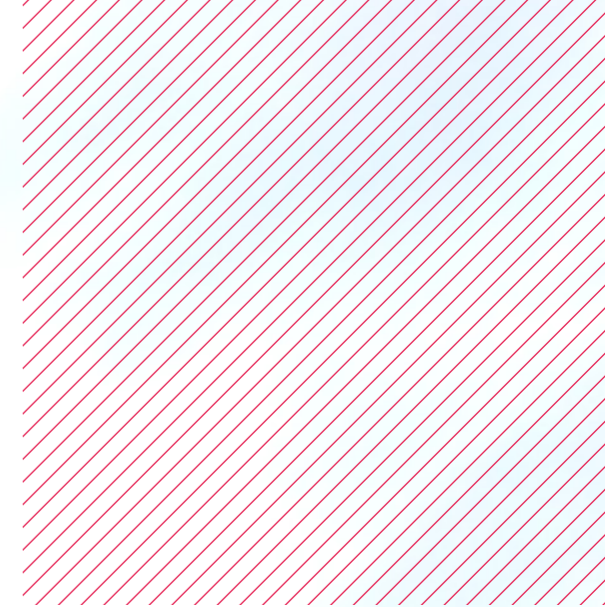
SAMSON-MED – A BIOPHARMACEUTICAL COMPANY SINCE 1937

Samson-Med company is one of the first pharmaceutical companies in the Russian Federation.

Since its foundation, Samson-Med has developed and implemented a number of unique technologies for the production of active pharmaceutical substances and original drugs. Along its history the company's portfolio included hormone-enzyme preparations, plasma-replacing infusion solutions, injection analgesics and other groups of drugs. The company carries out a full range of activities from development and research to the full-cycle production of biological products and their marketing support in the markets of Russia and the near abroad.

In addition, Samson-Med is developing and manufacturing medicines on a contract basis.

Being the center of scientific and technological competencies, Samson-Med company maintains a strong position in the pharmaceutical segment of biological drugs.



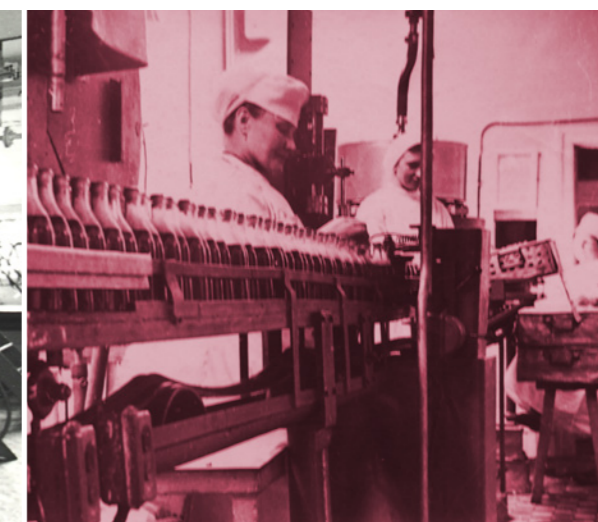
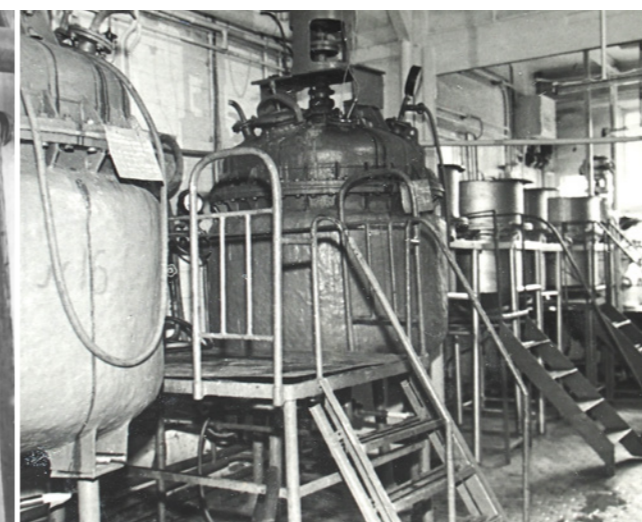
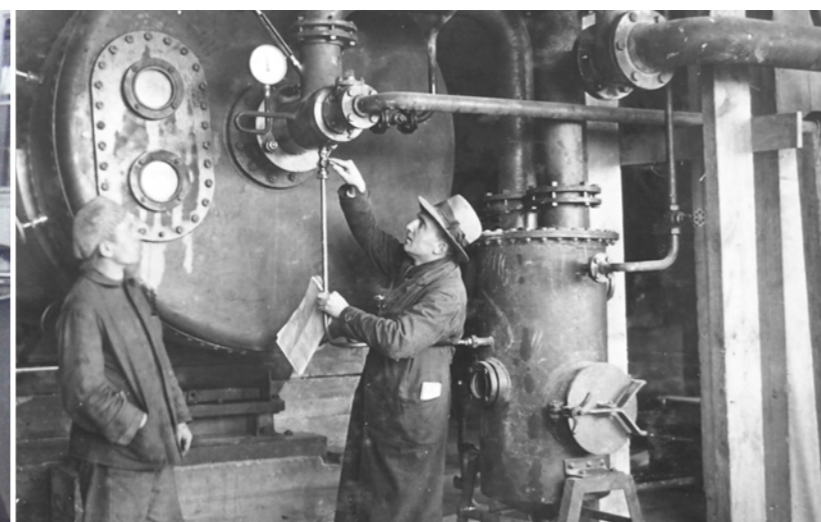
values

- Years of experience and competence building
-
- High quality of products
-
- Affordable biopharmaceutical products
-
- Long term partnerships

mission

We use our unique competencies and expertise in the field of biopharmaceutical products research and production to improve human quality of life and health

OUR HISTORY



1937. Foundation of the Company

In 1937, the facility for the processing of raw materials was created at the Kirov meat processing plant in order to obtain enzymes. At the time of its foundation, the plant produced the simplest preparations from endocrine-enzyme raw materials: pepsin, hematogen, gastric acid

1941-1945. World War II

Samson-Med Company launches the production of penicillin and insulin, which are important for the military industry. The company was the first to introduce insulin production using ion-exchange resins. During the war, the territory of the plant had strategic importance: there was a line of defense, and the highest point of the plant was the observation and coordination center

1963. Production of Chymopsin and Chymotrypsin

The company began production of Chymopsin and Chymotrypsin, which are still used in surgery and dentistry

1970s. Start of production of blood substitutes

A number of plasma-substituting drugs were developed and launched into production together with the Leningrad Hematology and Transfusiology Research Institute: Disol, Trisol, Acesol

1975-1980. Start of production of Cytochrome C and infusion preparations

The development of an injection form of Cytochrome C was completed together with the Russian Hematology and Transfusiology Research Institute. The production of infusion solutions was launched on the basis of the blood substitutes workshop. The workshop of blood substitutes and infusion solutions was considered an object of special purpose, since it produced drugs not only for the civilian population, but also "special orders" for the army: Aminopeptide, Hydrolysin, etc.

1980s. Beginning of the production of peptide biological products

Together with the S.M. Kirov Military-Medicine Academy has developed a number of peptide drugs, among which Thymalin® and Samprost®. At that time, Samson-Med product portfolio included more than 40 types of drugs

1998. Launch of Samprost®

Samson-Med company has registered and started production of the Samprost® drug, which became one of the first biological products for the treatment of chronic prostatitis in the Russian Federation

2010. New Manufacturing Plant and Pharmaceutical Cluster

Samson-Med becomes a member of Saint-Petersburg Pharmaceutical cluster. The Resolution of the Government of St. Petersburg on the construction of a new production complex Samson-Med in the Pushkinskaya Industrial Zone had been signed

2016. A project of strategic importance

Samson-Med becomes a resident of Saint-Petersburg Localization and Import Substitution Center. The project of the new Samson-Med manufacturing plant construction is recognized as strategic one for the city by the Saint-Petersburg Government Resolution

2017. The 80th Anniversary

The company celebrates its 80th anniversary. The project of building a new plant is being actively implemented, the R&D direction is developing: many projects are launched to modernize existing products and technologies, and active cooperation is being conducted with leading research institutes of the Russian Federation to develop new products

2019. The second phase of the new plant construction and rebranding project

The company completes the second phase of the new plant construction and completes the rebranding project

PARTNERSHIP OPPORTUNITIES

THE NEW PRODUCTION PLANT MAIN CHARACTERISTICS

- Contract manufacturing
 - Market access through local partnerships
 - Modern high quality technological equipment
 - Experienced team
- Start - Q1 2022



PHARMACEUTICAL PRODUCTION

dosage forms



LYOPHILIZATES



SUSPENSIONS,
CONCENTRATES



SOLUTIONS

- production launch - Q1 2022
- investments volume - 5.2 billion rubles
- 411 jobs
- plant territory - 2.74 ha
- 5 main buildings: finished drugs production building, active pharmaceutical substances production building, office and laboratory building, warehouse building, engineering building
- own steam-gas boiler house operating on natural gas
- API of endocrine-enzyme origin production capacity: 5,000 kg (91 kg of lyophilized substances)
- contract bottling and lyophilization capacity: 35 mln vials/year (including the high-tech bottle preparation, filling and corking OPTIMA line's capacity of 18 thousand vials/h)
- the main vial format is 2R, 4R (optional: vials 10R, 20R, 50R, 100R)
- freeze drying - 25 m²
- 100% IPC control
- compliance to international standards of cGxP pharmaceutical production standards and environmental standards (closed organic solvents turnover cycle, full treatment of industrial effluents)

OUR SERVICES ON A CONTRACT BASIS

1. Project plan development, project analysis

- Technical specification development
- Market research
- Technological process analysis

2. Pharmaceutical development

- raw materials provision
- compatibility study
- stress testing
- stability studies
- analytical methods development and validation
- regulatory and process documentation development
- intellectual property protection support

3. Drug manufacturing technology scaling and transfer

- incoming inspection of raw materials
- analytical methods transfer
- pilot series development
- processes validation
- stability study (natural and accelerated conditions, including photostability)

4. Preclinical and clinical trials

- samples development in GMP conditions
- packaging, labeling
- output control of samples
- research centers selection (GLP and GCP)
- each study progress monitoring
- study results analysis and practical application

5. Registration dossier preparation

- documents package preparation in the CTD format (common technical documentation)
- drug registration support

6. Contract manufacturing

- technology transfer
- technology validation
- drug registration on the site
- provision of raw materials, materials, production facilities
- samples production for pharmaceutical expertise
- drug release

7. Analytical services

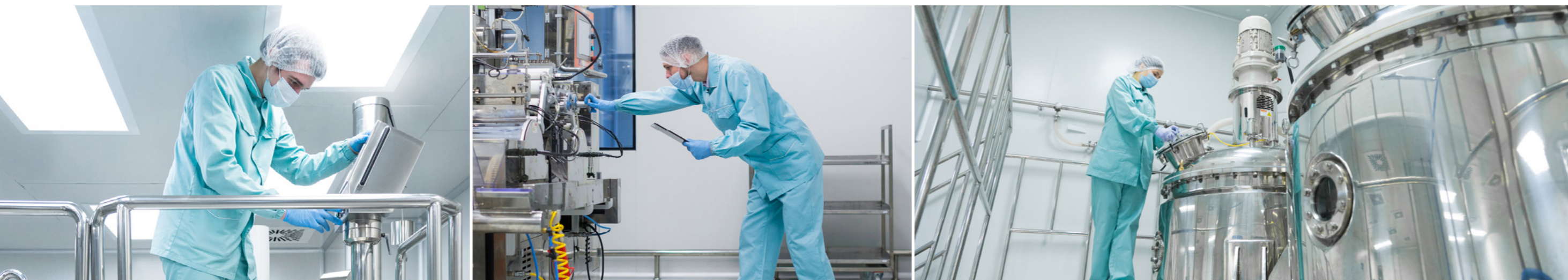
- analytical methods development
- analytical methods validation
- analytical methods transfer
- comparative kinetics test of solid dosage forms dissolution
- drugs composition analysis
- organic and inorganic substances determination methods development in various objects using the following methods: fluorescence spectroscopy; uv spectrophotometry; ir spectroscopy gas and high performance liquid chromatography;
- documentary support

8. Production technology justification

- laboratory samples preparation
- documentary support
- compatibility, stability study
- process scaling

OUR INDUSTRIAL PARTNERS

The main technological equipment installed at the production site was manufactured by leading manufacturers in Europe and China:



Optima (Germany) -
insulating line for filling and lyophilization in bottles

Block (Czech Republic)
clean room engineering and design

Pall (international holding) -
ultrafiltration plants

Gea Westfalia (Germany) -
separators and centrifuges

Bauch + Strobell (Germany) -
labeling machine, sterile dosing system

Stilmas (Italy) -
purified water, injection water and pure steam production

Olsa (Italy) -
tank equipment for the solutions preparation

Farmo Res, Romaco (Italy)
- packaging line

CMP (Italy) -
inspection machine

Comas (Italy) -
filling and capping line

Bergami (Italy) -
cartoning equipment

Riera Nadeu (Spain) -
Centrifuge

Steelco (Italy) -
automatic washers, sterilizers, hot-air ovens

Tofflon (China) -
sterile API section lyophilizer, vials filling and lyophilization line(RABS)

Quarco (China) -
Vessel Equipment

OPTIMA VIALS FILLING LINE

- Fully automated rotary washer with continuous vials transporting system.
- Sterilization and depyrogenation tunnel with unidirectional vortex-free flow. Includes feed zone, heating zone and cooling zone.
- Fully automatic vials filling and closing machine. To minimize losses, a function is provided for dispensing the solution into vials by weight of filling, with the possibility of topping up in automatic mode.
- Fully automatic vial caps crimping machine. Has 10 crimping stations.
- A fully automatic row-by-next vials loading and unloading system. The surface area of one lyophilizer is 25.41 m². The number of vials per load ≈ 100 000 pcs.
- Isolation room. Filling and capping system, including loading/unloading systems.



key line characteristics

Vial Formats: Ø 16mm x 35mm (2R), Ø 16mm x 45mm (4R)

Cap formats: lyophilic stopper and stopper for bottling liquid preparations Ø 13mm.
Other formats can be ordered from the manufacturer

The system allows the production of both lyophilisates and liquid dosage forms

100% IPC control without loss of performance

API PRODUCTION



- The K-Prime 40 II industrial chromatographic system with a Quikscale chromatographic column, which allows the purified protein substances separation and isolation.
- Pharmaceutical-grade Pall Tangential Filtration System with Centrasette cassettes with a 10 m² filter area.
- AISI 316L stainless steel vessel equipment with agitator, jacket, mirror-polished surfaces, heat-insulated, with valve control cabinets, instrumentation.
- Enamelled vessel equipment with agitator, jacket, thermally insulated, valve control cabinets and measuring instrumentation.
- Glass vessel equipment with agitator, jacket, valve control cabinets and measurement instrumentation. Enamelled and stainless steel AISI316 L drook-filters for sediment separating.
- Organic solvents plant regeneration (up to 4000 l/day).

FPP PRODUCTION

fpp production building



- 1 floor:**
- injectable lyophilized preparations and pharmaceutical substances production (including material and personnel airlocks, auxiliary rooms, technical zones);
 - inspection, labeling and secondary packaging premises;
 - intermediate storage rooms for raw materials, packaging and printing materials, finished products and the entire necessary auxiliary premises complex
- 2 floor:**
- injectable lyophilized preparations production (including material and personnel airlocks, auxiliary rooms, technical areas);
 - injectable drugs secondary packaging;
 - intermediate storage rooms for raw materials, packaging and printing materials, finished products and the entire necessary complex of auxiliary premises
- 3 floor:**
- ventilation chambers of industrial and auxiliary premises
- The following premises are provided in the building for servicing production sites:**
- waste collection, sorting and packaging facilities
 - domestic facilities (bathrooms)
 - technical area for maintenance of lyophilizers, CIP/SIP plants for solution preparation area reactors
 - washing and sterilizing
 - water treatment system
 - electric switchboard room
 - processing information server of industrial buildings

R&D LABORATORY, QA LABORATORIES

r&d laboratory

Modern technological and analytical equipment of leading world manufacturers is used to implement the full range of tasks in the research laboratory: Agilent Technologies, Shimadzu, Mettler Toledo, IKA, Bio-Rad, Beckman Coulter, Bruker, Sartorius, Memmert etc. This equipment allows to solve tasks in the field of development, scaling, conducting stability studies, transfer of technologies and analysis methods.

The laboratory equipment park includes: HPLC, GC, spectrophotometers and spectrofluorimeters, plate reader, high-speed centrifuges with cooling volume of 2ml up to 6l, visible particle counter, moisture analyzer, cell analyzer, programmable vacuum cabinet, climate chambers, analytical scales, pH meters, conductometers, programmable preparative medium-pressure chromatograph with fraction collector based on Peltier elements, pilot unit.



the quality assurance department (qad)

The Quality Assurance Department (QAD) ensures the production of finished products meets the requirements of current regulatory documents. The core functions of the department are: incoming control implementation of raw materials, production processes compliance monitoring in accordance with the technological regulations requirements, intermediate products control, technological processes and quality of products compliance.

The quality assurance department includes following laboratories: testing (analytical), microbiological and a group of controllers of interoperational control. The laboratories are equipped with the necessary modern equipment from leading world manufacturers, providing analyzes and tests according to the parameters provided in the regulatory documentation.

The studies conducted:

- physicochemical (HPLC, gas chromatography, polarimetry, ionometry, UV spectrophotometry, IR spectrometry, thin layer chromatography and other methods)
- microbiological (sterility and microbiological purity control of the feedstock, intermediate and finished products, product control according to the «Bacterial endotoxins» indicator, microbiological monitoring of the production environment, production environment air monitoring for the aerosol particles, monitoring of process media)



OUR R&D PARTNERS



St. Petersburg Institute of Bioregulation and Gerontology



North-Western State Medical University named after I.I. Mechnikov



Saint-Petersburg Chemical-Pharmaceutical University



Research and technology association «Dom Farmacii»



KorolevPharm. Contract manufacturing and packaging

OUR INDUSTRY PARTNERS

Medical and pharmaceutical projects. XXI century

Samson-Med is a member of the St. Petersburg Pharmaceutical Cluster and is actively involved in industry and educational events



OUR BUSINESS PARTNERS

National and regional distributors

The long-term and mutually beneficial cooperation is facilitated by the company's flexible commercial policy, as well as the consistently high quality of products noted by partners. Samson-Med LLC is constantly expanding the geography of supplies. The company's products are supplied to the CIS countries, Mongolia, etc.



Drug manufacturers

For decades, Samson-Med has been the sole supplier of a number of APIs to major drug manufacturers.



OUR STRENGTHS



- a company with 80 years of history, with vast experience in the pharmaceutical market
- wide range of competencies and own production technologies
- full cycle production from active pharmaceutical substances to finished dosage forms
- more than 25 years of experience as a contract manufacturer, incl. more than 15 years of cooperation with the international company STADA Arzneimittel AG
- compliance with GMP standards
- new modern equipment of European manufacturers
- high performance lines (18,000 vials/h)
- the company has demonstrated growth in financial performance over the past 6 years
- own R&D laboratory
- good geographical location (St. Petersburg, industrial zone «Pushkinskaya» («Vostochnaya»), proximity to the largest highways of the city - Moskovskoye and Pulkovskoye shosse)

ADDITIONAL PARTNERSHIP OPTIONS

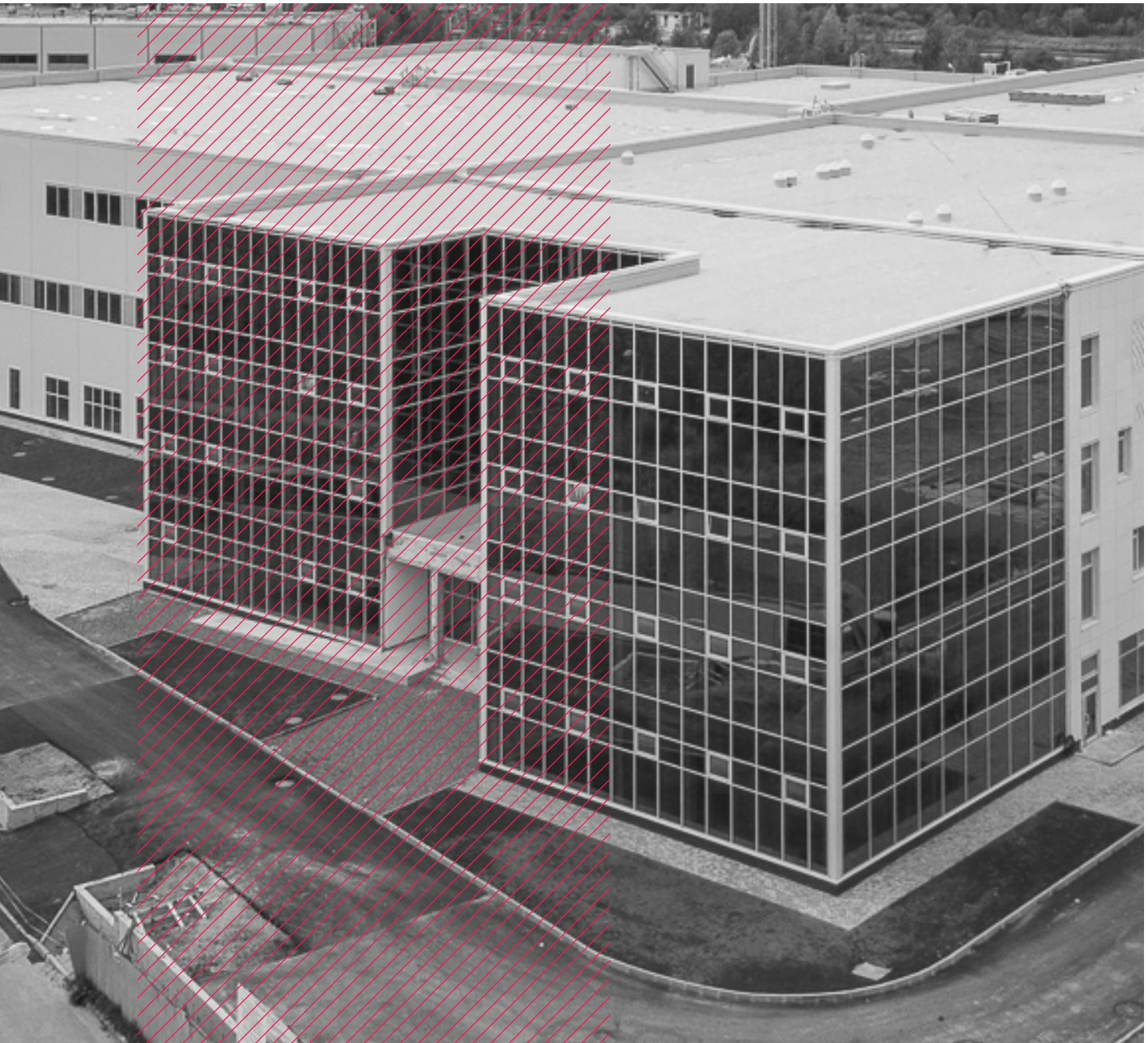


Joint venture

- Access to the best resources, including experienced staff, technology and finance
- Improving technology capabilities through collaborative R&D
- Distribution of risks and costs between partners

Acquisition of rights to pharmaceutical products

- License/permits sale profit that does not fit into the partner's current product portfolio
- Regular royalty option based on sales



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