

VECTOR-BIALGAM, PC

The company was founded in **1996** on the basis of the State Scientific Center of Virology and Biotechnology “Vector” (naukograd Koltsovo, Novosibirsk region)

Company profile:

production of pharmaceutical immunobiological preparations and probiotic products.



Leonid Nikulin
Chief Executive Officer of Vector-BiAlgam, PC

PRODUCTION BASE OF VECTOR-BIALGAM, PC

- GMP Quality Control System
- HACCP Quality Control System
- ISO Quality Management System

Injectable products:

- Vaccine for the prevention of viral Hepatitis A "ALGAVAC[®]M"
(the preparation is a suspension of purified, concentrated and inactivated and hepatitis A virions (strain LBA-86), adsorbed onto aluminum hydroxide. One milliliter of the vaccine contains at least 320 ELISA units of hepatitis A virus antigen.)

Probiotic production:

- Probiotics (dietary supplements)
- Starter cultures and technologies for the dairy industry
- Dry bacterial biomass
- Bioproducts
- Lysates of probiotic microorganisms

Contract manufacturing:

- Preparation of injectable solutions and filling in syringe dispensers, ampoules and vials.
- Development and production of multi-factor probiotics

MANUFACTURE OF INJECTABLE PRODUCTS BY VECTOR-BIALGAM, PC

- Vaccine for prevention of viral hepatitis A "ALGAVAC[®] M"

Vaccine against hepatitis A "ALGAVAC® M"

Vector-BiAlgam, PC is the only company in Russia that produces a vaccine for the prevention of viral hepatitis A — ALGAVAC® M — which is just as effective as its counterparts of foreign manufacture.

The production the "ALGAVAC® M" vaccine corresponds to requirements of international standard GMP:

- Quality control of the materials and production technology
- Personnel qualification
- Compliance with requirements to the facilities

Vector-BiAlgam, PC, guarantees:

- Exceptional quality
- High level of safety
- Effectiveness



Vaccine against hepatitis A "ALGAVAC® M"

ALGAVAC® M is a suspension of purified, concentrated and inactivated hepatitis A virions (strain LBA-86), adsorbed onto aluminum hydroxide. The continuous cell line 4647, permitted for the production of medicinal immuno-biological preparations, was used for strain cultivation.

- ❑ The vaccine is available in two forms: for children from three years of age and for adults
- ❑ One milliliter of the vaccine contains at least 320 ELISA units of hepatitis A virus antigen.
- ❑ The preparation does not contain any antibiotics or preservatives
- ❑ The vaccine has been duly registered and entered into the State Register of Medicines of the Russian Federation
- ❑ Vaccination involves two injections that must be done 6-12 months apart
- ❑ A full vaccination series ensures the development of a long-term specific immunity in 99-100% of the vaccinated patients





Vector-BiAlgam

MANUFACTURE OF PROBIOTIC PRODUCTS BY VECTOR-BIALGAM, PC

- Probiotics (dietary supplements)
- Starter cultures and technologies for the dairy industry
- Dry bacterial biomass
- Bioproducts
- Lysates of probiotic microorganisms

Probiotic products (dietary supplements)

Vector-BiAlgam, PC, produces complex multi-strain probiotic products for multifactor treatment of dysbiosis:

- ❑ High-concentrated probiotics based on bifidus bacteria and lactobacilli in liquid form: "**Bifidum BAG**" and "**Trilact**"
- ❑ "**Ecoflor**" is a unique probiotic combined with an ultra-selective intestinal sorbent
- ❑ Balanced synbiotics of the "**Probioflor**" series in capsule form

- ❑ Manufacture is certified in accordance with HACCP and GMP standards
- ❑ Product quality is confirmed by clinical effectiveness.
- ❑ The series includes over 80 strains of probiotic microorganisms



Starter cultures and technologies for the dairy industry

Vector-BiAlgam, PC manufactures starter cultures for the dairy industry, which, in turn, are used for the production of traditional dairy products, as well as dairy products enriched with probiotic bacteria.

The line of products based on starter cultures includes:

Ryazhenka Fermented baked milk, Varenets, Sour Cream, Cottage Cheese, Yogurt, Matsun (Matsoni), Kumis, Southern Yogurt, Bifacil, Acidophilin, Acidophilus Yogurt, Bifatonic and Bifiton.

Probiotic starter cultures contain compositions of **bifidus bacteria**, **lactobacilli** and **propionic acid bacteria**. In addition, Vector-BiAlgam, PC, offers a package of regulatory and technological documentation for the manufacture of probiotic products for dairy industry enterprises.

Dry biomass of probiotic bacteria

Dry biomass of probiotic microorganisms "**Astera**" is a lyophilized biomass of microorganisms of the genus **Bifidobacterium** or **Lactobacillus**, grown on a culture medium with or without the addition of growth-stimulating factors.

The biomass is intended for use in the food industry, specifically for the production of probiotic functional food products, or for the production of dietary supplements.

- ❑ The "Astera" biomass is characterized by a high titer of beneficial bacteria. Its contains following amounts of Bifidobacterium: $1 \cdot 10^{10}$ CFU / g, and Lactobacillus bacteria: $1 \cdot 10^9$ CFU / g.
- ❑ Multi-strain compositions can be developed at individual orders, depending on the intended use of Biomass.

Bioproducts

With the help of its own production facilities and research base, the company manufactures following probiotic functional food products for daily use for therapeutic and dietary nutrition of children and adults:

- ❑ **"NariLac-Forte-V"** is a complex bioproduct for functional nutrition containing a high concentration of live probiotic microorganisms.
- ❑ **Fermented milk products** enriched with probiotic cultures of the **"BIFIDOM"** series for daily use: **Bifatonic, Bifacil and Bifidokefir**
- ❑ Starter cultures of probiotic cultures indented for direct use for preparation of fermented milk products at home: **Bio-Yoghurt, Bio-Snezhok, Bifatonic and Bifacil**



The mission of Vector-BiAlgam, PC is aimed at the protection and restoration of the human health

Lysates of probiotic microorganisms

Lysates of probiotic bacteria are the product of bacterial cell cleavage and includes fragments of bacterial cell walls and intracellular contents.

Lysates have a wide range of properties, such as immunomodulating, anti-inflammatory, antiallergic, antioxidant and membrane-stabilizing properties.

Vector-BiAlgam, PC, produces the following types of lysates:

- Liquid bifidus bacteria lysates "BifiLys"**
It consists of 6 strains of bifidus bacteria of the following species: *B. longum*, *B. bifidum*, *B. adolescentis*
- Liquid lysate of lactobacillus "LactoLys"**
It contains 6 to 8 strains of lactobacilli species *L. acidophilus*, *L. fermentum*, *L. bulgaricus*, *Str. Thermophilus*
- Liquid lysate of propionic acid bacteria "PropioLys"**
It contains 2 strain propionic acid bacteria of the species *Propionibacterium shermani*



Lysates are used in various industries:

- Food industry
- Biotechnology
- Medicine and cosmetology



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CONTRACT MANUFACTURING BY VECTOR-BIALGAM, PC

- ❑ Preparing and filling injectable solutions:
syringe dispensers
ampoules
vials
- ❑ Development and production of probiotics

Contract manufacturing of injectable products

Vector-BiAlgam, PC provides contract manufacturing services involving preparation and filling of injectable pharmaceuticals in syringe dispensers, ampoules and vials, as well as preparation and filling of probiotics at the company's own production facilities.

Vector-BiAlgam, PC provides:

- ❑ The following operation cycles performed: preparation (preparation of the finished medicine from the pharmaceutical substance), in-bulk filling, labeling and packaging
- ❑ Preparations filled in full compliance with GMP standards
- ❑ Full compliance with the Customer's requirements for the production cycle and product quality control.

A filling section:

- ❑ Line for filling injectable preparations into syringe dispensers (pre-filled syringes)
- ❑ Combined line for filling injectable preparations into ampoules and vials

Line for filling injectable preparations into syringe dispensers

- ❑ Capacity: 9,000 pcs/hour
- ❑ Filling various injectable preparations (including vaccines, serums, anatoxins, antidotes, vitamins, preparations based on recombinant proteins, etc.)

The line consists of:

- ❑ Main unit (syringe filling machine, ROTA, Germany)
- ❑ Denester (removing syringes from the original packaging)
- ❑ Inspection machine (control of mechanical impurities, level of filling, presence of the piston)
- ❑ Machine for the insertion of rods, backstoppers and marking
- ❑ Blistering machine (individual blister cells)



Combined line for filling injectable preparations into ampoules and vials

- ❑ Capacity: to 9,000 ampoules/ hour and to 6,000 vials/hour
- ❑ Filling various injectable preparations (including vaccines, serums, anatoxins, antidotes, vitamins, preparations based on recombinant proteins, etc.)

The line consists of:

- ❑ Washing machine for ampoules and vials (WR16)
- ❑ Depyrogenation tunnel (DEPYR601) for sterilization of ampoules and vials)
- ❑ Filling and sealing machine for ampoules and vials RSF03 with a capping system.
- ❑ Automatic inspection machine (control of mechanical impurities, level of filling, tightness) A35LD
- ❑ Automatic labeling machine RL-F30



Development and production of multi-component probiotics and synbiotics

"Vector-BiAlgam", PC provides services of contract production of probiotic drugs from the substance to the finished product. The producer strain is the key element for the most bio-products. The collection Vector-BiAlgam, PC has more than 80 probiotic producer strains, which you can use to create a variety of effective biological products.

Forms of preparations:

- Liquid forms of dietary supplements and probiotics in vials or bottles
- Solid forms of probiotic and synbiotic preparations: pills, powders in sachets and capsules.

The company conducts the following processes under controlled conditions:

- Fermentation
- Immobilization
- Aseptic filling
- Lyophilization
- Mixing dry components
- Capsule filling
- Packing in sachets-bags



Development and production of multi-component probiotics and synbiotics

Production capacity of the probiotic filling line

- ❑ Production of liquid biomass by deep fermentation: up to 10,000 liters/month.
- ❑ Aseptic filling of liquid probiotics: up to 300,000 vials/month
- ❑ Production of dry biomass by lyophilization: up to 40 kg/month
- ❑ Production of probiotics in capsule form: up to 500,000 pcs/month
- ❑ Sterile enzymatic bacterial lysates: up to 600 liters/month

Development and production of multi-component probiotics and synbiotics consists of the following main stages:

- ❑ Development of the preparation microbial basis from different types of probiotic bacteria. This stage is quite complex, since such conditions must be created in which one type of bacteria would not suppress another one. Consortia must be cultivated multiple times and bacteria must be rejected based on following parameters: titer, preservation and activity.
- ❑ Selecting and using prebiotic components for preparations: e.g., lactulose (stimulates the growth of bifidus bacteria and lactobacilli), vitamin C (involved in redox processes), myelokariocyte (elimination of toxins and radionuclides). Incompatibility of components is a challenge that must be tackled
- ❑ Process optimization: fermentation, freeze-drying, mixing, encapsulation.

Vector-BiAlagam, PC

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