caff
Better Access.
Better Health.

CZECH PHARMA MANUFACTURERS BOOKLET

LIFE 4.0 SCIENCES

B R N O

jihomoravský kraj

Better Access.
Better Health.

Content

This brochure was funded with the support of the statutory city of Brno within the project "Connecting Life Sciences – Life Sciences 4.0" from a grant from the budget of the city of Brno, grant contract no. 1523094994.

Implemented with financial support from the South Moravian Region within the project "Life Sciences 4.0 - Regional Office for Networking and Partnership Support," contract no. JMK 091657/24/ORR.

CZECH ASSOCIATION OF PHARMACEUTICAL COMPANIES

Photo source: oncomed manufacturing

1/ The Czech Republic and the **Pharmaceutical Industry**

Rich tradition of pharmaceutical manufacturing

Dozens of pharmaceutical manufacturers are involved in all phases of the production cycle, from raw materials and intermediates to APIs, final dosage forms, adjustments and packaging.

The top 10 manufacturers in the Czech Republic represent 95% of the country's pharmaceutical production (8 of them are members of the ČAFF Association).

The activities of pharmaceutical manufacturers in the Czech Republic are primarily focused on the development and production of off-patent medicines, incl. Value Added Medicines.

Foreign companies representations in the innovative sector collaborate with numerous prominent research institutions and leading healthcare providers, particularly in the area of clinical trials.

Academic institutions are proactive in collaborating with the industrial sector. The two largest universities in the Czech Republic work with pharmaceutical companies in pharmaceutical, chemical, and technological fields.

An ecosystem for cooperation between large manufacturers, academic and research institutions, start-ups and spin-offs based on technology platforms is being created with the aim of developing an environment in the Czech Republic that supports the pharmaceutical industry.

The pharmaceutical industry has been identified by the Czech government as a strategic industrial sector (as part of the new Economic Strategy of the Czech Republic). There is ongoing cooperation with the government in the development of R&D and manufacturing activities.

12.2
thousands

Number of employees in the manufacturing pharmaceutical industry in the Czech Republic

80,000
eur

Gross value added per employee (the pharmaceutical industry in the Czech Republic has one of the highest added value per employee)

1.7
%

Share of the pharmaceutical industry in GVA in the Czech Republic

2/ Pharmaceutical market in the Czech Republic

470
Market Authorisation Holders

9,900
variants of medicines active
8,118 Rx (82%)
1,183 OTC (12%)
633 others (6%)

10.5 mln
Country population

64,500
variants of medicines registered for the Czech market

Big 4
distributors
= 96% market control

3,930
mln EUR
Pharma market value in the Czech Republic

2,800
pharmacies
41% virtual chain
38% chain
21% non-chain

+7.8%
Average yearly growth in sales over the last 10 years

3/ The Czech Association of Pharmaceutical Companies (ČAFF)

- The Czech Association of Pharmaceutical Companies (ČAFF) brings together the leading manufacturers and suppliers of generic and biosimilar medicines in the Czech Republic, including domestic pharmaceutical producers.
- It has more 32 members, 12 of which have manufacturing sites in the Czech Republic. Together, their production represents the vast majority of what is produced in CZ.
- ČAFF members supply around 4,000 variants of medicinal products in CZ, representing 117 million packages to the Czech market annually, worth 840 mln EUR.
- Their portfolio includes oncology, neurology, diabetology, dermatology, cardiology, gastroenterology, and radiopharmaceuticals. They also supply the Czech market with antibiotics, painkillers, and anti-inflammatory drugs and provide flu vaccines for Czech patients.

The member companies of ČAFF supplied medicinal products with a total value of over CZK **17 billion**.

The member companies of ČAFF have supplied the Czech market with more than **4,000** types of medicinal products.

10 out of **20** of the most sold generic medicinal products were supplied by the member companies of ČAFF.

CZECH ASSOCIATION OF PHARMACEUTICAL COMPANIES

Our partners

ČAFF is a member of the Czech Chamber of Commerce, the Confederation of Industry of the Czech Republic, and the Union of Employers' Associations of the Czech Republic, a technology platform Life Sciences 4.0.

MINISTERSTVO ZDRAVOTNICTVÍ ČESKÉ REPUBLIKY

VŠEOBECNÁ ZDRAVOTNÍ POJIŠŤOVNA ČESKÉ REPUBLIKY

Česká lékárnická komora

medicines for europe
better access. better health.

SÚKL

AVEL
asociace velkodistributorů léčiv

ASOCIACE PROVOZOVATELŮ LÉKÁRENSKÝCH SÍTÍ

HOSPODÁŘSKÁ KOMORA ČESKÉ REPUBLIKY

U2S
UNIE ZAMĚSTNAVATELSKÝCH SVAZŮ ČESKÉ REPUBLIKY

aifp
Asociace inovativního farmaceutického průmyslu

LIFE 4.0 SCIENCES

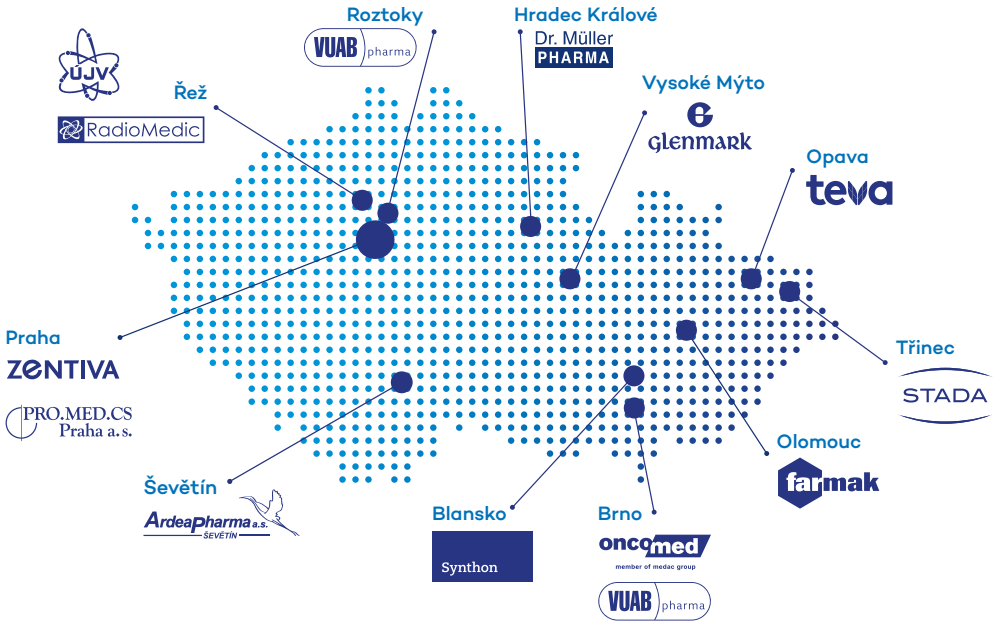
SVAZ ZDRAVOTNÍCH POJIŠŤOVEN ČR

4/ What we do

- Advocacy for the pharma industry as a whole; governmental affairs services.
- We represent the pharmaceutical industry in working groups and advisory boards at both the governmental level and within regulatory authorities.
- We facilitate connections between member companies and regulatory authorities, service providers in the fields of market access and regulatory affairs, as well as key stakeholders.
- Monitoring European and Czech legislation and decision-making practices of authorities in areas relevant to marketing authorization holders and pharmaceutical manufacturers.
- Providing highly specialized consultancy in pharmaceutical regulation, particularly in market access.
- Bringing together representatives of member companies to share information and experiences, and to prepare joint positions and strategies.

** ČAFF is the primary contact point for the Ministry of Industry and Trade of the Czech Republic and the Ministry of Health of the Czech Republic in communication with pharmaceutical manufacturers and marketing authorization holders of off-patent medicines.*

5/ ČAFF Members with manufacturing **sites** in the Czech Republic



Member Companies

ČAFF member companies produce or supply a wide range of medicines, including life-saving drugs aimed at treating conditions such as:

- anaphylactic shock, cardiac arrest,
- chronic heart failure, atrial fibrillation,
- all forms of thrombosis,
- ow blood pressure,
- arthritis, rheumatoid arthritis,
- bronchial asthma,
- organ transplant rejection, psoriasis,
- atopic dermatitis,
- Parkinson's disease, multiple sclerosis,
- epilepsy, cancer.

APIs produced by ČAFF member companies, e.g.:

- epinephrine,
- nystatin,
- dacarbazine,
- norepinephrine,
- digoxin,
- heparin,
- dofetilid
- prednisone,
- cyclosporine,
- warfarin,
- riluzol,
- mycophenolate mofetil.

ČAFF Manufacturing Working Group and **Life Sciences 4.0 cluster**

ČAFF is also a participant in the Regional Chamber of Commerce Brno's project, the Life Sciences 4.0 technological platform, which aims to support pharmaceutical science and the pharmaceutical industry.

Together we actively facilitate connections between industry, government institutions, scientific organizations, universities, and biotech startups to ensure that the pharmaceutical sector contributes to transforming the Czech economy towards higher added value.


Inovace
pro život
Innovation
Dostupnost zavedených léčivých přípravků
v Česku
jak posílit odolnost a konkurenceschopnost národními
nástroji lékové politiky – 2 kazuistiky
Tomáš Doležal
COGVIO

6/ The Czech Association of Pharmaceutical Companies (ČAFF)

- We established a strong partnership with the Czech Ministry of Industry and Trade and became part of its Working Group for the Pharmaceutical Industry, with the ČAFF Executive Director serving as its vice-chairman.
- We collaborated with Ministry of Health in developing a methodology for the procurement of medicines in hospitals through public tenders.
- We successfully advocated for a legislative change that classified selected pharmaceutical manufacturers as protected gas consumers.
- We successfully advocated for changes in strict regulations for over-the-counter products, allowing pharmaceutical companies to request permission to release foreign-language batches of these medicines in cases of supply shortages.
- We pushed for the completion of a sectoral analysis of the pharmaceutical manufacturing industry in the Czech Republic.
- As a result of our efforts, the Czech government recognized the Czech pharmaceutical manufacturing industry as a strategic sector in the Economic Strategy of the Czech Republic.
- Our member companies donated hundreds of thousands of medicine packages to Ukraine. As an exclusive partner of the Czech Ministry of Health, ČAFF developed a model for the donation and distribution of medicines for humanitarian purposes.

... and many other achievements.

7/ ČAFF and Media

900

Media mentions

Number of media appearances 2022–2024

2 078.21

Gross Rating Points

2022–2024

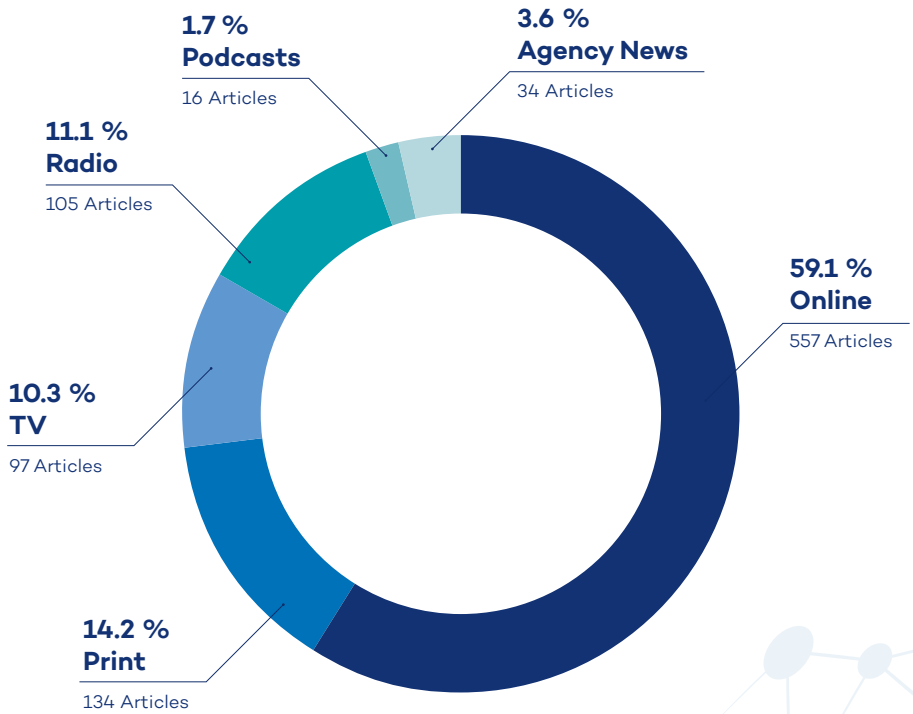
35

Press releases

Number of published Press releases 2022–2024

Social media

Including Filip Vrubels LinkedIn personal account.



Mediatyp

- Online
- Print
- TV
- Radio
- Podcasts
- Agency News
- Newsletters
- Social media

ČAFF and Media

- **Engaging with the media**
  Active communication with the media promotes the views and interests of ČAFF members.
- **Organising media breakfasts**
  Regularly scheduled breakfast meetings with journalists facilitate open dialogue and media engagement.
- **Issuing press releases**
  Press releases are issued to ensure timely dissemination of important updates and developments.
- **Promoting educational content**
  Educational videos are promoted via LCD screens in Czech hospitals, raising awareness on key topics.
- **Crisis management response**
  Timely and effective responses are provided in times of crisis to ensure clear communication and resolution.
- **Offering media monitoring and advisory**
  Daily media monitoring and advisory services are available to all member companies, providing timely insights and guidance.
- **Publishing monthly newsletters**
  A comprehensive monthly newsletter is published, offering detailed updates on ČAFF's activities and initiatives.

Česká televize · Český rozhlas · ČTK · Frekvence 1 · Hospodářské noviny · Forbes · Medical Tribune · DNES · zdravotnický deník · Novinky.cz

"Communication is the beginning of understanding."

Josepf Priestley
English chemist, natural philosopher, theologian

8/ Contact

The Czech Association of Pharmaceutical Companies (ČAFF)

Vista House
Na Pankráci 1618/30
140 00 Prague
Czech Republic

caff@caff.eu
www.caff.eu

čaff

Better Access.
Better Health.

Filip Vrubel

ČAFF Executive Director

filip.vrubel@caff.eu

LIFE SCIENCES 4.0

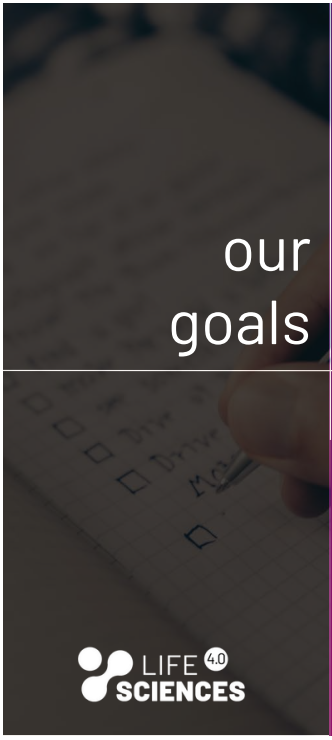

LIFE 4.0
SCIENCES

about us

We are a cluster connecting businesses and universities in the life sciences. We enable experts to meet and collaborate. The aim is to support both local and supraregional business environment and to popularise these topics.

Meet people in the life sciences field. We create opportunities for you, develop your ideas, support businesses. Take advantage of the opportunity to create a life sciences environment together.

Life Sciences 4.0 is under the umbrella of the Brno Regional Chamber of Commerce and its cooperating partners are Masaryk University, Brno University of Technology and especially the Statutory City of Brno and South Moravian region which supports our activities with subsidies.



our goals

- Support regional and nationwide business environment
- Create an environment and opportunities for meeting and cooperation
- Organise cooperation events, joint projects, trade missions
- Inform about news, business opportunities
- Lobbying
- Popularise life sciences topics
- Enhance the attractiveness of the research environment

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REGIONÁLNÍ HOSPODÁŘSKÁ KOMORA BRNO

jmk

strategic areas

01 MED-TECH

- Telemedicine
- Medical devices
- In-vitro diagnostics

02 PHARMA

- Pharmaceutical companies
- Manufacturing
- Cooperation with ČAFF

03 WELL BEING

- Cosmetology
- Food supplements

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REGIONÁLNÍ HOSPODÁŘSKÁ KOMORA BRNO

jmk

Legislative insights and implementation support

We help you tackle pressing topics, focusing on the smooth implementation of new legislative measures.

Custom tailored grant development

Receive expert guidance in crafting proposals that align with your strategic goals and maximize funding opportunities.

Processing your insights and proposals

We turn your ideas into actionable plans, fostering growth and innovation in your business.

Opportunities to share and exchange essential information

Benefit from a dynamic network where crucial knowledge and best practices are exchanged freely.

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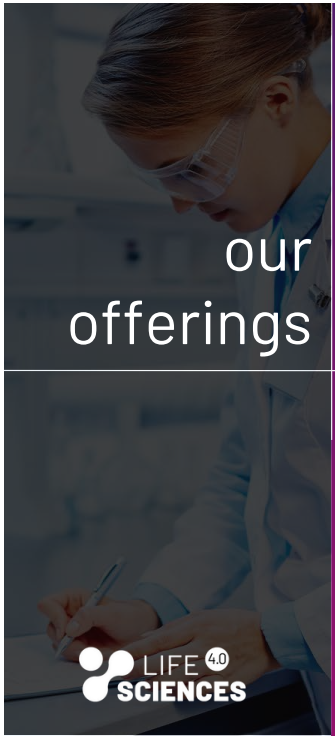
jmk



Podcasts to elevate your brand visibility

Tap into the power of podcasting to engage your audience and increase your reach.

Roundtables on topics you choose

Lead conversations that matter, with expert-driven discussions tailored to your interests.

Event spaces for your gatherings

Host your meetings, events, and activities in our spaces designed for creativity and collaboration.

Join existing LS 4.0 workgroups (or initiate new ones)

Collaborate with industry experts in ongoing workgroups or create your own to shape the future of your field.

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REGIONÁLNÍ HOSPODÁŘSKÁ KOMORA BRNO

jmk

Let’s unlock exciting opportunities for collaboration together!

www.lifesciences40.cz

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LIFE 4.0 SCIENCES

MEMBERS

1

DR. MULLER PHARMA

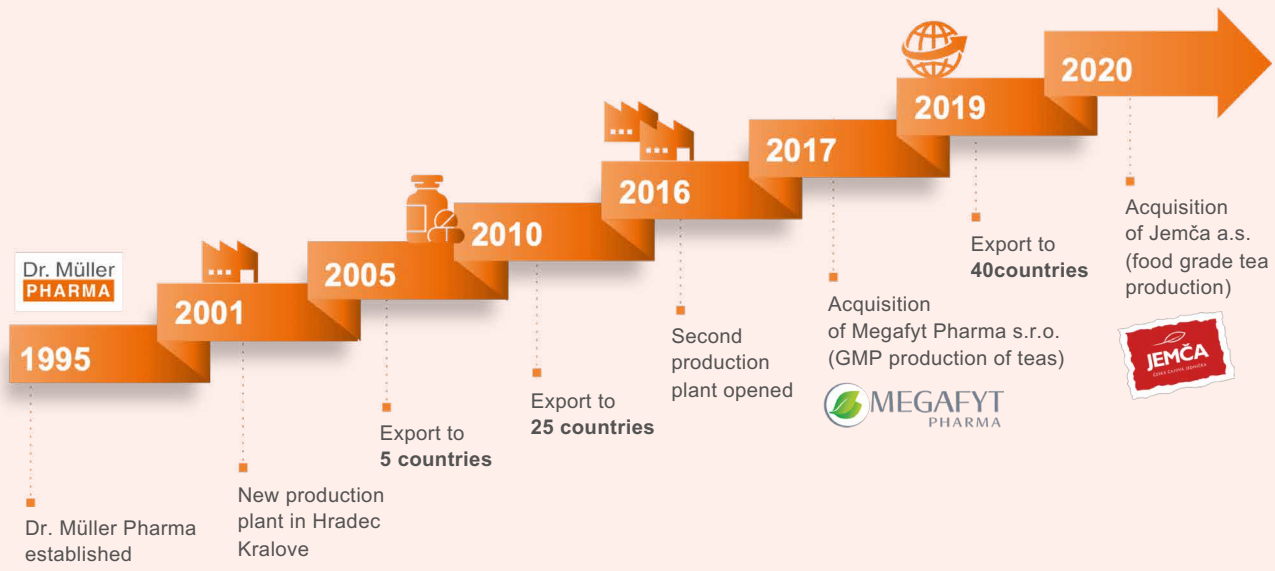

Dr. Müller
PHARMA
COMPANY PRESENTATION

Introduction

- Dr. Müller Pharma s.r.o. is a producer of **medicinal products, medicinal herbal teas, medical devices, food supplements and cosmetics**.
- It is a family company **established in 1995** with headquaters in Hradec Králové, Czech Republic, currently having **180 employees.**
- Dr. Müller Pharma’s branded products are well established on the Czech and Slovakian market since 1995.
- Yearly turnover (2023) is 50 MIO EUR
- Approximately 60% of the production is exported to more than 40 countries worldwide, e.g. Denmark, Sweden, Germany, Poland, Austria, Switzerland, Slovenia, Bulgaria, Baltics, Kosovo, Kuwait, Katar, Morocco, Egypt, Vietnam, Mongolia, Hong Kong, USA.

Milestones

Dr. Müller PHARMA



Portfolio of Dosage Forms

Dr. Müller PHARMA

DOSAGE FORMS:
Non-sterile semi-solids

TOTAL OUTPUT
4-5.000 units á 100 ml/hour
(4 production lines)

DOSAGE FORMS:
Non-sterile liquids

TOTAL OUTPUT
2.500 units á 100 ml/hour
(2 production lines)

DOSAGE FORMS:
Suppositories & vaginal globules

TOTAL OUTPUT
60.000 units/hour
(1, 2nd production lines in 2025)

DOSAGE FORMS:
Hard boiled lozenges

TOTAL OUTPUT:
2 tons/hour
(1, 2nd production lines in 2026)

DOSAGE FORMS:
Tablets

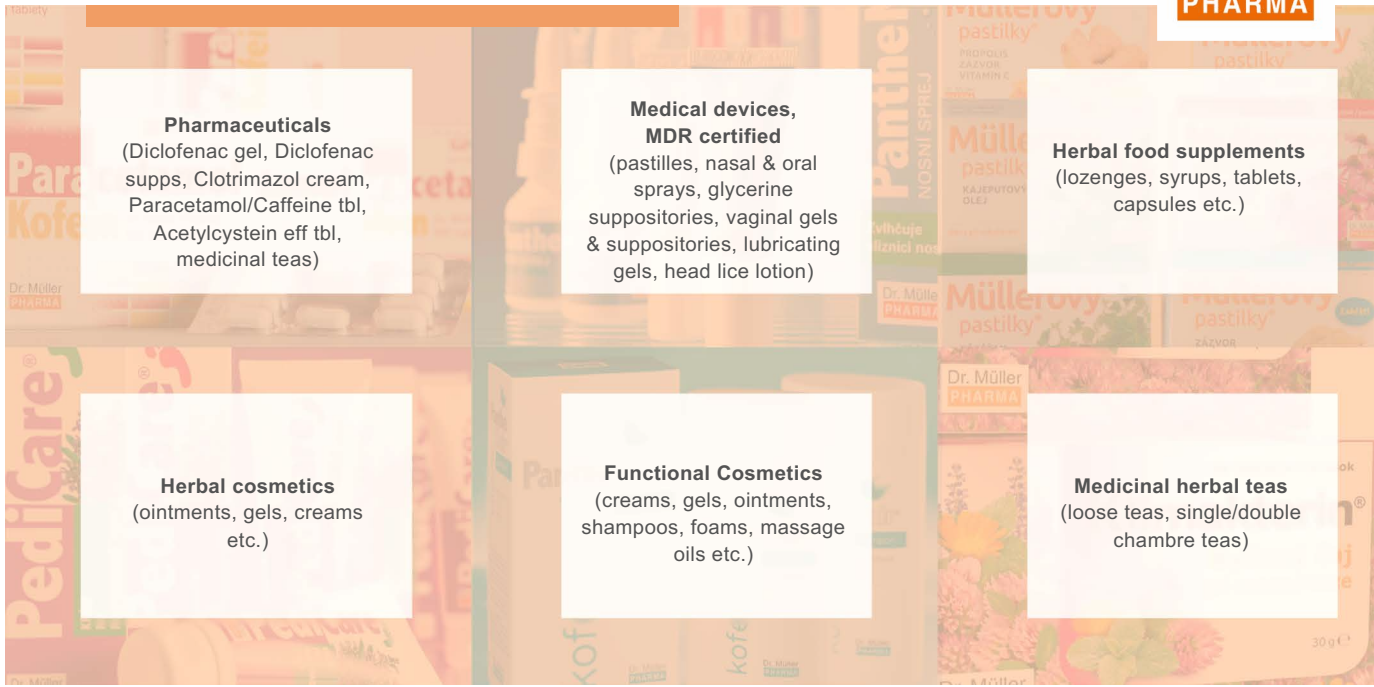
TOTAL OUTPUT:
150.000 units/hour
(1 production line)

DOSAGE FORMS:
Medicinal teas

TOTAL OUTPUT:
4-5.000 units á 100 ml/hour
(4 production lines)

Portfolio of Branded Products

Dr. Müller PHARMA



Pharmaceuticals
(Diclofenac gel, Diclofenac supps, Clotrimazol cream, Paracetamol/Caffeine tbl, Acetylcystein eff tbl, medicinal teas)

Medical devices, MDR certified
(pastilles, nasal & oral sprays, glycerine suppositories, vaginal gels & suppositories, lubricating gels, head lice lotion)

Herbal food supplements
(lozenges, syrups, tablets, capsules etc.)

Herbal cosmetics
(ointments, gels, creams etc.)

Functional Cosmetics
(creams, gels, ointments, shampoos, foams, massage oils etc.)

Medicinal herbal teas
(loose teas, single/double chambre teas)

Certifications

- **EU-cGMP for**
  - Manufacturing
    - Non sterile semi-solids
    - Liquids for internal and external use
    - Suppositories and vaginal globules
  - Primary & secondary packaging
  - Distribution
  - Warehousing
  - Quality control
- **ISO 9001, 13485, 22000**
- **IFS Food**

Services offered

- Private label manufacturing
- Contract manufacturing & packaging (customized products)
- Development of new products
- QA, QC and QP support
- Import to EEA from third countries
- Regulatory Consulting
- Quality control services

Looking for

- Distributors seeking private label manufacturers
- Distributors of branded products of Dr. Müller Pharma

Dr. Müller PHARMA

Contact us

Dr. Müller Pharma s.r.o.
U Mostku 182
503 41 Hradec Králové
Czech Republic

info@muller-pharma.cz
+420 495809111
www.muller-pharma.com

MEMBERS

2

INTERLACTO GROUP

Interlacto Group
pharmaceutical division

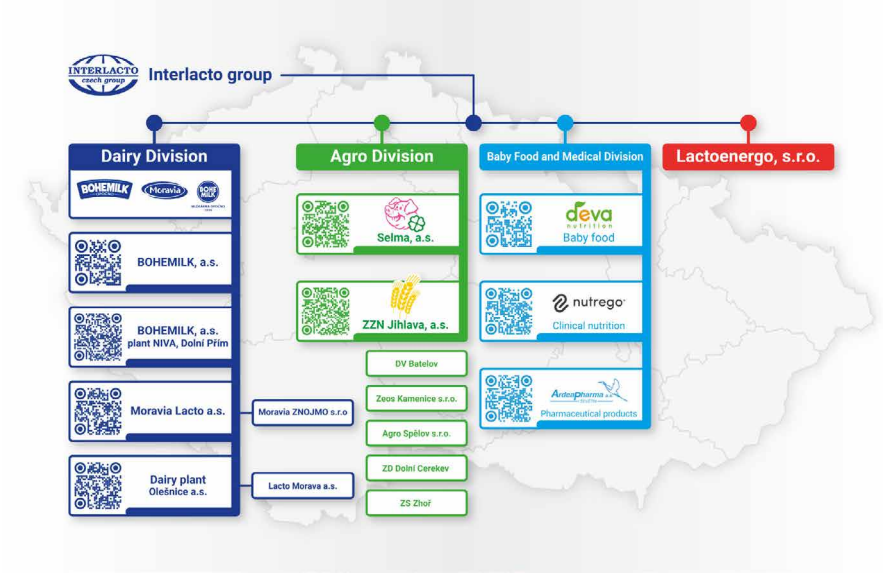
contract manufacturing of sterile and non-sterile liquid dosage forms, solutions for infusion Ardeapharma product line

private label manufacturing of clinical nutrition, Nutrego product line

stable source of blood plasma for medical processing

Interlacto, Ltd.

- **Participant:** MUDr. Ondřej Gojiš, Ph.D.; ondrej.gojis@interlacto.cz; http://www.interlacto.cz/



- **1991** – establishment of the company Interlacto Ltd., its core business – export of the dairy products
- **1994** – majority interest in dairy plant Jihlava (presently Moravia Lacto, a.s.)
- **2000** – purchase of interest in agriculture-oriented companies in the Jihlava region
- **2006 – 2023** – purchase of dairy plant Olešnice, dairy plant Bohemilk, a.s., dairy plant Niva Dolní Přím
- **2018 – 2022** – expansion into new business areas - baby fruit purees and fruit drinks production (Deva Nutrition a.s.), products of clinical nutrition (Nutrego brand) and pharmaceutical products from ionic solutions to enteral nutrition (Ardeapharma, a.s.)
- **2023** - acquisition of Plazma Plus company with 12 modern plasma collection centers in the Czech Republic

INTERLACTO
czech group

Where we export our products

NUTREGO

- **Participant(s):** MUDr. Ondřej Gojiš, Ph.D.
- **Email:** ondrej.gojis@interlacto.cz
- **Web:** https://www.nutrego.cz/
- **Products and Services:**

Clinical nutrition Nutrego is produced in the Czech Republic and complies with the highest quality standards. All our products are registered by the State Institute for Drug Control as foods for special clinical purposes. Nutrego can also be got from a network of pharmacies as an over-the-counter medicine. Actual production with the capacity of 30 000 000 pcs per year (expansion is feasible). The dairy plant had all modern technologies available – both for the production and packaging of dairy products and baby food (holder of IFC and ISO)

Together with its partners, provides services in the fields of nutrition therapy. We help to ensure comprehenssive services in the area of nutritional care for malnourished patients or patients with eating disorders, oncological diseases, patients before or after a surgery, patients after gastrointestinal surgeries and last but not least, for geriatric patients. The company was founded in 2018 and is fully controlled by the joint-stock company Charing Cross Scientific a.s.

ARDEAPHARMA a.s.

- **Participant(s):** MUDr. Ondřej Gojiš, Ph.D.
- **Email:** ondrej.gojis@interlacto.cz
- **Web:** http://www.ardeapharma.cz/
- **Products and Services:**

ARDEAPHARMA a.s. is a producer of pharmaceutical products with a rich history. The company has operated on the market since 1996. It was created by way of a division of the original large-scale supplier joint-stock company into two independent entities. The current company was created from the part which had focused on pharmaceutical production. We hold a number of certificates (SVP GMP, ISO, laboratory for quality assurance of medical and auxiliary substances).

Our main program is the production of injection, infusion and other parenteral solutions filled into glass containers. Furthermore, we carry out chemical, microbiological and biological tests for other pharmaceutical and medical manufacturers. We also sell packaging material for pharmaceutical purposes. Production with the capacity of 3 000 000 pcs per year (production of injection, infusion and other parenteral solutions).

PLAZMA PLUS s.r.o.

- **Participant(s):** MUDr. Ondřej Gojiš, Ph.D.
- **Email:** ondrej.gojis@interlacto.cz
- **Web:** http://www.plazmaplus.com/
- **Products and Services:**

Plazma Plus is one of the leading companies in the Czech Republic specializing in blood plasma collection. Thanks to a network of modern, well-equipped centers and a team of more than 300 experienced healthcare professionals, we ensure safe and high-quality plasma collection, which is an irreplaceable resource for the production of life-saving medicines. Our centers, located in many Czech cities, meet the highest standards of quality and safety.

Our primary goal is to help patients access plasma-derived medicines, which are an essential resource in the treatment of various diseases. To achieve this goal, we have gradually built a network of collection centers, with our first branch opening in 2019.

Why partner with us ?

Interlacto's pharmaceutical division is committed to offering top-quality products and services, adhering to strict regulatory standards. We are a reliable partner for companies looking for high-quality production and innovative solutions in clinical nutrition, solutions for infusion, GMP certified manufacturing and blood plasma collection.

You can contact us directly or check our websites:

Jiri Hanzlik, Global Business Development Manager
email: hanzlik@nutrego.cz phone: +420 720 834 366

www.nutrego,cz www.ardeapharma.cz www.plazmaplus.com

MEMBERS

3

ONCOMED MANUFACTURING A.S.


345
0.00034
oncomed manufacturing a.s.
oncomed
member of medac group

who are we?

We are oncomed – a Contract Development and Manufacturing Organization (CDMO) specialized in aseptic processing of injectables in clinical and commercial scales. As a part of CDMO medac group, we focus on high potent and low potent drugs, biologicals and ADCs.

oncomed
member of medac group

about us

oncomed
member of medac group

portfolio scope

formulations

- liquid
- liquid terminally sterilized
- freeze-dried

dosage forms

- vials
- syringes
- (cartridges)

manufacturing scale

- **small scale** (pre-clinical, clinical phase I & II)
- **large scale** (clinical phase III, commercial)

molecule type

- high potent
- low potent
- biologics
- ADCs

oncomed
member of medac group

production line 1

Production line 1 uses a RABS filling line concept that allows us to produce batches from 10 to 1,000 liters using stainless steel technology. Our line 1 is equipped with two freeze dryers with shelf area of 17 sqm each. The vial fill volumes range between 1 ml and 200 ml.

oncomed
member of medac group

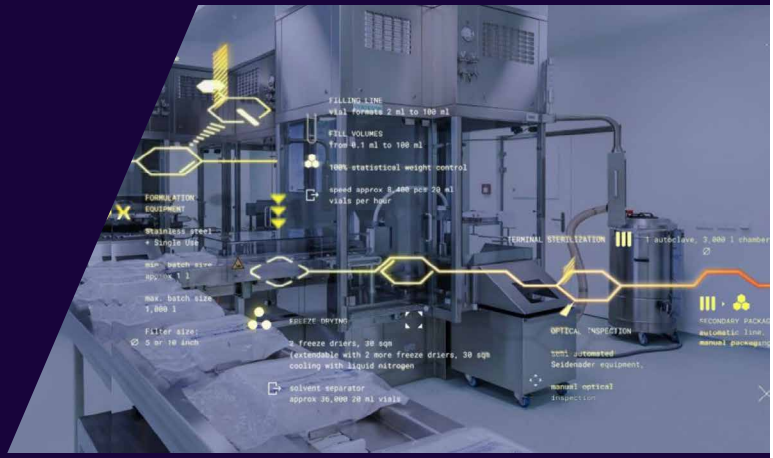
production line 2

Production line 2 uses an isolator concept and allows us to produce batches from 2 to 1,000 liters using stainless steel or single-use system technology. It is equipped with one freeze dryer with shelf area of 12 sqm. The vial fill volumes range between 0.5 ml and 100 ml

oncomed
member of medac group

production line 3

Production line 3 produces pre-filled syringes and in the future cartridges. The line uses stainless steel or a single-use system filling & filtration technology and its capacity is more than 100 million syringes (1mL) per year in batch sizes 1 l up to 500 l. The filling volumes range between 0.1 ml and 50 ml.



oncomed
member of medac group

GMP status

- European Authorities
- MFDS South Korea
- ANVISA Brazil
- Russian Authority
- Saudi Arabia Authority
- Kazachstan Authority

- US FDA expected 2025/26

oncomed
member of medac group

development services

Our in-house capabilities further support process development, optimization and scale-up. Stability studies, analytical and microbiological method development & validation are assured in-house and/or in cooperation with qualified external partners.

oncomed
member of medac group

clinical supply

Clinical batches are manufactured on commercial lines which assures cost savings related to scale-up and commercial supplies of the products. We offer various vial formats in wide range of batch sizes in order to cover all clinical phases.

commercial supply

We offer various vial formats in wide range of batch sizes in order to fulfil the commercial needs of our partners and adapt to unexpected market changes. The commercial supplies are assured via agile and seamless technology transfer. By using a single-use system technology, we offer commercial Fill & Finish services also for biomolecules and high-price APIs.

oncomed
member of medac group

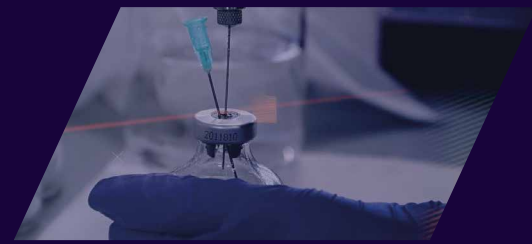
quality control

analytical laboratory

- HPLC (DAD + refractometric detection)
- LS-MS, GC-FID, UV, pH, TOC, FTIR
- Density meter
- Laser subvisible particle counter
- Microscope for particle count
- KF titrator (volumetric and coulometric)
- Potentiometric titrator
- Glove boxes and other common lab equipment

microbiological laboratory

- 2 biohazard boxes
- LAL test (gel method, turbidimetric method)
- Identification
- 9 incubators
- Clean rooms D – ready to install sterility isolator



stability

We are able to perform:

- registration and ongoing stability studies according to ICH Q1A(R2)
- photostability studies according to ICH Q1E
- in-use, infusion and transport studies (from -25 °C to +50 °C)

conditions	total volume of samples that can be stored
2 – 8 °C	1,500 l
25 ± 2 °C / 60 ± 5% RH	5,000 l
30 ± 2 °C / 65 ± 5% RH	5,000 l
30 ± 2 °C / 75 ± 5% RH	880 l
40 ± 2 °C / 75 ± 5% RH	450 l

oncomed
member of medac group

optical inspection

We offer semi-automated inspection for vials and fully automated inspection for syringes, or manual inspection by highly qualified operators for both.

oncomed
member of medac group

packaging & bulk release

We offer technical bulk release for further processing by our team of qualified persons. Packaging to market is assured via qualified external partner.

oncomed
member of medac group

contacts

Radek Fialka
Chief Business Officer

mobile: +420 602 435 374
e-mail: fialka@oncomed.cz

Zuzana Jorová
Marketing & Sales Manager

mobile: +420 777 481 815
e-mail: jorova@oncomed.cz

www.oncomed.cz

MEMBERS

4

RADIOMECDIC S.R.O.

RadioMedic s.r.o.

Manufacturer of Radiopharmaceuticals

Husinec-Řež 289, Řež, Czech Republic

Web: www.radiomedic.cz

CIN: 28389638

VATIN: CZ28389638

UJV Group
PEOPLE | INNOVATION | TECHNOLOGY

RadioMedic s.r.o. – a member of the UJV Group

UJV Group
PEOPLE | INNOVATION | TECHNOLOGY

NUCLEAR RESEARCH INSTITUTE

CVŘ Research Centre Řež

VZÚ PLZEŇ

ŠKODA PRAHA

RadioMedic

RadioMedic

2

RadioMedic s.r.o. – History Outline

- Date of establishment: May 12, 2008 - Spin-off of the Nuclear Physics Institute CAS, p.r.i.
- Change of RadioMedic s.r.o. owner: May 15, 2023 - 100% ownership share of ÚJV Řež, a.s.
  - Consolidation of supply capacity
  - More optimized availability of medicinal products and expansion of top services in the healthcare sector
- A total of 15 years of experience in the radiopharmaceutical market 2009-2024
- Equity capital: 2 million euros

3

RadioMedic s.r.o. – Professional Focus

- Production and distribution of PET/SPECT radiopharmaceutical medicinal products
- Production and distribution of PET radiopharmaceutical investigational medicinal products
- PET radiopharmaceuticals approved under the Specific Treatment Program
- Own research and development of the innovative radiopharmaceuticals
- Implementation of radiopharmaceutical production technology under GMP

4

RadioMedic s.r.o. – Portfolio PET

- **18F-FDG Fludeoxyglucose (^{18}F)**

Tumor cells visualization / myocardial viability studies / visualization of focal infectious and sterile inflammation including fever of unknown origin / specific neurological diagnosis

- **18F-FLT Fludeoxythymidine (^{18}F)**

Topographic detection of malignant tumors / detection and monitoring of tumor proliferation / evaluation of tumor stages / detection of metastasis of various origin

- **18F-NaF Sodium Fluoride (^{18}F)**

Detection and monitoring of bone tumors / regional bone changes and total metabolic turnover in bone system investigation / degenerative, traumatic and inflammatory bone diseases detection

- **18F-FMISO Fluoromisonidazole (^{18}F)**

Non-invasive detection of tumor hypoxia / accumulation of 18F-FMISO = decreased concentration of oxygen

- **18F-FES Fluoroestradiol (^{18}F)**

Detection of estrogen receptor (ER) positive lesions / adjunct to biopsy in patients with recurrent or metastatic breast cancer (MBC)

RadioMedic

RadioMedic s.r.o. – Portfolio SPECT

- Radionuclide Generator $^{81}Rb/^{81m}Kr$
- Investigation of lung ventilation – pulmonary embolism, chronic obstruction disease, chronic bronchitis, asthma, bronchogenic carcinoma and pre-operative examination
- Low radiation exposure of the patients / non-radioactive waste
- Combination of ^{81m}Kr (190.4 keV) and ^{99m}Tc (140.5 keV) enables parallel investigation of lung ventilation and perfusion providing a power-full diagnostic tools for pulmonary embolism

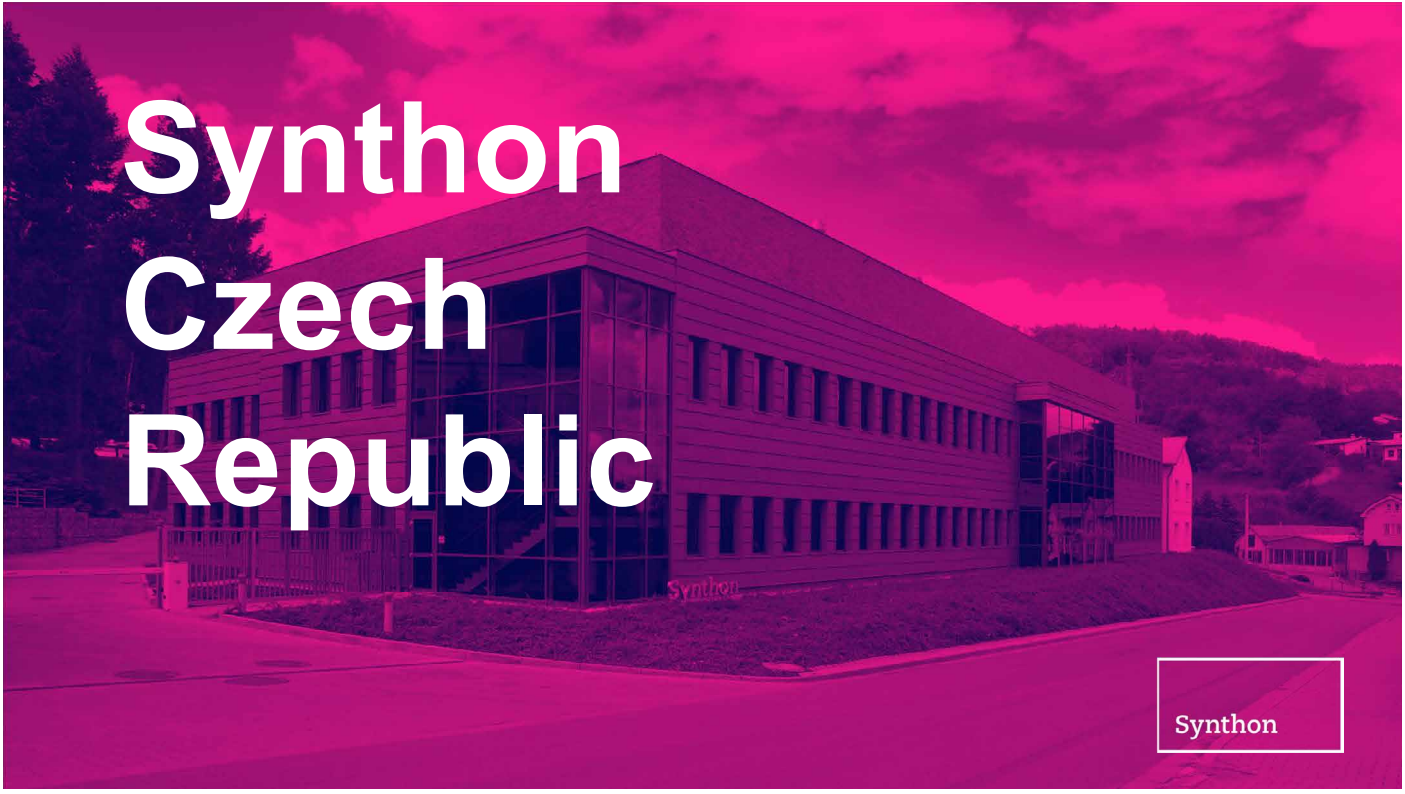
RadioMedic s.r.o. – Certification and Supply Reliability

- 99,9 % long-term supply reliability
- GMP, GDP and ISO 9001:2015 certification
- CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER
  - Human Medicinal Products
  - Human Investigational Medicinal Product
- CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

MEMBERS

5

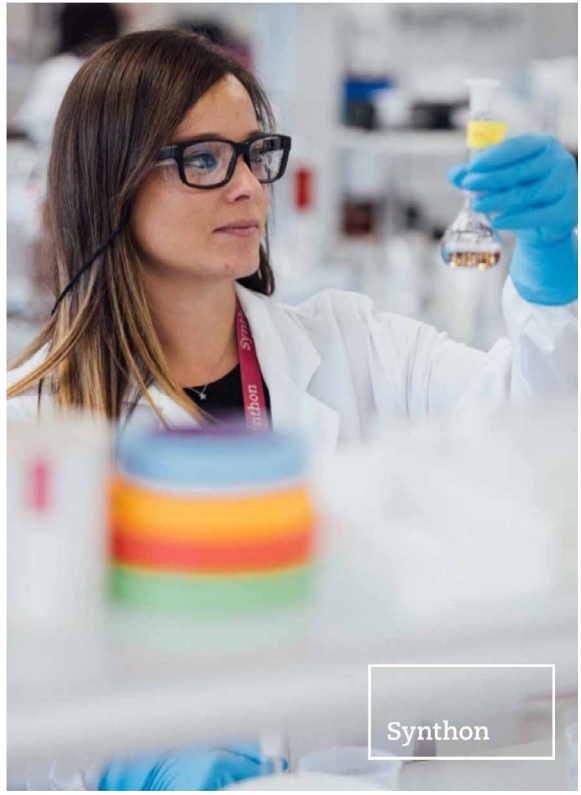
SYNTHON


Synthon Czech Republic
Synthon

Synthon

International pharmaceutical company

- Our mission is to **improve people's lives** worldwide by providing affordable medicines.
- We are a leading global manufacturer of **complex generic medicines**.
- Through excellence in research and development of best-in-class generics, and reliability in production, we have become a **significant B2B partner** in the generic industry."



Synthon globally

Therapeutic areas

- Oncology
- Central Nervous System
- Urology
- Allergy
- Cardiovascular
- Musculoskeletal
- Systemic Diseases

Synthon

Fully integrated model

ACTIVE PHARMECEUTICAL INGREDIENCE (API)	FINAL DRUG FORM
It is a substance intended to be part of a drug product that causes its effect.	It is a combination of an active substance with excipients, resulting in a finished product ready to be administered to the patient (tablets, injections, drops, patches, suppositories).

Synthon

Vertically integrated model

			Production			
	Research	Development	API	Final drug	Packaging	Local market supplies
NL	✓	✓				
CZ	✓	✓	✓			
ES	✓	✓		✓	✓	
CL	✓	✓		✓	✓	✓
AR		✓	✓			
MX					✓	✓

Synthon
Our people

- In Blansko, we focus on research, development, and production of APIs.
- Nearly 300 people contribute to this mission – researchers, technologists, laboratory technicians, production operators, as well as administrative staff and other professionals.
- The substances we produce in Blansko are sent to other company locations, where the final pharmaceutical product is manufactured, which reaches patients worldwide.

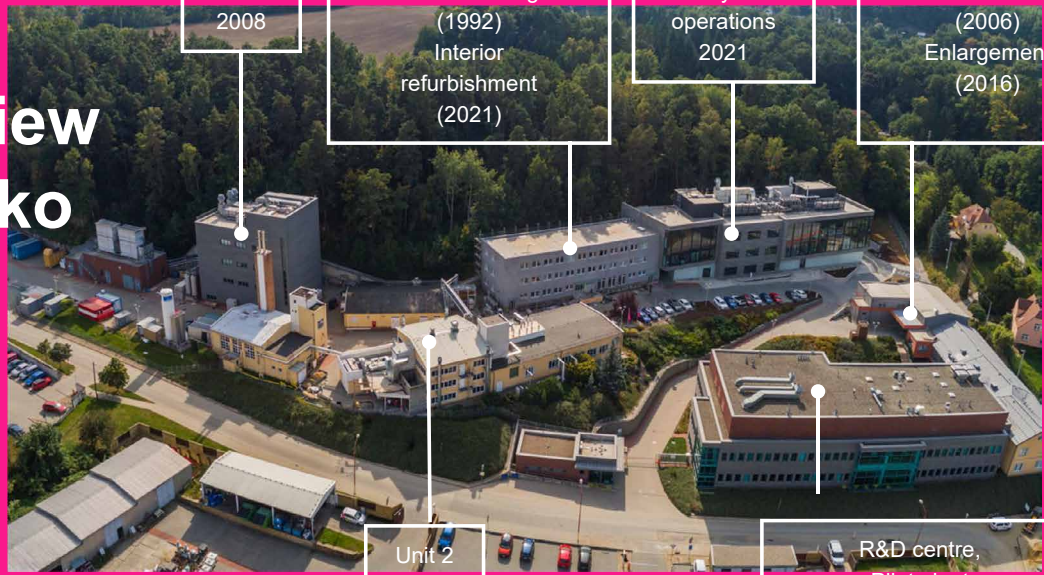
Collaborate

Partners

200+ **Global** partners

- Oncology
- Central Nervous System
- Urology
- Allergy
- Cardiovascular
- Musculoskeletal
- Systemic Diseases

Site view Blansko



Synthon Blansko

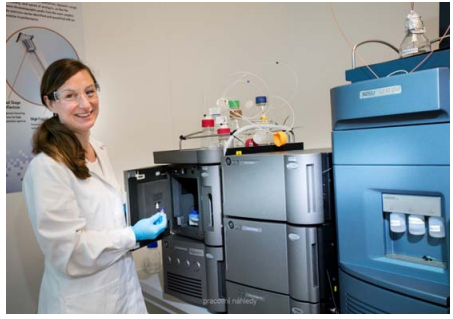
- Fully integrated site for active pharmaceutical ingredients (API), housing **API research, development and manufacturing** facilities.
- Manufacturing facilities with the highest Occupational Exposure **Banding (OEB) level E** that enables working with **highly potent APIs.**
- Synthon s.r.o. holds **the ISO14001** and **OHSAS16** certifications.

Our Portfolio

- Anagrelide
- Axitinib
- Bicalutamide
- Bortezomib
- Donepezil
- Exemestane
- Flumazenil
- Fluvoxamine
- Gefitinibe
- Ibandronate
- Ivabradine
- Levocetirizine
- Palbociclib
- Pemetrexed
- Pomalidomide
- Sugammadex
- SYD980
- Tamsulosin
- Azacitidine
- Cabozantinib
- Enzalutamide
- Vismodegib

RESEARCH&DEVELOPMENT

- **Chemical R&D**
  - New synthetic routes development
  - Standards synthesis
  - pXRD measurement
- **Analytical Research&Development**
  - Method development
  - Validation of methods
  - Certification of standards
- **Technology and Pilot Plant**
  - Handling of HP drugs.



R&D

Pilot plant 1

- Submission batches 1-3 kg batch size
- Small scale commercial production (50 L)
- Full GMP, SUKL (EMA) and FDA approved
- Handling of HP drugs, OEB class A-E

R&D

Pilot plant 2

- Linker Drug Production.
- Submission batches, 1-3 kg batch size .
- Small scale commercial production (50 L) .
- Full GMP, SUKL (EMA) and FDA approved
- Handling of HP drugs, OEB class A-E

PRODUCTION
Unit 1

- Two independent production lines (1600 L and 250 L).
- Full GMP. SUKL (EMA) and FDA approved.
- Handling of HP drugs. OEB class A-E
- SUKL (EMA), FDA approved.

PRODUCTION
Unit 2

- Three dependent production lines of 250-1600 L .
- Autoclave 250 L.
- Full GMP, SUKL (EMA) and FDA approved
- Handling of APIs OEB class A-C

AO
Analytical Operations

- Sample preparation, release and stability testing
  - 11 stability chambers (Vötch, Weiss)
  - 3 Walk-in chambers
- Method validation / verification / transfers
- Classical and instrumental methods
- Broad measurement equipment:
  - 29 HPLCs/ 15UPLC
  - 13 GC - HS
  - FT IR; Raman spectroscopy
  - 2 Malverns (PSD)
  - UV/VIS
  - LC-MS, GC-MS
  - Titrators (Karl-Fisher)
  - Conductometers, pH-meters, Refractometers

Oligonucleotides
Pilot Plant Production

Oligonucleotides are increasingly used in medicine as therapeutic agents due to their ability to specifically target and modulate gene expression. Oligonucleotides offer new possibilities for the treatment of genetic, neurodegenerative and infectious diseases. Oligonucleotides act based on their ability to specifically pair with complementary nucleic acid sequences (DNA or RNA) through hydrogen bonds between nucleotides. This specific binding allows oligonucleotides to target and affect specific DNA or RNA sequences in cells.


Synthon
Science.
People.
Affordable Medicines

MEMBERS

6

TEVA CZECH INDUSTRIES

We are all in for better health

An introduction to Teva – a new kind of pharmaceutical company

Better health is about more than just the medicines we create – it is Teva's vision for a Healthy Future

Access to Medicines & Healthcare

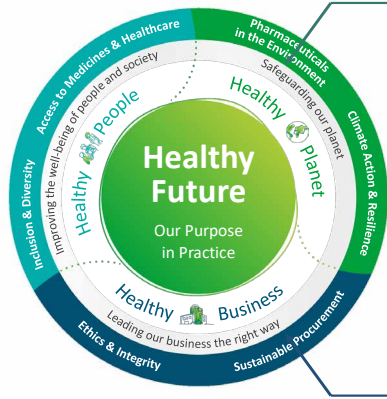
Create equitable and sustainable solutions to enable more people to get the medicines they need, while contributing to health systems strengthening

Inclusion & Diversity

Foster an inclusive culture and diverse representation to enable business excellence and innovation

Ethics & Integrity

Uphold the highest standards of business conduct



Pharmaceuticals in the Environment

Minimize the environmental impact of pharmaceuticals in our operations and supply chain and encourage appropriate use of our products

Climate Action & Resilience

Reduce our environmental footprint to help fight climate change, while preparing to adapt to its impacts

Sustainable Procurement

Further integrate priority sustainability factors in our engagement with suppliers

Teva now

A strong specialty medicines portfolio

Revenue 2021:
$15.9 billion

37,000
Employees

The leading global generic company

53
Manufacturing sites

60
Markets

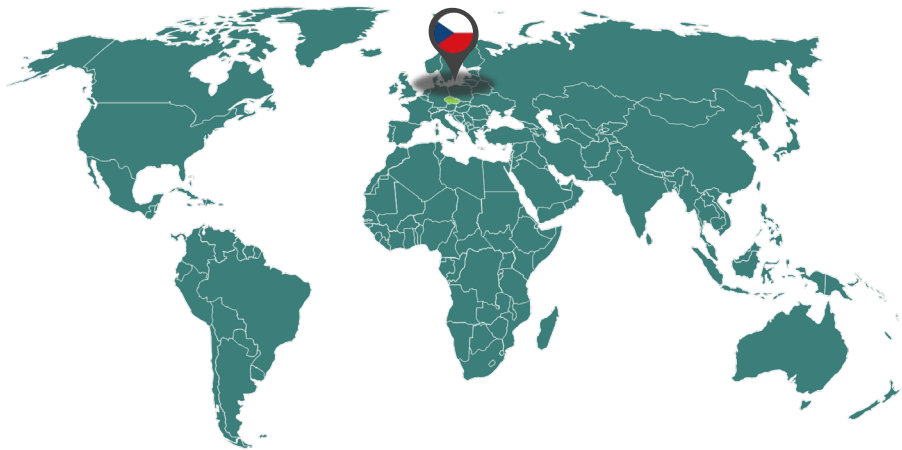
Over the counter medicines & active pharmaceutical Ingredients (API)

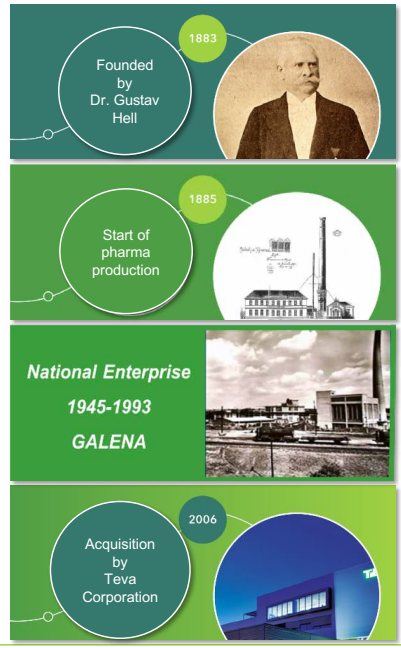
Teva Czech Industries s.r.o.

Site introduction

October 2024

Teva Czech Industries s.r.o. - History





Teva Czech Industries s.r.o. - Identity

4 Manufacturing facilities

~1 000 Colleagues

~45 Markets served

$240m Total COGS

2 Launches

~650 Stock Keeping Units (SKUs)

~85 Products families

9 Dosage Forms

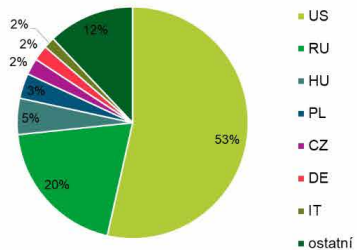
8Bn Tbl.

Teva Czech Industries s.r.o. - Mission

Czech republic

Site Mission	Manufacture & supply Gx IR products at competitive cost (Standard/ High Potent/ Cytostatic tablets and capsules) Manufacturing & supply of Specials at competitive cost (Liquid dosage, Nasal sprays, Soft gel capsules)
Market	US, EU, International, Canada
Site designation	Commodity
Other activities	R&D Launches of Nasal sprays and Nonsterile Liquids/ Solutions Modernization – building of Factory of the future

Markets split by sales



Key Authorities Approvals

FDA U.S. FOOD & DRUG ADMINISTRATION

SÚKL Státní ústav pro kontrolu léčiv

Health Canada Santé Canada

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РОССИЙСКОЙ ФЕДЕРАЦИИ

Teva Czech Industries s.r.o. - Portfolio

Taking TGO to the Next Level

	**OSD and HAPI** (above 30 product families) • 0SD 25 molecules • HAPI 4 molecules • Tablets, coated tablets, hard gelatine capsules	8 B tbl 3 000 Batches
	**CYTO (**14 product families) • Coated tablets, hard gelatine capsules	120 M tbl 180 Batches
	**LDF** (36 product families) • Nonsterile liquids, solutions, syrups, Nasal sprays • Followed by optimisation and utilization increase	70 M bottles 1 000 batches
	**SGC** (5 product families) • Dedicated workshop for 1 molecule • Soft gel capsules, Solution	75 M cps 400 batches

Teva Czech Industries s.r.o. - Opava

- The biggest pharmaceutical producer in territory Czech Republic
- Over 1 500 employees (1 000 Teva, 500 TAPI)
- Total area: 15 hectares
- Two managerial units of legal entity:
  - Teva: 4 types of manufacturing facilities
  - TAPI: active pharmaceutical ingredients
- As part of Teva total investment to production of more than CZK 10.3 bil. (508m$)
- Results Teva Czech Industries s.r.o. (2022)
  - Revenue: 11.3 bil. CZK (514m$)
- Among 20 TOP taxpayers in the Czech Republic

Teva in Czech Republic - Contacts

Manufacturing site:

Teva Czech Industries s.r.o.
Ostravská 29, 747 70 Opava, Komárov, Czech Republic

- Tel.: +420 553 641111
- E-mail: Info-Opava@tevapharm.cz
- IČ: 26785323
- DIČ: CZ26785323

(The company is registered in the commercial register kept by the Regional Court in Ostrava under file number section C, insert 27159)

Commercial unit:

- Teva Pharmaceuticals CR, s.r.o.
  Business park Futurama, Sokolovská 651/136A, 180 00 Praha 8
- Tel.: +420 251 007 111
- Fax: +420 251 007 110
- E-mail: infoteva@teva.cz

MEMBERS

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UJV GROUP


NUCLEAR
RESEARCH
INSTITUTE
UJV Group
PEOPLE | INNOVATION | TECHNOLOGY
WELCOME

NUCLEAR
RESEARCH
INSTITUTE

UJV Group
PEOPLE | INNOVATION | TECHNOLOGY

UJV Group is a group of companies providing:

- research and development,
- design, engineering services,
- production of special products and facilities,
- expert activities in the power, industry, and health sectors.

Group leader

NUCLEAR RESEARCH INSTITUTE

Subsidiaries

CVŘ
Research Centre Řež

ŠKODA PRAHA
ŠKODA PRAHA a.s.

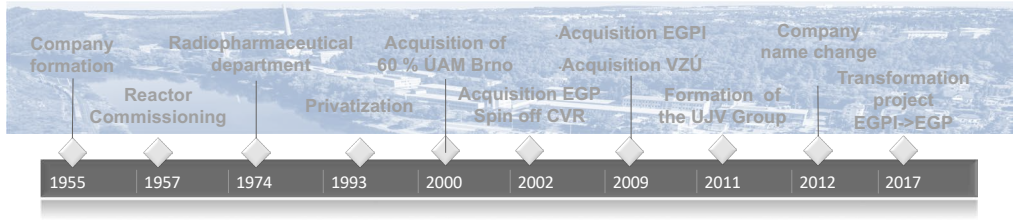
VZÚ PLZEŇ
Research & Testing Institute Pilsen

RadioMedic

NUCLEAR RESEARCH INSTITUTE

HISTORY OF THE UJV GROUP

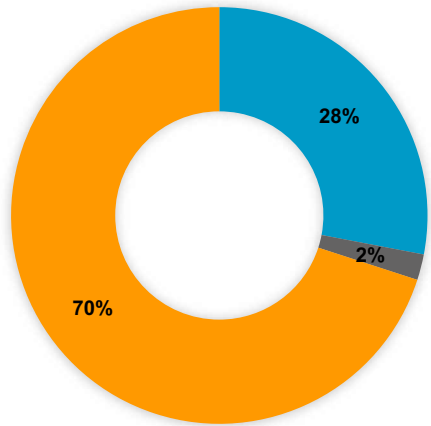
NUCLEAR RESEARCH INSTITUTE



- **1955** – Formation of the Institute of the Nuclear Physics
- **1957** – Commissioning of the first research reactor in the CR VVR–S with power output of 2 MWt
- **1972** – Reorganization of the former Institute and formation of the Nuclear Research Institute
- **1974** – Establishment of the Radiopharmaceutical department
- **1993** – Privatization of NRI and formation of a joint stock company
- **2000** – Acquisition of the 60 % share in the ÚAM Brno – acquiring 100% share in 2004
- **2002** – Formation of the R&D focused subsidiary Research Center Rez
- **2002** – Acquisition of the ENERGOPROJEKT PRAHA
- **2009** – Acquisition of the EGP INVEST, spol. s r.o.
- **2009** – Acquisition of the Research and Testing Institute in Pilsen (today VZU Pilsen)
- **2011** – Formation of the UJV Group
- **2012** – Change of the company name to ÚJV Řež, a. s.
- **2017** – Transformation project - EGP INVEST, spol. s r.o. split up, merging with ENERGOPROJEKT PRAHA division. Operation of SUSEN (CVŘ) Infrastructure
- **2020** – Acquisition of the company ŠKODA PRAHA a.s.
- **2023** – Acquisition of the company RadioMedic s.r.o.

SHAREHOLDERS

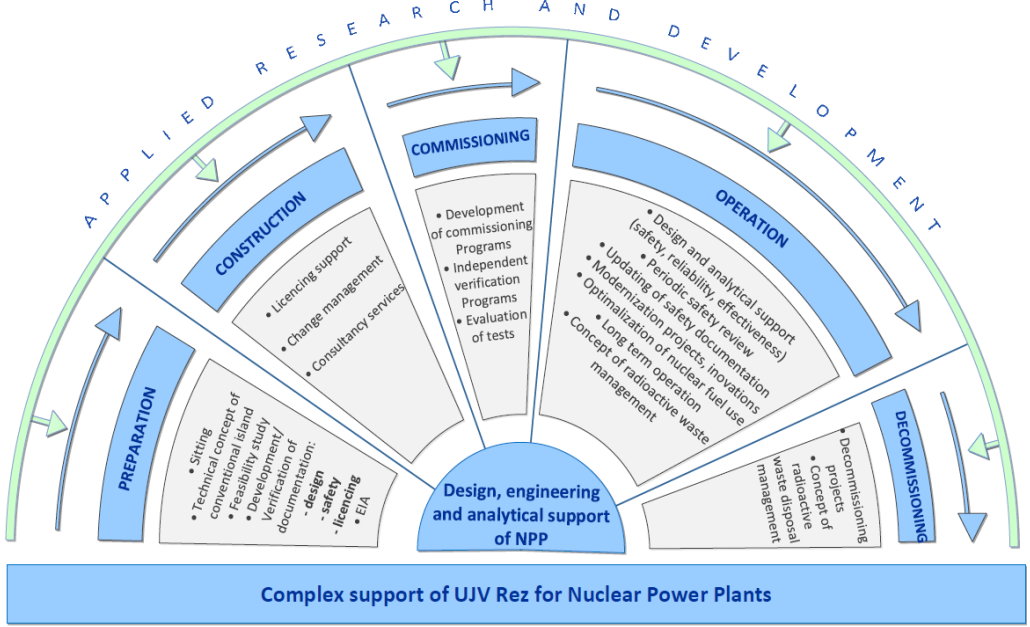
- ČEZ, a. s.
- Slovenské elektrárne, a. s. (ENEL group)
- Husinec Municipality



NUCLEAR RESEARCH INSTITUTE

NUCLEAR RESEARCH INSTITUTE

SCOPE OF SERVICES



NUCLEAR RESEARCH INSTITUTE

RADIOPHARMACEUTICALS PRODUCTION

- 3 fully equipped production sites in Czech Republic (cyclotron, QC lab, production lab)
  - PET Center Prague (launched 1999)
  - PET Center Brno (2008)
  - PET Center Řež (2013)
- Daily deliveries to hospital's nuclear medicine departments in Czech Republic:
  - 18 hospitals using in total 23 PET scanners - 3 PET/MRI, 20 PET/CT
- 99,7 – 99,9 % long-term supply reliability
- GMP and ISO certified
  - CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER
    - Human Medicinal Products
    - Human Investigational Medicinal Products
  - CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR
  - ISO 9001:2015, ISO14001:2015, ISO 45001:2018
- Cooperation with local and foreign partners

PET RADIOPHARMACEUTICALS

- Besides FDG, the Radiopharma Division of ÚJV Řež, a. s., holds the MA for [^{18}F]sodium fluoride (NaF) for bone imaging
- The Division runs development/implementation projects focused on enabling the (routine) clinical use of more PET radiopharmaceuticals in the country
- 2019 [^{18}F] fluorocholine for prostate carcinoma, hepatocellular and parathyroide adenoma - market authorized
- 2020 [^{11}C]methionine for glioma diagnostics (brain tumors) - market authorized
- 2024 – [^{18}F] FDOPA (neuroendocrine tumors, gut tumors, psychiatric and neurological disorders) - market authorized
- Perpetual effort in implementing other novel radiopharmaceuticals for Czech patients
- International collaboration actively seeked
- Intentions and plans to engage again in modern radiotherapeutic nuclides

CURRENT SITUATION

50500
PET scans per year

100%
Increase in PET scan count in 10 years

95%
of PET radiopharmaceutucals used in Czech republic are produced by UJV

100+
FDG doses per day produced by ÚJV

3
PET Centres ran by ÚJV

4
Different PET RP with MA produced by ÚJV

NUCLEAR RESEARCH INSTITUTE

THE POTENTIAL

- **Potential cooperation on novel tracers for PET:**
  - Synthesis development and implementation
  - License manufacturing
  - Animal testing (if possible)
  - Clinical evaluations collaboration
- **Potential cooperation on therapeutic/theranostic radiopharmaceuticals:**
  - Cooperation with LVR-15 reactor and Research Centre Rez
  - Development of manufacturing processes and equipment
  - Irradiation services
  - Animal testing (if possible)
  - Clinical evaluations collaboration
- **Waste management:**
  - Expanding the cooperation with the Waste Management Division
  - Cyclotron decommissioning (exchange of experience)

LVR-15 REACTOR - CURRENT ACTIVITIES

Reactor in the ownership of Research Centre Rez, a subsidiary of UJV

- **Production of ^{99}Mo for worldwide supply chains (for IRE processor)**
- **Irradiation to produce other nuclides**
  - **^{131}I (traditional therapeutic isotope)**
  - **^{166}Ho (for theranostic microspheres)**
  - **^{177}Lu**
  - **^{161}Tb (research joint project)**
  - **Boron neutron capture therapy**

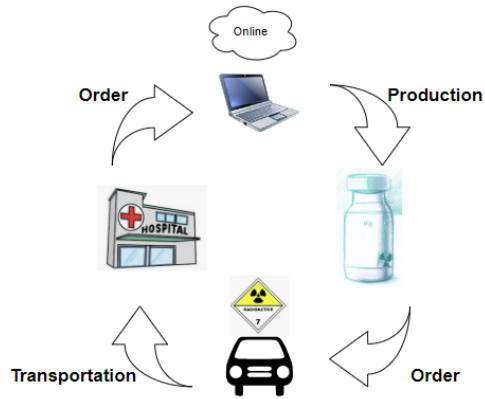
CYCLOTRON DECOMMISSIONING

- Replacement of the longest-serving cyclotron in Prague after 22 years of production
- Relatively unique opportunity in Europe
- Old cyclotron removed and stored in UJV by the Radioactive Waste and Decommissioning division (4-5/2022), installation of new Kiube 150 (6-12/2022).
- The project was implemented by SKODA PRAHA (a subsidiary of UJV)
- Following steps are to measure activation of different cyclotron

ONLINE PRODUCTION MANAGEMENT SYSTEM - iPETpro

Developed by UJV to exactly follow production process and allow online access

- Accepting **customer orders** and changes of orders
- Batch calculations
- **Production** documents printing
- **QC** data and trends
- Monitoring of clean premises
- Releasing of produced batch by **QP**
- **QA** overview
- **Transportation** and tracking of Type A packages – connection with mobile app
- Economic overview



TYPE A PACKAGES - UJV DESIGN

Shielding material depleted uranium

Online tracking system of Type A containers through mobile app

Advantages

- Total weight 9 kg (inner container 7 kg)
- Compatible with hospital dispensers (Karl100, Intego, IRIS)
- High level of radiation safety, reduction of staff dose rate

Disadvantages

- Contains depleted uranium (under legislation)
- Limited use outside the country borders

NUCLEAR RESEARCH INSTITUTE

MEMBERS

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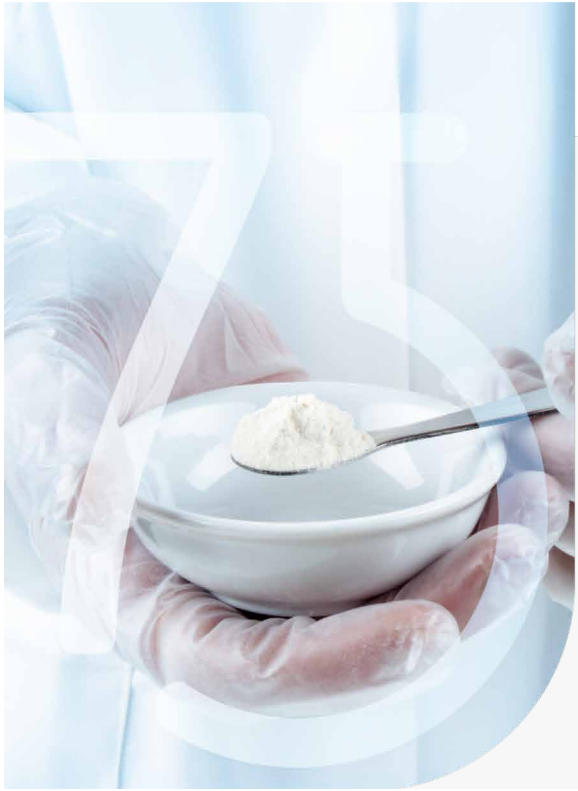
VUAB PHARMA

VUAB Pharma a.s.

ROZTOKY | October 2024

SAFICHEM group

VUAB pharma 75 LET YEARS



About us

- VUAB Pharma a.s., is a pharmaceutical company that manufactures and markets medicines in the Czech Republic since 1949.
- The excellent reputation acquired by VUAB Pharma a.s.at the pharmaceutical industrie's level is based on its tradition, experience and responsible approach of employees.
- VUAB Pharma a.s., marking its 75th anniversary this year, boasts a rich legacy in pharmaceutical manufacturing.
- Our diverse product lineup includes hospital injectiones, nystatin API, oncological APIs and green biosynthesis of pharmaceutical enzymes with manufacturing facilities in Roztoky, Brno and České Budějovice.
- We are proud to be among the world's top three producers of *nystatin* API. Widely utilized in surgeries globally, our hospital injections are integral to healthcare systems.

200 employees

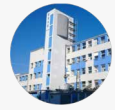
Turnover in 2023: **15,13 mil. EUR**

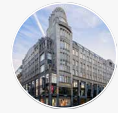
Export **>78%**

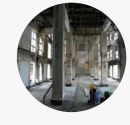
VUAB pharma 75 LET YEARS

History

Since then, there has been a link between the development and production of APIs and medicinal products







1949
Establishment of the state Penicillin factory

October 26, 1949
The production of *penicillin* was started

1951
VUAB arise Research institute for antibiotics

The production of *streptomycin*, infusion solutions *chlortetracycline, tetracycline, oxytetracycline, erythromycin, fungicidin, neomycin, chloramphenicol* continues

1958
Development and production in VUAB

Production of *nystatin, sucinylcholine iodide, pentobarbital, amifenazole, hydrocortison ephedrine* .....

1998
Privatisation and acquisition by ICN Pharmaceuticals Inc.

VUAB passes from state ownership to ICN Pharmaceuticals Inc.

2001
The flood in August 2021 from the Vltava River

The flood flooded the production area to a height of 4,5 m

2004
June – VUAB has become a part of SAFICHEM GROUP AG

SAFICHEM GROUP AG becomes the owner with a strategy to maintain production in the Czech Republic

2005
December VUAB Pharma a.s.

Return to the original name VUAB, now VUAB Pharma a.s.

2010
Aqqusition of production unit in Brno

VUAB Pharma expands its portfolio to include production of oncology APIs

2015
Construction of a new filling line has begun

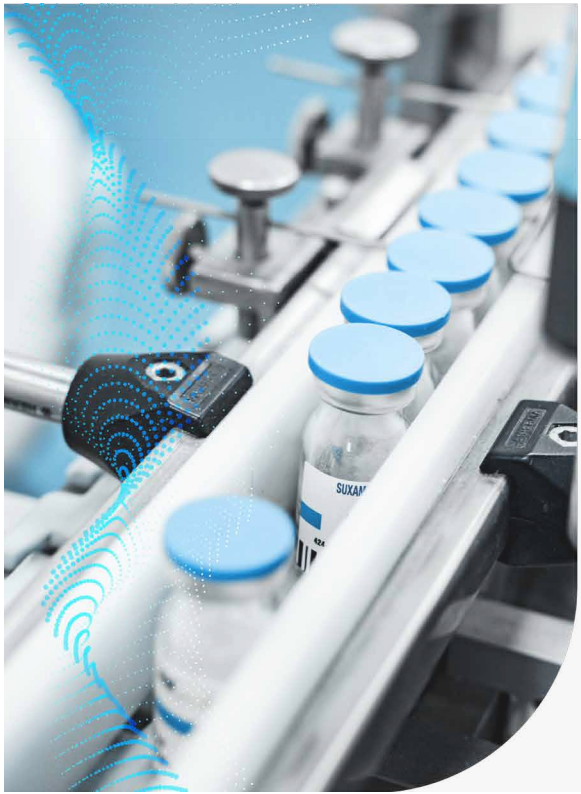
Construction of a new filling line for dry and liquid injections has begun

2023
Acquisition of a production unit in České Budějovice

VUAB Pharma becomes a manufacturer *via* Green synthesis of Nucleosides e.g.cladribine – API/FDFs in České Budějovice

This year we are celebrating our 75th anniversary

VUAB pharma 75 LET YEARS

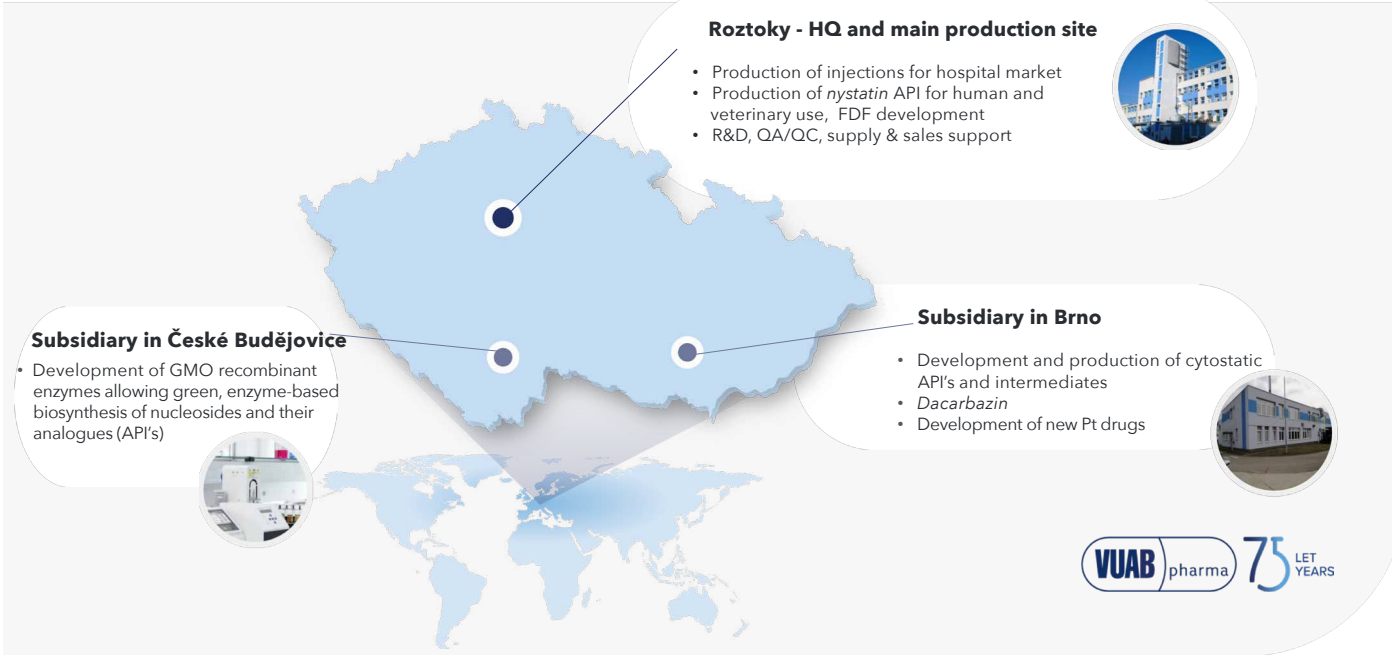


Advantages of the company

- Research, development, production, trade and transition from research to production
- 75 years of experience in the field of pharmacy
- GMP and FDA certifications
- Intellectual property - patents, trademarks
- Manufacturing processes, etc
- Green synthesis of enzymes and nucleosides

VUAB pharma 75 LET YEARS

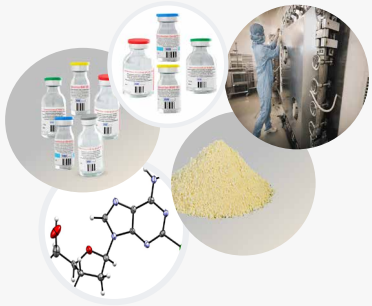
Our locations



Portfolio

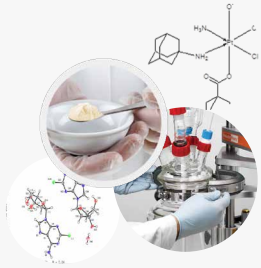
Commercialized products

- Dry and liquid injections for hospital market
- *Nystatin* API for human and veterinary use
- *Dacarbazine* API
- Platinum IM for platinum antitumor drugs



Under development/pipeline

- *Nystatin* FDF for antifungal therapy
- Green synthesis of enzymes and nucleosides
- *Cladribine* – API/FDFs
- New platinum antitumor drugs TU31 and TU106



Services

- Contract manufacturing
  - **New production line for injections** - insulator technology with lyophilization for filling both liquid and dry injections directly in vials
  - **New filling line for injections** - filling to ampoules, vials and prefilled syringes
- EU release site services
- Canabinoid analyses
- Heavy metals, nitrosamins analytics
- Analytical Services

VUAB pharma 75 LET YEARS

Commercialized products - dry and liquid injections for hospital market

Thiopental 0,5, Thiopental 1 g
powder for injection - Anaesthetic

Hydrocortison 100 mg
powder for injection - Hormon

Suxamethonium 100 mg
powder or liquid form for injection - Myorelaxans

Chloramphenicol 1 g
powder for injection - Antibiotic

Well established use in the hospital markets

New production line in insulator design is put into operation

GMP compliance certificate

VUAB pharma 75 LET YEARS

Thiopental 0,5 g a 1,0 g
Dry injections

INDICATION

Thiopental is indicated
• as the sole anesthetic agent for brief (15 minutes) surgery procedures
• for induction of anesthesia prior to administration of other anesthetic agents
• to supplement regional anesthesia
• to provide hypnosis during balanced anesthesia with other agents for analgesia or muscle relaxation • for the control of convulsive states during or following inhalation anesthesia, local anesthesia, or other causes
• in neurosurgical patients with increased intracranial pressure, if adequate ventilation is provided
• for narcoanalysis and narcosynthesis in psychiatric disorders

COMPOSITION

Active substance:
Thiopental VUAB 0,5 g: Thiopental sodium 0,5g in one injection vial.
Thiopental VUAB 1,0 g: Thiopental sodium 1,0g in one injection vial

PHARMACEUTICAL FORM

Powder for solution for injection. Thiopental VUAB inj.plv.sol. is a yellowish powder

CHARACTERISTICS

Thiopental is barbiturate anesthetic and is used as ultrashort-acting thiobarbiturate for intravenous anesthesia for brief surgery procedures and for induction of anesthesia.

PACKAGING

Pure glass injection vial, rubber stopper, flip off cap.
One vial with a label and package leafl et in a paper box.
Content of a pack: Thiopental VUAB 0.5 g: 1 x 0.5 g Thiopental VUAB 1,0 g: 1 x 1 g

Hydrocortison 100 mg
Dry injections

INDICATION

Boosting your body with extra corticosteroid such as Hydrocortison VUAB 100 mg can help when injected by a doctor or nurse if your body cannot produce enough corticosteroid due to problems with your adrenal glands (e.g. adrenal insufficiency). Corticosteroids can also help treat shock following surgery, injuries, hypersensitivity (anaphylactic) reactions or other stressful conditions. These include inflammatory or allergic conditions affecting the:
• bowel and gut e.g. Crohn's disease (inflammation of the gut) or ulcerative colitis (inflammation of the lower bowel)
• lungs e.g. bronchial asthma
• skin e.g. Stevens-Johnson syndrome (an auto-immune disorder in which an immune system causes the skin to blister and peel), or systemic lupus erythematosus (lupus)
Hydrocortison VUAB 100 mg may be prescribed to treat thyreotoxic crisis (hyperfunction of or conditions other than those listed above).

COMPOSITION

Active substance: One injection vial contains hydrocortisone 100 mg as hydrocortisone hydrogensuccinate.

PHARMACEUTICAL FORM

Powder for solution for injection. Hydrocortison VUAB 100 mg is white to almost white powder.

CHARACTERISTICS

Hydrocortison belongs to a group of medicines called corticosteroids or steroids. Corticosteroids are hormones produced naturally in your body and are important for many body functions.

PACKAGING

Pure glass injection vial, rubber stopper, flip off cap. One vial with a label and package leafl et in a paper box.
Content of a pack: 1 x 100 mg or 10 x 100 mg

VUAB pharma 75 LET YEARS

Suxamethonium chlorid 100 mg Dry injections

INDICATION

Suxamethonium chlorid VUAB is used as muscle relaxant with general anesthesia. It is used in anesthesia as a muscle relaxant to facilitate endotracheal intubations, particularly rapid intubations, mechanical ventilation and a wide range of surgical and obstetric procedures. It is also used in severe laryngospasm and to reduce the intensity of muscular contractions associated with pharmacologically or electrically-induced convulsions

COMPOSITION

Active substance: Suxamethonium chloride dihydrate 110 mg (corresponds to 100 mg of Suxamethonium chloride) in one injection vial

PHARMACEUTICAL FORM

Powder for solution for injection. Suxamethonium chlorid VUAB is white to almost white powder.

CHARACTERISTICS

Suxamethonium chlorid VUAB belongs to drugs known as muscle relaxants (relax muscle tension).

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PACKAGING

Pure glass injection vial, rubber stopper, flip off cap. One vial with a label and package leafl et in a paper box. Content of a pack: Suxamethonium chlorid VUAB 100 mg: 1 x 100 mg

Chloramphenicol 1 g Dry injections

INDICATION

Chloramphenicol has a wide spectrum of effects including common gram-positive and gram-negative pathogens, as well as intracellularly growing "atypical" bacteria (rickettsia, chlamydia, mycoplasmas or spirochetes) and anaerobes. It has excellent penetration into different tissues of the organism, including the central nervous system. It also permeates well into macrophages and other cells.

COMPOSITION

Active substance: Chloramphenicol sodium succinate 1,38 g, which corresponds to 1 g of Chloramphenicol in one injection vial.

PHARMACEUTICAL FORM

Powder for solution for injection. Chloramphenicol VUAB 1 g is white to yellowish powder.

CHARACTERISTICS

Chloramphenicol VUAB 1 g is synthetic wide-spectrum bacteriostatic antibiotic. Chloramphenicol is reserved for serious infections caused by susceptible microorganisms, which cannot be treated by other, less toxic antibiotic.

PACKAGING

Pure glass injection vial, rubber stopper, flip off cap. One vial with a label and package leafl et in a paper box. Content of a pack: 1 x 1 g

VUAB pharma 75 LET YEARS

Commercialized products – biotechnological **API NYSTATIN**

NYSTATIN API for human use

- is polyene macrolide antibiotic obtained from the fermentation. of the strain *Streptomyces noursei*.
- effective against moulds and yeast, mainly against *Candida Albicans*. Candida causes fungal infections of the skin, mouth, vagina and the gastrointestinal tract.
- has shown no problems of drugs interactions and side allergic. or resistance effects since 1950 when discovered.

Nystatin has very low toxicity, it does not irritate locally and adverse effects on gastrointestinal tract are rare and moderate. Nystatin is often used as prophylaxis for patients who are at risk for fungal infections, such as AIDS patients, patients receiving chemotherapy, immunosuppressant drugs and patients with diabetes. The substance is widely used for production of suspensions and topical preparations (cream, ointment, lotion, vaginal tablets, etc…).

Parameters	**Limits**
Loss on drying	**not more than 5 %**
Microbiological assay	not less than 4400 IU/mg (dried substance) or not less than 5000 IU/mg (dried substance) for oral use
Particle size	The particle size distribution range of nystatin is typically: 100 % of particles is less than 40 μm 90 % of particles is less than 10 μm

Pharmacopoeial Quality
USP, Ph. Eur., BP

Regulatory information/Certification
GMP, Certificate of Suitability, US DMF # 14056, EIR from FDA, U.S.A., national registrations in many countries all over the world

Packaging and Shipping
Double polyethylene bags in fiber drums. Weight per bag: 30 kg.

Shelf-life
3 years in the original packaging

Storage conditions
Store below 25°C, in tight, light persistent container

NYSTATIN CRUDE (Feed Grade) API for veterinary use

- Nystatin crude is mycelium of the production strain of *Streptomyces noursei* containing active nystatin. It is yellow-brown amorphous powder. The substance is used as an intermediate for the extraction of nystatin and as a feed-additive for veterinary use.
- Nystatin is used for prevention and treatment of diseases and disorders caused by candida spp.overgrown in the GI tract. Nystatin stops horizontal and vertical transmission of candida.
- Is an affective antifungal feed additive for the treatment or prevention of crop mycosis and mycotic diarrhoea in poultry.
- Prevent candidiasis and white discharge.
- Is a growing promoter, food preservation, nutrition component mainly in poultry and pig industries.

Parameters	**Limits**
Loss on drying	**not more than 10 %**
Microbiological assay	not less than 2240 IU/mg (dried substance)
Sulfated ash	not more than 12 %

Packaging and Shipping
Double polyethylene bags in fiber drums. Weight per bag: 30 kg.

Shelf-life
2 years in the original packaging

Storage conditions
Store below 25°C, in tight, light persistent container

VUAB pharma 75 LET YEARS

Commercialized products - oncology

- ***Dacarbazin* API** - active ingredient for the manufacture of medicinal products
  - cytostatic intended for the treatment of malignant diseases
  - thanks to modern technology, we achieve quality that surpasses other global manufacturers
  - we hold internationally required GMP and CEP certificates

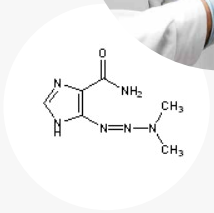
VUAB pharma 75 LET YEARS

DACARBAZIN

is an antineoplastic agent used in cancer chemoterapy like:
- malignant melanoma
- Hodgkin´s disease
- sarcoma

STANDARD PRODUCTION

- Quality: according to Ph.Eur.
- Regulatory information/Certification
- GMP, EDQM Certificate of Suitability
- Shelf-life Three years
- Storage conditions
  Store below 25°C, in tight, light – resistant container
  (absence of light necessary)



VUAB pharma 75 LET YEARS

Under development/pipeline

- New platinum drugs for the treatment of cancer TU31 & TU106
- Final dosage forms for the treatment of candidiasis
  - Nystatin VUAB 100 000 IU/g Oral gel 50 g
    - OTC
  - Nystatin VUAB 100 000 IU/g Peroral suspension 60 ml
    - Rx
- Green synthesis of nucleosides

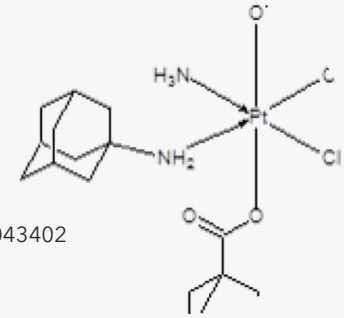
VUAB pharma 75 LET YEARS

Under development/pipeline

NEW PLATINUM DRUGS

New Pt(IV) complex TU31

- broad antitumor efficacy, low toxicity
- worldwide patent protection WO2016/034214
- clinical phase 2



New Pt(IV) complex TU106

- next generation, worldwide patent protection WO 2021/043402
- development stage

VUAB pharma 75 LET YEARS

Under development/pipeline

GREEN SYNTHESIS OF NUCLEOSIDES – API/FDFs

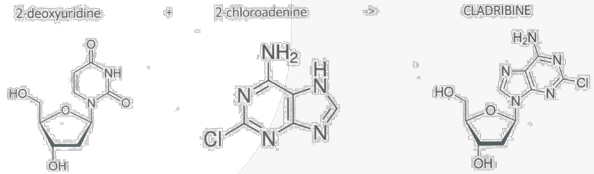
- **Competitive price** - own development of recombinant enzymes allowing production at extremely competitive costs
- **Simplicity - green synthesis** ("one step, one pot" process, minimum waste, organic solvent free, no chromatographic purification), which is very time effective and simple, whereas the process is being controlled from start to end
- **Purity** - produced API complies with both USP and EP specifications
- **Flexibility** - the technology can be used to develop other enzymes and molecules
- Development of two recombinant trans-glycosylases successfully completed at laboratory scale (samples available);

VUAB pharma 75 LET YEARS

Under development/pipeline

GREEN SYNTHESIS OF NUCLEOSIDES – API/FDFs

- Several new enzymes currently in pipeline including:
  - e.g. **Adenosine deaminase, Asparaginase II, Alkaline phosphatase**;
- Vertically integrated process and technology of Cladribine production (enzymatic synthesis and formulation) completed at laboratory scale
  - Patent non-infringing oral formulation (patent on MAVENCLAD)
  - Novel concentrated parenteral formulation of Cladribine for s.c. application (does not exist on the market yet)
- Target: integrated production of any nucleosides



VUAB pharma 75 LET YEARS

Our further services

- **Contract Manufacturing**

  - New production line for injections - insulator technology with lyophilization for filling both liquid and dry injections directly in vials; capacity 10 million vials/year

  - New filling line for injections - filling to ampoules, vials and prefilled syringes; capacity 15 million units

- **Cannabinoid analyses** - we offer complete testing using pharmacopoeia methods
- **Heavy metals & nitrosamines analyses** - confirmatory testing on **NDSRIs** - Nitrosamine Drug Substance-Related Impurities
- **Analytical Services** - free capacities of chemical and microbiological GMP certified laboratories
- **EU release site services**

VUAB pharma 75 LET YEARS

Registrations and certificates obtained

GMP certificate issued by SÚKL

- Production of dry injections
- *Nystatin* API production
- *Dacarbazine* API production

U.S. FDA inspection

(FDA – Food and Drug Administration)

On the production of *nystatin* API since June 2000

CEPs

(EDQM)

(Certificates of Suitability, European Directorate for the Quality of Medicines and HealthCare)

- *Nystatin* API production
- Permission to handle narcotic drugs
- *Dacarbazine* API production

VUAB pharma 75 LET YEARS

Where we deliver

Thank you for your attention

VUAB Pharma a.s.

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E-mail: info@vuab.cz

www.vuab.cz

VUAB pharma 75 LET YEARS

MUDr. Bc. Miloslav **Dvořák**, MBA
Generální ředitel
General Manager

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mdvorak@vuab.cz
mobil: +420 **602 396 141**
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SAFICHEM group

VUAB pharma 75 LET YEARS

MEMBERS

9

ZENTIVA

Zentiva – this is us!

October 2024

ZENTIVA

Zentiva at a glance – a Pan-European company delivering high-quality and affordable medicines to more than 100 million people

A strong track record during the last 5 years

ZENTIVA 2028 Roadmap
SHAPING OUR FUTURE. TOGETHER.

2018–2023

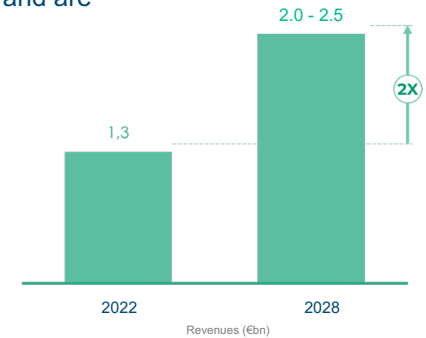
We have just celebrated 5 years of growth at Zentiva. We have doubled the size of our company in both revenue and in number of colleagues

2024–2028

We kicked off another growth phase for Zentiva in 2024 and are aligned on our strategic vision for the next 5 years

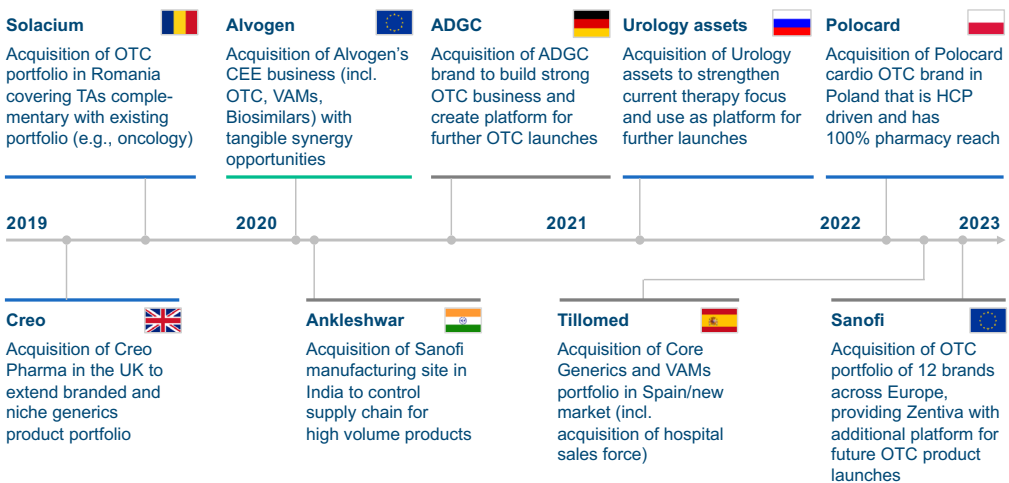
We will deliver that through:

- Product Launches across our Core Portfolio
- Expansion of CHC and our Specialty Business
- Commercial Excellence in Execution
- Relentless Drive for efficiency gains
- Targeted M&A



Strong M&A and Integration capabilities, ranging from Product Bolt-Ons to Transformational Acquisitions

Zentiva M&A track-record



Acquisitions to expand product portfolio in differentiated categories incl. CHC, and capturing synergies

Integration of Alvogen, Ankleshwar & Sanofi portfolio and carve-out from Sanofi exemplify carve-out management capabilities (incl. exiting MSA/TSA on time without business disruption)

Zentiva's Management

Steffen Saltofte
CEO

Executive Committee

Thomas Spitzenpfeil
CFO & Head of IT

Bridget Olde Olthof
Head of People & Organisation

Anant Atal
Head of Strategy & Transformation

Martin Albert
Chief Scientific Officer

Jeff Rope a.i.
Head of Product Supply

Paul Geymayer
Head of Commercial, WE

Hacho Hatchikian
Head of Commercial, CEE

Leadership Team

Tereza Ber
Head of Legal & Compliance

Khatira Mansouri
Chief Quality Officer

Ines Windisch
Head of Comms, Corporate Affairs & Sustainability

Ivailo Georgiev
Head of Business Development

Pavel Sebek
Development Director

Philippe Seminati
Head of Supply Chain

Josef Matousek
Head of ITS

Thomas Koene
Head of Zent2U

Our Strategic Priorities

Zentiva is able to leverage excellence in core Generics to launch new products across markets

1. Prague product development centre

Develop and register products so they can be launched immediately upon originator patent expiry and capture initial market share opportunity

2. Low-cost manufacturing organisation (Prague, Bucharest, Ankleshwar)

High market share on launched products translates into lowest cost of supply as manufacturing scales, securing position to hold share in mid term as price stabilizes

3. Multi-market commercial team 1,500 FTEs

International commercial organization drives local share - development and manufacturing spend can be absorbed across multiple EU markets, further improving cost position

4. Infrastructure leveraged into adjacent segments

Commercial organization can be leveraged into adjacencies that have the same call point and supply chain (e.g. Consumer Health), embedding position

5. Market insights and financial scale enable development of differentiated products

Scale enables the business to develop differentiated versions of old medicines, and move into higher risk/higher reward specialty products

Zentiva is the fastest growing Pan-European Commercial Platform [1]

powered by a strong portfolio, leading product development and a low-cost supply chain

I	**Fast-growing pan-European platform** operating in **growing & robust generics, OTC & specialty** markets	
II	**Scalable commercial model with tailored Go-to-Market approach** based on the characteristics of each market	
III	**Large, diversified and resilient portfolio** with **high and growing share in specialty categories** and branded generics	
IV	**Best-in-class development** (R&D and BD&L) **and launch** capabilities	
V	**Well-invested in-house manufacturing** operations supporting **top-quartile COGS leadership position,** with strategy to further drive **productivity & unit cost optimization**	
VI	**Strong M&A and integration capabilities**, with optionality on future direction of travel	
VII	**Solid financial track-record**, with **future organic growth underpinned by strong launch pipeline, commercial execution and operating leverage**	
VIII	**Strong management team** fully committed to **sustainability**	

We develop…

Generic research and development make high-quality modern medicine ACCESSIBLE and AFFORDABLE, with new ADDED VALUE for the patient

Market entry at original product

LOSS OF EXCLUSIVITY

ACCESSIBLE

Manufacturing

COST REDUCTION

AFFORDABLE

Improved originals with

HIGHER VALUE FOR THE PATIENT

VALUE ADDED

SUSTAINABLE

ZENTIVA

Our Strong Product Development Capabilities enabled 300+ launches over 2018-2022

Drug & API Product Development

Reformulations and bioavailability adjustment from hard to make bioavailable to supra-bioavailable formulations

Physical form engineering

Specific API manufacturing technologies incl. particle engineering, hydrogenation

Focus on high volume LoE and VAMs

Business Development and Portfolio

Full range of BD activities covering in-licensing, marketing and distribution, asset acquisitions and co-development

Project & Portfolio management

Management of new projects, **regulatory, supply, and launch** related activities

Focus on medium and low volume LoE, Generics portfolio completion, Biosimilars, OTC and hard to make products

90%+

Success rate in bioequivalence studies since 2015

50+

Patent submissions between 2018 and 2022

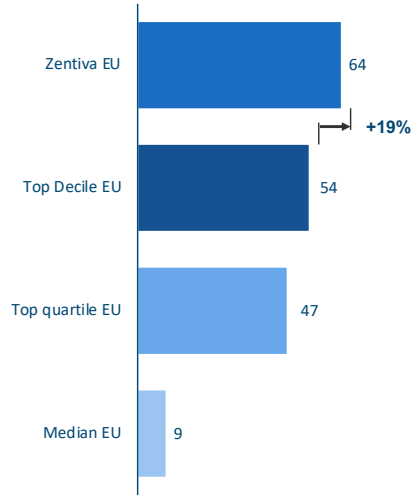
100+

Regulatory submissions per year handled by scientific services team of 100+[1] FTEs who are also responsible for dossier maintenance and regulatory submissions

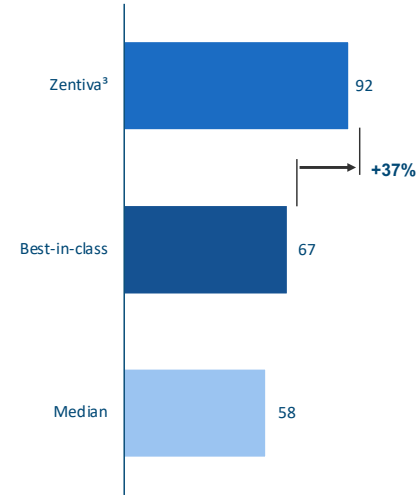
1. Additional 100+ FTEs when also including non-Regulatory incl. Development

… allow leading LoE coverage and on-time filings
Strong launch performance is reflected in best-in-class-Freshness Index[1]

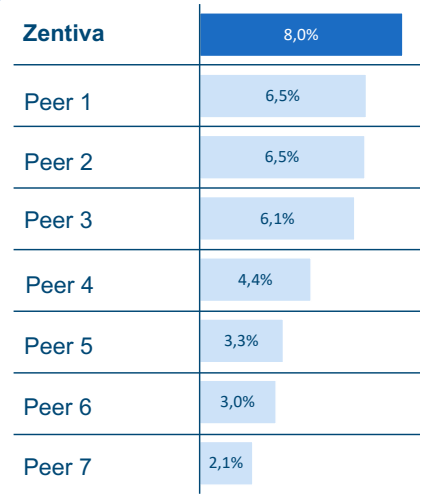
LoE Coverage 2022[2], % of Number of LoEs



On-time Filing[3], %



Freshness Index vs. Peers 2021 – 22, %



1. Freshness index defined as: Reported gross sales from new launches in last 24 months vs. Total reported gross sales in the last MAT; 2. Benchmarking of top 20 companies by number of launches between 2019-2022. Includes LoE in CZ, RO, IT, Bulgaria, Estonia, PO, FR, DE, Latvia, Lithuania, Portugal, Slovakia; 3. GRADE Benchmark; 3. N=13, selected dataset for on-time filing analysis (incl. target filing dates) of in-house developments;

We produce…

Best in class manufacturing sites

Balanced and flexible manufacturing footprint
- **Expertise in internal manufacturing as well as external sourcing**
- **Flexible geographical footprint combining facilities in Eastern Europe with access to international**

Competitive conversion cost
- **Historical track record of significant COGS improvement**

Best-in-class manufacturing assets…

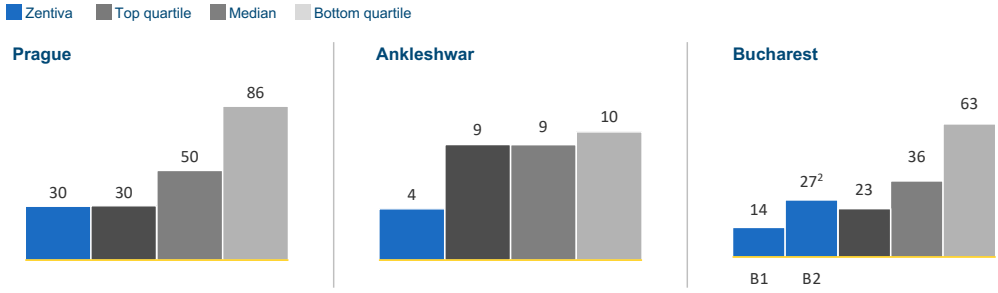
…with complementary external CMO network

Site	PRAGUE	BUCHAREST	INDIA	ESO (CMOs)
Key Site Details	▪ **850** Employees ▪ **260** Formulations ▪ Volumes 2022: **142 million boxes (5.8 BGU)** ▪ Specialized in **solids, injectable solutions, eye drops, sterile ointments and hormones** ▪ **Very competitive production cost**	▪ **850** Employees ▪ **230** Formulations ▪ Volumes 2022: **158 million boxes (5.2 BGU)** ▪ Specialized in **solids, injectable solutions** ▪ **Very competitive production cost**	▪ **1000** Employees ▪ **49** Formulations ▪ Volumes 2021: **101 million boxes (7.0** BGU) ▪ **300 t** of API & intermediate produced in 2022. ▪ Specialized in **solids, API & intermediates** ▪ **Very competitive production cost**	▪ Network of **over 300 CMOs for finished products** ▪ Longstanding relationships

ZENTIVA

Competitive Cost position based on best-in-class unit conversion costs, with opportunities for further optimization

Best in Class Unit Conversion Cost[1], € cent per PU



Future Cost Optimization Levers

Insourcing volumes
Strong internal COGS position

Operational improvements
Close productivity gaps across Bucharest and Prague sites

Network strategy
Potential to improve operational efficiency

Procurement improvements
Procurement savings in API, finished dosages and direct material

Key Takeaways

Unit conversion costs top tier across manufacturing sites[3]

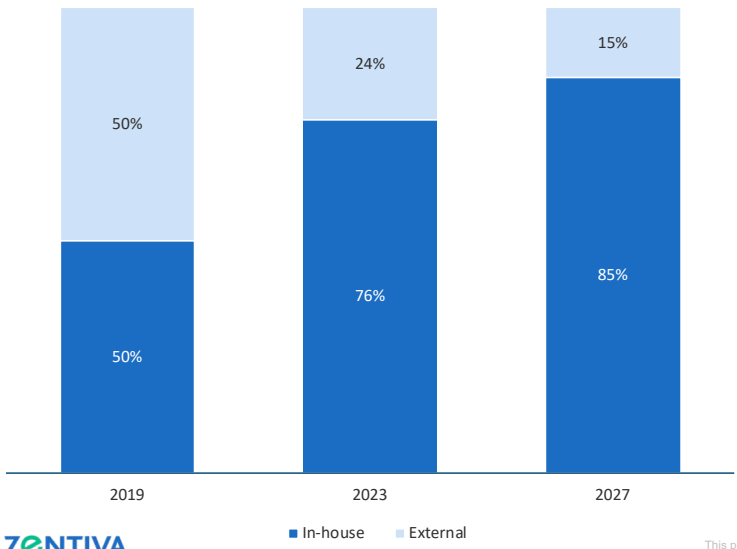
Conversion cost performance driven by best-in-class labor productivity (Ankleshwar) and **labor costs** (Prague)

Future cost optimization driven by insourcing volumes, operational improvements, network strategy & procurement levers

1. Unit costs not adjusted for energy price inflation; detailed analysis in deep-dives; 2. Ongoing transfers to B2 site expected to improve capacity utilization and efficiency going forward – volumes forecast to increase from ~850m GU to >1.6bn GU by 2025. The site has ongoing programs to improve operational excellence, e.g., reviewing (increasing) batch sizes, reducing unit costs especially in quality release; 3. Bucharest site 2 in Tier 2 - initiatives in place to bring to Tier 1 by 2027, e.g, increase utilization and improve operational excellence. Source: Team analysis; POBOS

Our manufacturing footprint supporting strategic independence, Cogs leadership and Supply reliability

Production Volume, *% of Total Galenic Units*



Balanced and Flexible Manufacturing Footprint

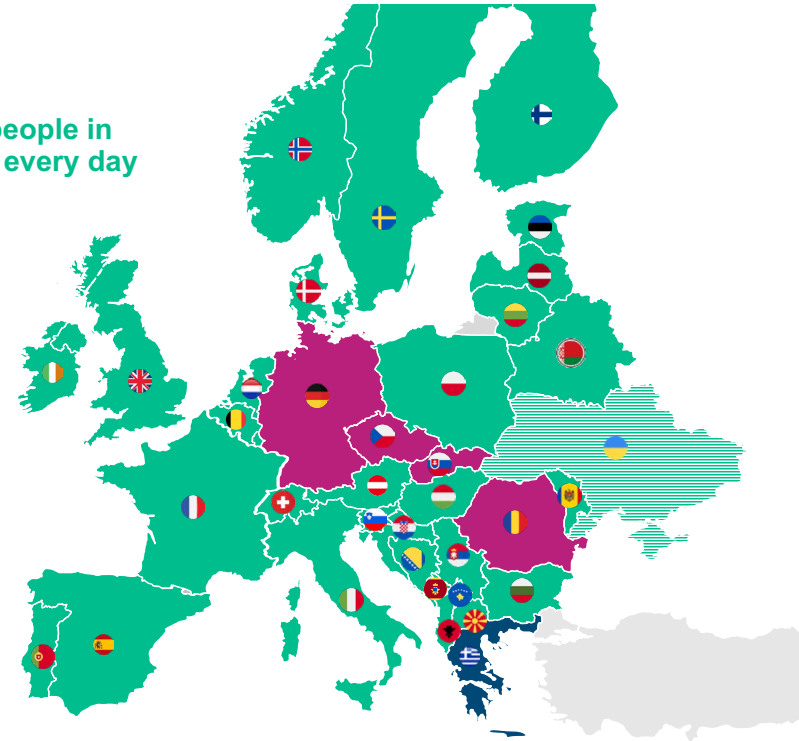
- Strong in-house manufacturing platform brings cost competitiveness and agility
- Network of 300 external partners – bringing range and coverage
- 70% capacity utilization with room to host growth aspiration
- Well invested network and capacity to support future growth ambitions – ~€100m capex invested over 2019-22
- Internal production currently at >70% of total Galenic Units supplied
- Sanofi MSA ended in 2023 with ~5% GU ongoing supply post MSA into 2024/2025
- Best-in-class unit conversion cost on par or better than top quartile

ZENTIVA

We serve…

Zentiva serves more than 100 million people in Europe who depend on our medicines every day

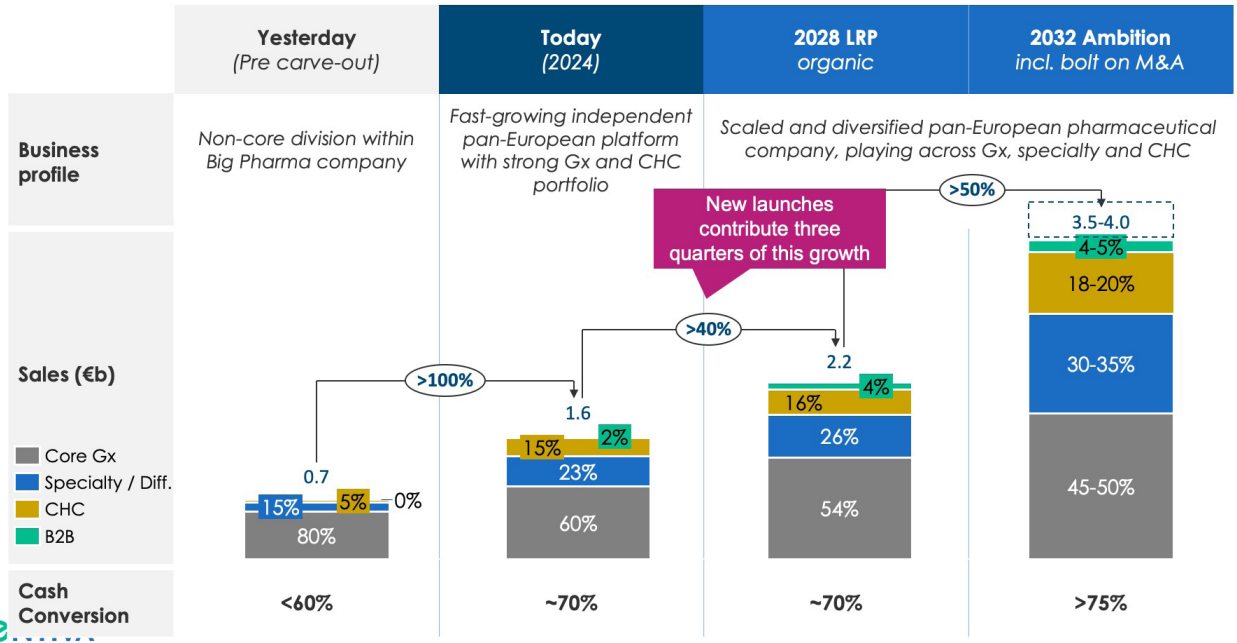
- Ranked #1
- Ranked in the Top 5
- Market Player
- Recent data N/A



ZENTIVA

1. Source: IMS IQVIA MIDAS data, representing Zentiva's market ranking. 2. Calculations for the Rx market are based on MAT value 04/24. 3. DE values based on MAT volume 04/24

Roadmap 2028 is our plan to achieve exciting growth



How will Zentiva look like in 2028?

ZENTIVA 2028 Roadmap
SHAPING OUR FUTURE. TOGETHER.

Zentiva will become a true Pan-European Pharma platform, able to drive growth in high-value market segments, building on in-house R&D and operations, capabilities driving pipeline and reliable supply.

I Building our portfolio

- **Core Gx:** Address €42bn LoE opportunity
- Expand in attractive and complementary **Specialty** (e.g. Cardio, Biosimilars) and **Consumer Health** segments

II Serving our customers

- "Power-up "core" **WE markets** with > 60% target share of sales from WE
- Continue to win in Branded Gx **CEE markets**
- Build platform in 2-3 **new/low scale** markets

III Excellence in Development and launches

- Cover >80% **LoE**
- Develop **Specialty / CHC** capabilities (Combis, VAM)
- Accelerate **launch speed and success**

IV Best-in-class Product Supply

- **Top quartile cost** of conversion and agile manufacturing
- **Best in class** service level
- Grow share of **internal supply to ~75%**

V Building a platform for growth through our Winning Team

- **Winning culture**, identity, purpose, values and image
- Excellent **financial rigor**
- **Operational excellence**
- Build **Zentiva's reputation in Europe** through strong Corporate Affairs, Stakeholder Dialogue and Market Access
- Drive **Sustainability**

At Zentiva, we provide health and wellbeing for all generations.

OTHERS

1

AUMED, A.S.

"Innovating Health, Empowering Life"

Bringing cutting-edge biotechnology to the forefront of immunology, bacteriophage therapy, and vaccine development. Grounded in expertise, driven by research, and committed to a healthier world.

About us

Innovative Health Solutions: At AUMED, a.s., we stand at the forefront of pharmaceutical innovation, dedicated to advancing healthcare through cutting-edge research and development. With a legacy rooted in the successful production of vaccines and immunological products, we leverage decades of expertise to deliver high-quality, impactful solutions.

Established Heritage: Building on the strong foundations of Sevapharma, we continue the tradition of excellence in biopharmaceuticals.

Global Perspective: Our strategic partnerships and collaborations extend our reach, ensuring that our products meet international standards and address global health challenges.

Commitment to Quality: We prioritize quality and safety in all our operations, striving for compliance with the highest industry standards.

Company structure

CEO (Chief Executive Officer):

- Leads the overall strategy, operations, and vision of the company.

COO (Chief Operating Officer):

- Oversees day-to-day operations and ensures the smooth functioning of the company's divisions.

CFO (Chief Financial Officer):

- Manages the financial strategy, budgeting, and investor relations.

CTO (Chief Technology Officer):

- Heads technological innovation and infrastructure, driving research and development in key areas.

Commercial Director:

- Directs sales, business development, and partnerships.

Together, they direct the following divisions:
Quality Control: Ensuring compliance with regulatory standards.
Quality Assurance: Overseeing production protocols and maintaining high standards.
Vaccines Division: Focuses on the development of key vaccines, including for whooping cough.
Immunology Division: Advances research into immune response therapies.
Research and Development Division: Fosters innovation across core research areas.
Bacteriophage Division: Focuses on bacteriophage treatments, including Stafal.
Bacteriophage Cosmetics: Develops skincare products leveraging bacteriophage technology.
Foreign Activities and Export Division: Manages global operations and export strategies.

Mission & vision

Our Mission

To enhance global health by providing innovative solutions in bacteriophages, immunology, and vaccines, backed by rigorous research and the highest standards of quality.

Our Vision

To be a leader in the pharmaceutical industry, recognized globally for our groundbreaking products and contributions to public health, while fostering sustainable practices that benefit communities and the environment.

Innovation: Constantly evolving our research capabilities to stay ahead of the curve.

Collaboration: Building strategic partnerships that amplify our impact on global health.

Integrity: Upholding the highest ethical standards in all our operations.

Together, we aim to make a significant difference in the lives of patients worldwide.

Our focus areas

Strategic Expertise in Key Areas
AUMED, a.s. specializes in four critical domains, ensuring we address the most pressing health challenges:

- **Bacteriophages**: Pioneering research and development of phage therapies to combat antibiotic-resistant infections.
- **Immunology**: Advancing therapies and products that enhance immune responses and improve patient outcomes.
- **Vaccines**: Innovating in the design and production of vaccines for infectious diseases and immunization programs.
- **GMP Clean Rooms Consulting**: Offering expert consulting services for the design and maintenance of GMP-compliant clean rooms.

Immunology division

- **Innovative Immunotherapy:** AUMED Immunology specializes in developing cutting-edge immunological products, including therapies based on transfer factors and vaccines for various diseases.

- **Transfer Factor Products:** We are pioneering the use of oral lyophilized tablets containing transfer factors to enhance immune response and combat infections.

- **Clinical Research:** Our ongoing clinical trials focus on establishing the safety and efficacy of our immunological products, with a commitment to meeting stringent regulatory standards.

- **Addressing Global Health Needs:** By targeting critical areas such as atopic eczema and bacterial vaginosis, we aim to fulfill unmet medical needs while advancing global health.

Vaccines division

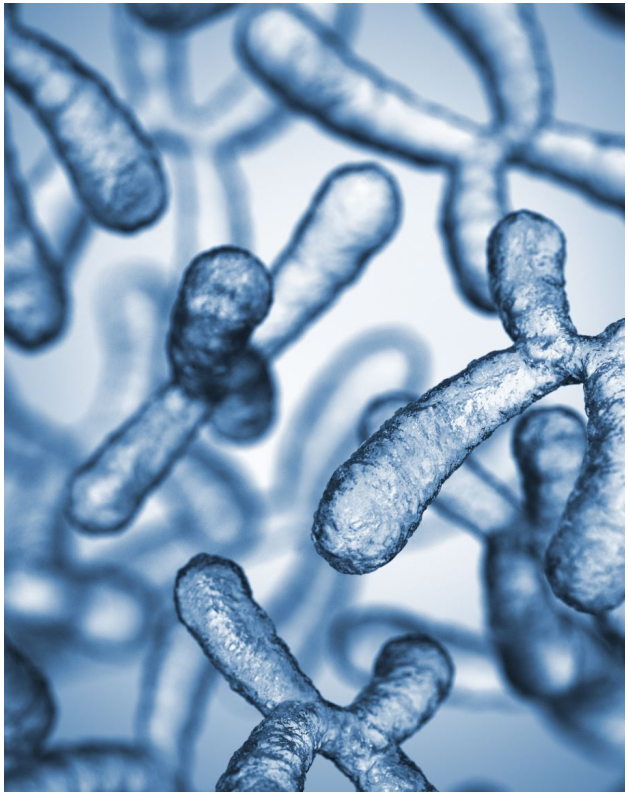
- **Next-Generation Vaccine Development:** AUMED is dedicated to creating innovative vaccines, including a novel Staphylococcus aureus vaccine designed to combat antibiotic-resistant strains.

- AUMED has undertaken a comprehensive multi-year project focusing on developing a new whole-cell vaccine against whooping cough (Bordetella pertussis). This initiative aims to address the limitations of acellular vaccines, which have shown reduced long-term effectiveness and immunoprotective capabilities.

- **Advanced Formulations:** Our vaccine candidates are developed using advanced methodologies, including exogenous toxoids, ensuring high safety and efficacy profiles.

- **Regulatory Compliance:** We prioritize compliance with Good Manufacturing Practices (GMP) throughout our vaccine development process, ensuring product quality and reliability.

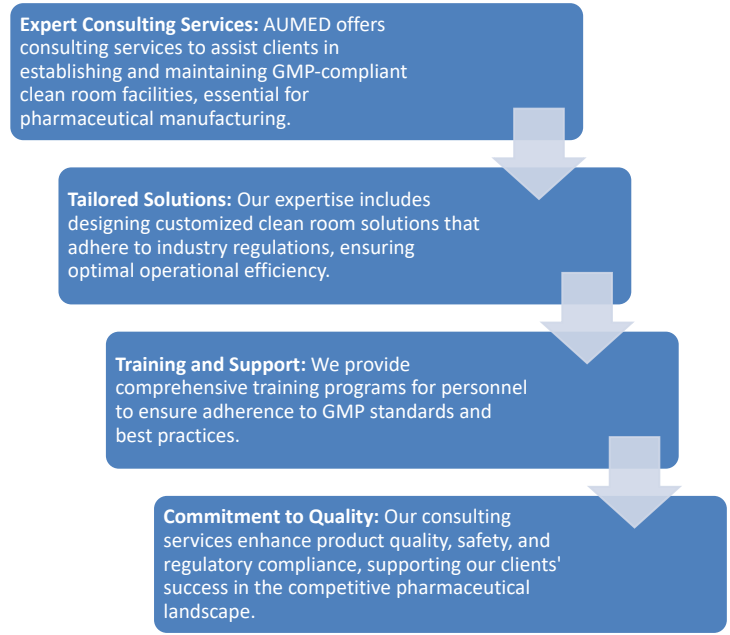
- **Future Licensing Opportunities:** Our research and development efforts position us for potential licensing agreements with leading pharmaceutical manufacturers, expanding our global reach.



Bacteriophage division

- **Innovative Therapeutics:** AUMED is at the forefront of bacteriophage research, exploring their potential as a novel therapeutic strategy against antibiotic-resistant bacteria.
- **PhageGlow Product Line:** Our flagship product, PhageGlow, offers targeted bacteriophage solutions for treating bacterial infections, harnessing the natural ability of phages to combat specific pathogens.
- **Research Collaboration:** We engage in collaborative research initiatives, aiming to leverage advanced phage technology and accelerate product development
- **Global Market Potential:** With antibiotic resistance rising globally, our bacteriophage solutions represent a promising alternative, positioning us for significant market impact.

GMP clean rooms consulting division



Summary

AUMED, a.s. is dedicated to **transforming healthcare through innovative solutions**.

Our focus on bacteriophages, immunology, vaccines, and GMP consulting positions us as leaders in the pharmaceutical industry.

With a legacy of resilience and commitment to quality, we invite you to join us in making a lasting impact on global health.

Thank you for your attention

We Value Your Interest

Thank you for taking the time to learn about AUMED, a.s.

We are excited about the opportunity to collaborate with partners who share our vision for advancing healthcare through innovation.

Let's Connect: We welcome your questions and insights, as they are vital to our mutual success.

Join Us on This Journey: Together, we can make a significant impact on global health and well-being.

Contact Us: Ing. Kristián Lorenc, Member of the Board, +420 733 738 115, kristian.lorenc@aumed.cz

We look forward to discussing how we can work together to create a healthier future!

OTHERS

2

BIOMEDICA, SPOL. S R.O.

BIOMEDICA

Where science meets nature

www.bio-medica.eu

BIOMEDICA - *We have been here for you for over 30 years*

Biomedica Ltd. was established in 1991 by its owner, RNDr. Hubert Koukol. The early 1990s in the Czech Republic saw new opportunities on the market for various herbal products. Their development and production became the primary business ambition of the new firm headed by its first director, MVDr. Josef Janíček.

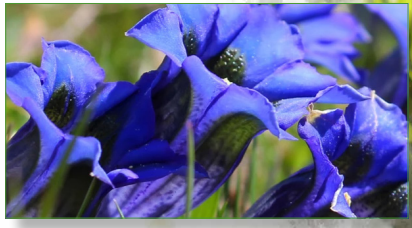
The first products, which were based on the principle of aromatherapy combined with herbal extracts, were developed in 1992. The product portfolio has continued to grow since that time.

In 1994, BIOMEDICA registered and produced BIOTUSSIL®, the first phytopharmaceutical product based on an original formula.

By the end of 1995, the company had become successful under the leadership of Ing. Jaroslav Říha, and in 2002 began building its own production facilities in the Hořátev Technological Park near the city of Nymburk.

In 2005, the product portfolio grew rapidly due to several new registered pharmaceuticals – Framykoin powder, Kalium chloratum tablets, and Lactulosa Biomedica syrup.

Cooperation with EU funds contributed to large investments, particularly in its new facilities and state of the art technology. The most recent significant expansion of the company happened in 2021 with the development of new dietary supplement technology and the addition of an extension to its warehouses.



Nowadays, the core of the company consists of three distinct but intertwined pillars:

- ***Development, registration, and sales of its own products*** – pharmaceuticals, medical devices, dietary supplements, and cosmetic products,
- ***Contracted production*** for pharmaceutical companies; firms operating in the field of medical products, veterinary products, dietary supplements, and cosmetics,
- ***Raw material business division*** for the food and pharmaceutical industry operating around the world.

BIOMEDICA Ltd. employs a team of experts active in the development, approval, and registration of pharmaceutical products, medical devices, and dietary supplements.

A major contribution to the rapid expansion of BIOMEDICA is its exclusive representation abroad, particularly in Germany, Slovakia and in Vietnam. BIOMEDICA Ltd. currently employs around 300 employees.

Production
of pharmaceuticals

The first pharmaceutical product made by BIOMEDICA was registered back in 1992. In very beginning, production was located in Prague. The relocation of production to the Hořátev Technological Park in 2005 allowed the firm to fully exploit its sustained experience and know-how, which resulted in the rapid expansion of its product portfolio.

Currently, BIOMEDICA has GMP authorization to produce the following:

- ***Infusion solutions,***
  filled into plastic bags with a volume of **20-5000 ml**,
- ***Solid-form pharmaceuticals,***
  production of tablets, packing in blisters and packaging, including serialization,
- ***Liquid-form pharmaceuticals,***
  homogenization and filling into glass bottles with a volume of **50-1000 ml**,
- ***Powders,***
  homogenization and filling into glass jars and packaging, including serialization.

The production facility consists of three buildings located in the Hořátev Technological Park.

Production
of medical devices

The production of medical devices of ***class II b (dialysis solutions), registered by the MDR at the ITC Zlín notified person***, takes place in a modern building constructed in 2014.

The size of production batches can vary from **300-2000 liters**.

The filling device is ideal for plastic bags with volumes ranging from **20-5000 ml**.

The package can be vacuum sealed immediately after the bag if filled or in the flow-pack system, after the sterilization of the autoclave.

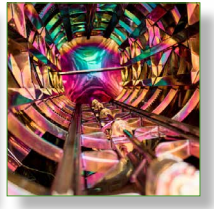
The sterilization process takes place in modern sterilization equipment operating by automated qualified procedure programs.

Medical devices of ***class I*** can also be produced in some of our other facilities, depending on the particular type of the product.

Production
of dietary supplements

BIOMEDICA produces dietary supplements in several production buildings, and since 2023 under the internationally recognized certificate FSSC 22 000.
The production is wide-ranging, from the blending of mixtures (even premixes) with the possibility of granulation, through manufacturing tablets and hard gelatinous capsules and coating them, packing them in blisters, and filling them in glass jars, to packaging the final product.

The homogenization and granulation processes can be adjusted, depending on the desired size of the product. Mixtures can be homogenized anywhere from twenty to hundreds of kilograms. Given the non-explosive nature of the manufacturing environment, it is possible to use alcohol in the production process.



Tablet production takes place on four tablet presses. Tablets made through the process of moist granulation or direct compression can be coated in the coating machine anywhere from **50 to 300 kg** of tablets at one time.

Diameter	Shape	Weight	Height
5 mm	Lentil with no bisecting line	50-70 mg	2,5-3 mm
9 mm	Lentil with bisecting line	200-350 mg	4-5 mm
9 mm	Lentil with no bisecting line	200-350 mg	4-5 mm
12 mm	Lentil with no bisecting line	500-700 mg	5-6 mm
13 mm	Flat tablet with bisecting line	700-800 mg	4-5 mm
19 mm x 8 mm	Flat tablet with bisecting line - Oblong	700-1000 mg	5-6 mm
21 mm x 8 mm	Flat tablet with bisecting line - Oblong	900-1400 mg	7-7,5 mm

Hard gelatinous capsules are filled at three separate automated devices and are made in four different sizes: 3, 1, 0, 00.

The production of ***soft gelatinous capsules*** has ceased, but in case of need, the order can be subcontracted out to our other external firm in Czech Republic.

All tablets and capsules can be filled in jars on our automated line with an induction closing system or ***packed in blisters*** of various sizes:

For blister packing	Number of pieces in a blister	Size
Hard gelatinous capsule size 0;1	10	66 x 89 mm
Hard gelatinous capsule size 0;1	20	100 x 130 mm
Hard gelatinous capsule size 0;1	20	72 x 125 mm
Hard gelatinous capsule size 0;1	4	38 x 89 mm
Hard gelatinous capsule size 0;1	10	66 x 89 mm
Hard gelatinous capsule size 0;1	15	80 x 125 mm
Soft gelatinous capsule	15	66 x 89 mm
Tablets – lentils 9 mm	10	38 x 89 mm
Tablets – lentils 12 mm	10	66 x 89 mm
Tablets – lentils 12 mm	10	55 x 80 mm
Tablets – oblong (19x8mm a 21x8 mm)	10	59 x 88 mm
Tablets - oblong (19x8 mm)	20	72 x 125 mm
Tablets – oblong	10	59 x 88 mm

Other formats are possible after prior mutual discussion and agreement.

BIOMEDICA's product portfolio also includes the ***production of syrups***, which can be based either on sugar, sorbitol, fructose, or fruit concentrates. For this process, we use big homogenization boilers with a capacity ranging from 250-1000 liters. Current volumes of processed products vary from 50-1000 liters. The production of syrups largely takes place in Luhačovice, near the border with Slovakia.

BIOMEDICA can also manufacture small packages of liquid dietary supplements. Some examples include drops in volumes of **10-50 ml**.

Production
of cosmetic products

BIOMEDICA produces a wide range of cosmetic products:

- ***Gels,***
- ***Creams*** with an oil/water or water/oil base,
- ***Emulsions,***
- ***Tensid cosmetics***, e.g., shampoos, bath foams and liquid soaps,
- ***Suspensions.***

For the ***homogenization*** of our production batches, we use a double-walled boiler with a 20-liter volume. In the production plant, there are also four other large homogenization boilers with volumes ranging from 100 to 1000 liters. Another option is manufacturing under vacuum. The heating medium of the boilers is steam.

Depending on the size of the batch, the final product can be filled either by a semiautomatic or automatic tube filling machine in volumes ranging from **10-200 ml**. Our filling line is capable of putting cosmetic products into tubes and jars at volumes of up to **1000 liters**.

Our production premises are also designed for the future production of medicinal products. Distilled water is used in the production process.

Quality control system and laboratory

Biomedica has implemented a quality control system, divided according to the type of products it manufactures. This system is reviewed annually, with the quality targets set and evaluated. Our own Quality Control Department is responsible for quality assurance within the company and has the power to control, monitor, evaluate and coordinate the quality control system.

We have established highly advanced laboratories for the quality control of our manufactured products. These laboratories are located in three different buildings, including the laboratory reserved for the quality control of medicinal products subject to strict oversight by state authorities.

Our laboratories contain the following laboratory equipment:
HPLC, AAS/AES, potentiometric titrator, IR spectroscopy, UV/VIS spectroscopy, dissolution apparatus, disintegration device, polarimeter, osmometer, a device for measuring particles below the visibility range in solutions, density meter and rotational viscometer.

BIOMEDICA

Development
and product registration

A large portion of our laboratory capacity focuses on the ***development of new products***. The BIOMEDICA research team can either develop your formula or help you improve it according to your expectations and needs, for all markets and commodities for sell.

Sale of raw materials

Since 1997, BIOMEDICA Ltd. has been a major importer and supplier of raw material for the cosmetic, food and pharmaceutical industries focusing on raw materials of natural origin.

- ***ethereal oils*** for cosmetic products, household chemicals, and the food industry,
- ***herbal oils and butters*** for care of the complexion in both regular and organic quality,
- ***water- and oil-dissoluble extracts*** – broad scale of effective and active herbal-based agents,
- ***menthol and camphor***,
- ***perfumes,*** vitamins, and preservatives,
- basic ***oleo-chemicals*** vital for the production of emulsions.

For the production of dietary supplements and for the food industry, BIOMEDICA offers a large portfolio of:

- ***dried herbal extracts,***
- ***seaweed,***
- ***ground herbs,***
- ***vitamins,***
- ***mineral substances,***
- ***pro-biotic cultures,***
- ***nutritional oils (including omega oils),***
- ***amino acids,***
- ***other nutraceutics used for making nutrients for the joints and for sports,***
- ***fruit concentrates of various flavors in liquid and powder forms***

BIOMEDICA Ltd. cooperates with major producers and distributors across the European Union, Asia, and America. In the Czech Republic, it represents the following companies on the market:

- ***Düllberg Konzentra*** (essential oils),
- ***CPL Aromas*** (perfumes),
- ***Industrial Quimica Lasem*** (oleo-chemicals),
- ***Parodi Nutra*** (herbal oils and butters),
- ***Kumar*** (active substances for cosmetics).

These raw materials can be delivered not only in standard packaging, but also in smaller amounts, precisely as requested by the customer. Our customers from all the segments of the industry mentioned above appreciate this option and frequently use it.

Our portfolio offers

more than 1600 types of raw materials,

all from verified sources. The supply of these raw materials is steadily increasing based on the latest trends and needs of our clients.

In connection with the sale of raw materials, BIOMEDICA provides an expert information service, and its documentation is in compliance with the latest legislation in force.

BIOMEDICA

Where science meets nature

BIOMEDICA

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www.deltamedica.de

OTHERS

3

CAYMAN PHARMA S.R.O.

Cayman CHEMICAL

Cayman PHARMA

GMP manufacturing and beyond

Cayman's CDMO Services:
A Trusted Partner from Molecule to Market

www.CaymanAPI.com

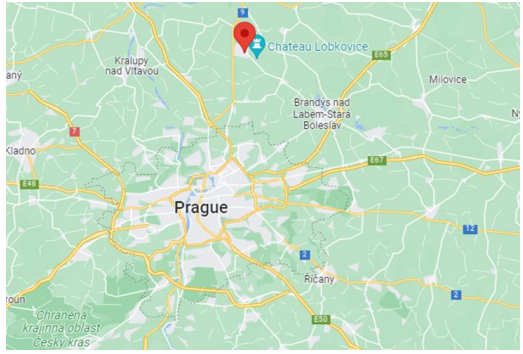
Helping Make Research Possible

Our mission is to help make research possible by supplying scientists worldwide with creative biochemical tools, products, and services to advance medical research and enable new therapies.

www.CaymanAPI.com

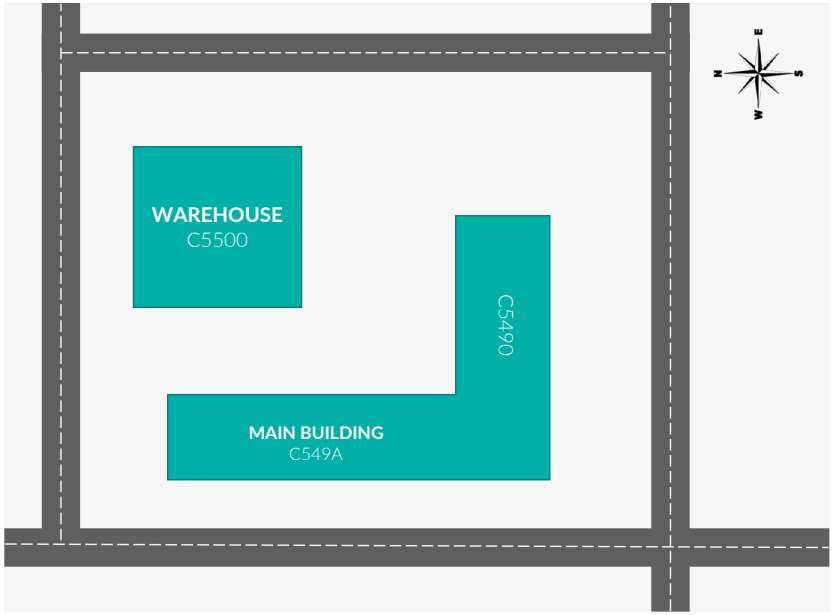
Cayman Pharma | Neratovice, CZ

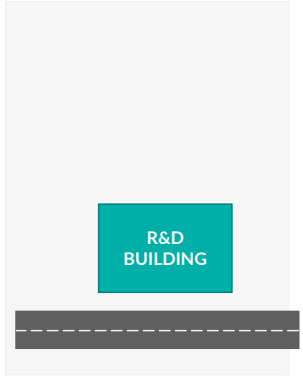
Located on the Spolana Campus



www.CaymanAPI.com

Cayman Pharma | Site Layout





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Cayman GMP Capabilities

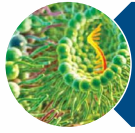
API Products & Services

Prostaglandins

- Generic APIs for Ophthalmologic, Veterinary, Cardiac Indications

Controlled Substances

- Psilocybin, Psilocin
- DMT, MDMA (in development)



Ionizable Lipids

- LNP excipients and APIs for use in GMP formulations

Custom APIs

- Nucleoside analogs
- Tryptamines
- Aminoisoquinoline and Aminoisoquinolone Analogs
- Novel Heterocyclic NCEs

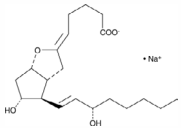
Cayman Pharma s.r.o.
Prague · Czech Republic

Cayman Chemical Company
Ann Arbor, MI · United States

www.CaymanAPI.com

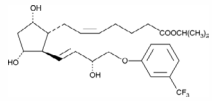
Ophthalmology API Portfolio

Bimatoprost



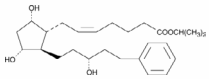
- **Use:** Bimatoprost is a potent FP receptor agonist that finds clinical use as an ocular hypotensive agent for the treatment of glaucoma.
- DMF on file in most developed countries

Travoprost



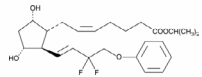
- **Use:** Travoprost is a potent FP receptor agonist that finds clinical use as an ocular hypotensive agent for the treatment of glaucoma.
- DMF on file in most developed countries

Latanoprost



- **Use:** Latanoprost is the most widely used prostaglandin for the treatment of elevated intraocular pressure (IOP) in glaucoma.
- DMF on file in most developed countries

Tafluprost

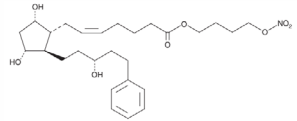


- **Use:** Tafluprost is a potent FP receptor agonist; it is used for the treatment of elevated IOP in glaucoma.
- DMF available upon request

www.CaymanAPI.com

Ophthalmology API Portfolio

Latanoprostene Bunod

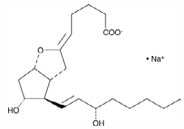


- **Use:** Latanoprostene Bunod is used for the treatment of IOP in patients with open-angle glaucoma or ocular hypertension which targets the trabecular meshwork and uveoscleral pathways.
- DMF available upon request

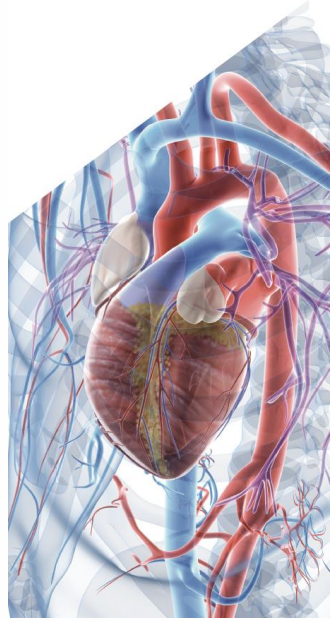
www.CaymanAPI.com

Vascular API Portfolio

Epoprostenol sodium salt



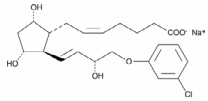
- **Use:** Epoprostenol is a potent vasodilator and antiplatelet substance with a very short physiologic half-life. It is used for the treatment of pulmonary hypertension.
- DMF on file in most developed countries



www.CaymanAPI.com

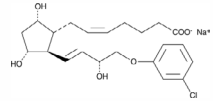
Veterinary API Portfolio

(±)-Cloprostenol sodium salt

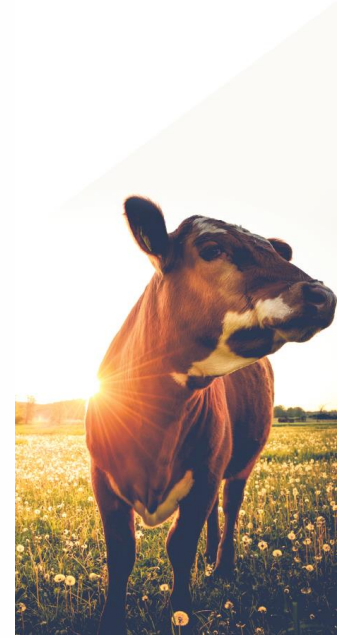


- **Use:** Cloprostenol is used in veterinary medicine as a luteolytic agent for the induction of estrus and the treatment of reproductive disorders in cattle, swine, and horses.
- DMF on file in most developed countries

(+)-Cloprostenol sodium salt



- **Use:** (+)-Cloprostenol is the active enantiomer of Cloprostenol.
- DMF on file in most developed countries



www.CaymanAPI.com

Cayman Regulatory Filings

Cayman Chemical Company
Ann Arbor, MI · United States
· Headquarters
· API/GMP Manufacturing

Cayman Pharma s.r.o.
Prague · Czech Republic
· API/GMP Production

www.CaymanAPI.com

Integrated Management System and GMP Compliance

- ISO 9001, 14001 and 45001 certification
- Audits of regulatory authorities
  - Czech SÚKL and ÚSKVBL (EU GMP)
  - US FDA
  - Brazilian ANVISA
- Internal audits
  - Review of GMP and IMS compliance in individual departments based on annual plan
- GMP Audits performed by customers
- CP audits key suppliers to verify fulfillment of GMP/ISO rules

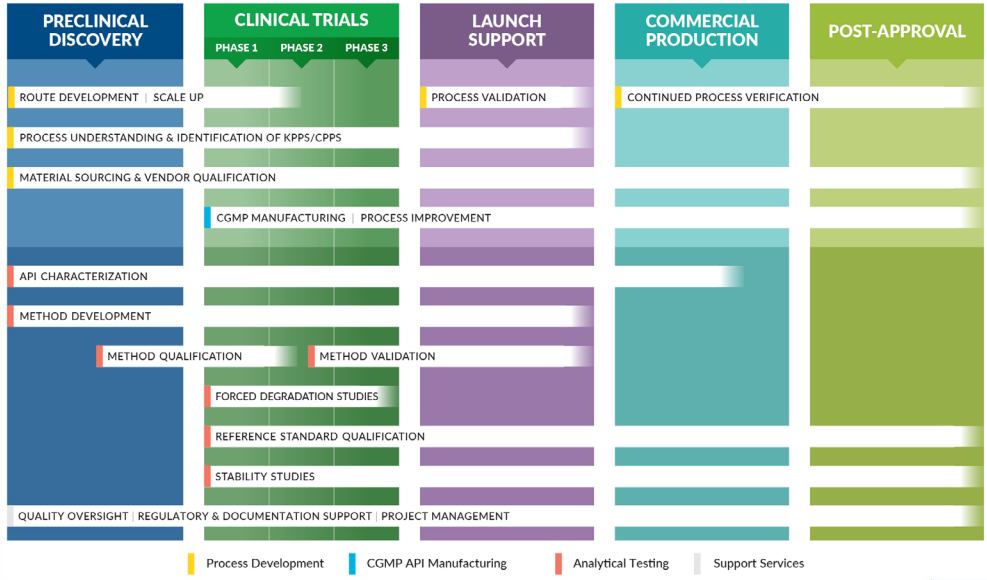
Research & Development

- Expansion of product portfolio and enhancement of competitive ability of current production (production scale-up, identification of critical synthesis parameters, etc.)
- Cooperation with drug product manufacturers regarding marketing applications (impurity standards preparation, impurity profile determination)
- Creating development program for the company

www.CaymanAPI.com

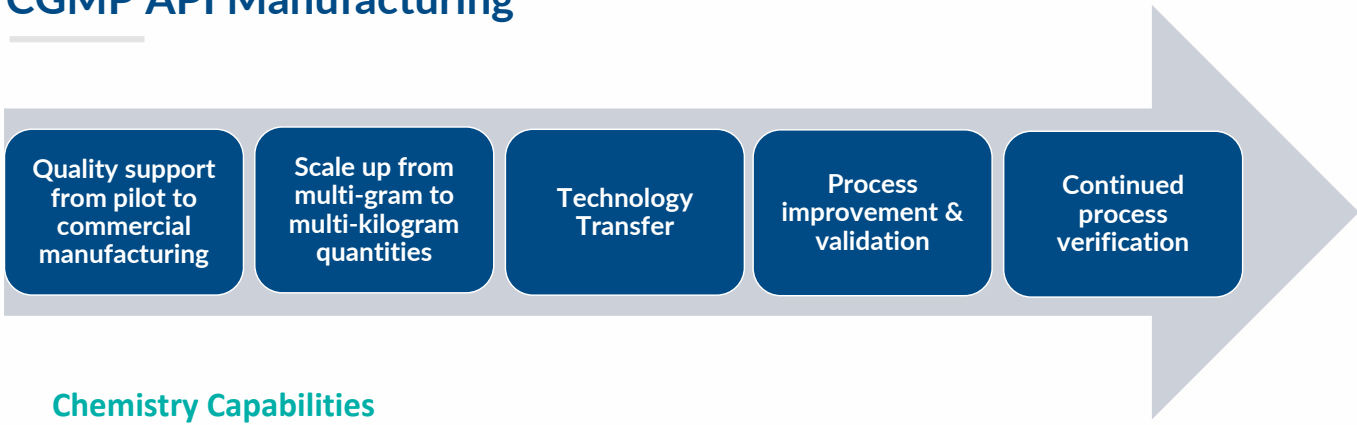
Our Excellence

Supporting CGMP development from preclinical discovery though commercialization



www.CaymanAPI.com

CGMP API Manufacturing



Chemistry Capabilities

- Prostaglandins & prostanoids
- Nucleoside analogs
- Aminoisoquinolines & related analogs
- Tryptamines & other psychedelics
- Ionizable cationic lipids
- Heterocyclic compounds
- Custom molecules upon request

www.CaymanAPI.com

Why Cayman?

Client-centric Approach

Adaptability

Excellence

> Cayman Chemical places paramount emphasis on meeting customer needs and fulfilling their specific requirements. The manufacturing site stands out for its impeccable cleanliness, efficient organization, and appropriate equipment setup, particularly tailored for the production of APIs.“
>
> Contract Auditor
> **Rephine**

Thank you for your attention

www.CaymanAPI.com


Cayman
CHEMICAL
Cayman
PHARMA

OTHERS

4

MB PHARMA S.R.O.


MB PHARMA
You need. We know.
Pharmacy and
Microbiology

EXPERIENCE AND TRADITION

MB Pharma, **founded in 2012**, is a Czech pharmaceutical company focused on research, development, and innovations mainly in the field of microbiology and biotechnology.

Since 2016, MB Pharma has been certified according to the **Good Manufacturing Practice** (GMP) as the producer of APIs, HIMPs, and IMPs.

MB Pharma run various research and development activities of **bacteriophages**, bacterial lysates and bacterial enzymes.

The main aim of MB Pharma is to bring new and perspective biotechnologies into the **human medicine** practice.

MB Pharma is a **strong and reliable partner** in pharmaceutical and biotechnology industry.


ROZTOKY
Production laboratories certified according to GMP
Number of employees: 5
POLAND
OSTRAVA
Production laboratories certified according to GMP
Number of employees: 7
GERMANY
PRAGUE
Company management, administration
Number of employees: 5
SLOVAKIA
BRNO
Research and development laboratories
Number of employees: 8
AUSTRIA

WHERE we are

GMP PRODUCTION FACILITY **OSTRAVA**

200 sq. m of clean rooms

fermentation capacity **8** litres in bottles

QC laboratory

clean rooms **A** class for sterile fill and finish

20 litres in bioreactor

-80 °C freezers for banks storage

RESEARCH AND DEVELOPMENT FACILITY **BRNO**

- development of upstream, downstream and analytical methods
- phages isolation, sequencing and characterization
- development of microbial processes before transfer to the GMP
- storage of collection of microorganisms

GMP PRODUCTION FACILITY **ROZTOKY**

600 sq. m of clean rooms

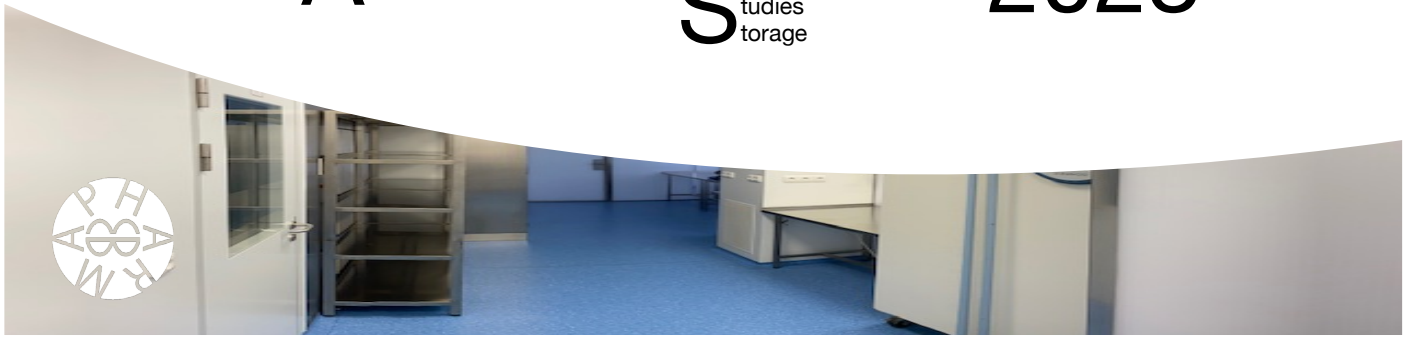
fermentation capacity **200** litres in bioreactor

10 km from Prague

clean rooms **A** class for sterile fill and finish

S tability tudies torage

2023 put in operation



PHARMACEUTICAL SERVICES

Manufacturing Operations

- Fermentation, cultivation
- Aseptic fill and finish Lyophilisation
- Batch certification
- Primary and secondary packaging

Quality Testing

- microbiology titration
- PCR
- visual control, pH
- HPLC methods
- ELISA assays

Contractual Manufacturing

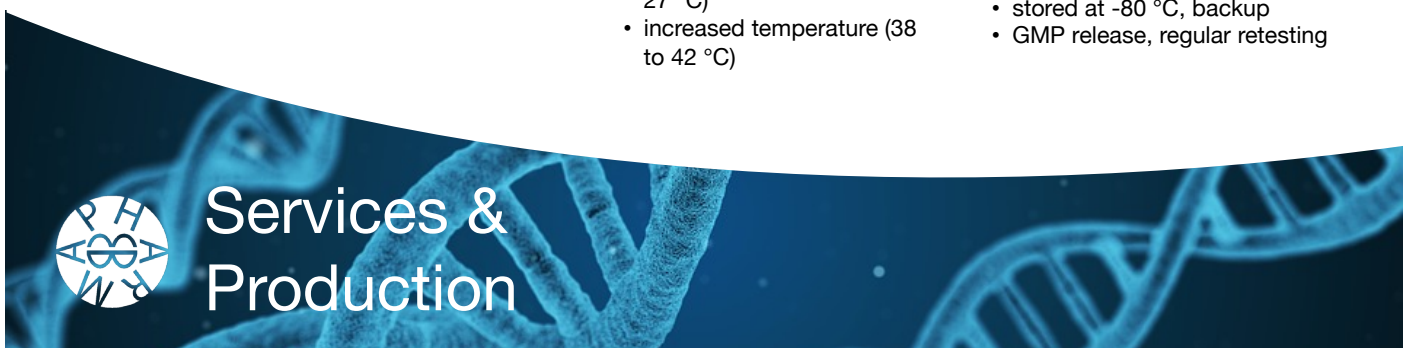
- Active Pharmaceutical Ingredients (API)
- Drug Products (DP)
- Investigational Medical Products (IMP)

Stability Studies

- regular, accelerated
- cooled (2 to 8 °C)
- room temperature (23 to 27 °C)
- increased temperature (38 to 42 °C)

Microbial Banks Storage

- research banks, master banks
- implemented seed lot system
- stored at -80 °C, backup
- GMP release, regular retesting



Production

1 Bacteriophages

- human therapy
- veterinary medicine
- food safety
- cosmetics

2 Enzymes

- collagenase, benzonase, endolysins and others
- recombinant production on genetically modified bacteria

3 Bacteria

- lysates for pharmaceutical use
- host strains for phage production
- cell extracts

LYZODOL

Revolutionary new generation food supplement based on bacterial lysates

The unique innovated product **LYZODOL** contains **inactivated bacteria of four selected bacterial strains**, which are most often involved in the development of **inflammation of the upper respiratory tract** - *Staphylococcus aureaus, Klebsiella pneumoniae, Lelliottia amnigena, Cutibacterium acnes*.

Development and clinical trials of a modern drug to treat bacterial infections

DUOFAG®

DUOFAG® is an innovative **biological medicinal product. DUOFAG®** can heal where **antibiotics fail.**

It is a product containing **bacteriophages** - viruses, that highly selectively attack bacteria *Staphylococcus aureus and Pseudomonas aeruginosa.*

DUOFAG® is aimed at the treatment of infections in **open wounds** – diabetic foot, burns, postoperative wounds, open wounds, etc.

It will contribute to the fight against **increasing microbial resistance** to antibiotics, which is one of the main current **priorities of the WHO.**

Products

CONTACT

Company site:

MB Pharma s.r.o
Rubešova 72/9
120 00 Prague 2
Czech Republic

Contact person:

Ing. Milan Buňata
E-mail: bunata@mbph.cz
Phone: +420 725 261 020


MB PHARMA
You need. We know.
www.mbph.cz

OTHERS

5

PRAGUE SCIENTIFIC BY ZENTIVA

...high-quality services from the heart of Europe

About Prague Scientific

Our mission is to provide top-tier development and scientific affairs services to our partners through knowledge and innovative science.

We are dedicated to support our clients in creating life-changing therapeutic solutions that enhance the quality of life for patients worldwide.

With our pan-European presence, we offer end-to-end solutions - from development and manufacturing of the product to successful launch and compliant maintenance.

We offer:

- API and Drug Product Development
- Regulatory Affairs
- Pharmacovigilance

Additionally, we offer academic cooperation The Pharmaceutical Applied Research Center (PARC).

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Accelerate Timelines & Generate Return on Investments

Outstanding complexity

Trusted Partner
Our commitment to reliability and excellence, positions us as the partner of choice for achieving ambitious goals and creating lasting value

Integrated CDMO
Our integrated approach accelerates drug development, ensuring time and cost efficiency from initial concept through to commercialization, leading to greater market success

Global Experience
Our global experience enables us to satisfy diverse market needs

Expertise
With nearly 200 experts on our team, we offer knowledge pool to navigate complex challenges and deliver innovative solutions

Value Creation
Our team specializes in creating added-value medicines that distinguish us in competitive markets, enhancing both therapeutic impact and commercial success

Flexibility
Our model enables participation in projects of any scale or type, from generics to new chemical entities

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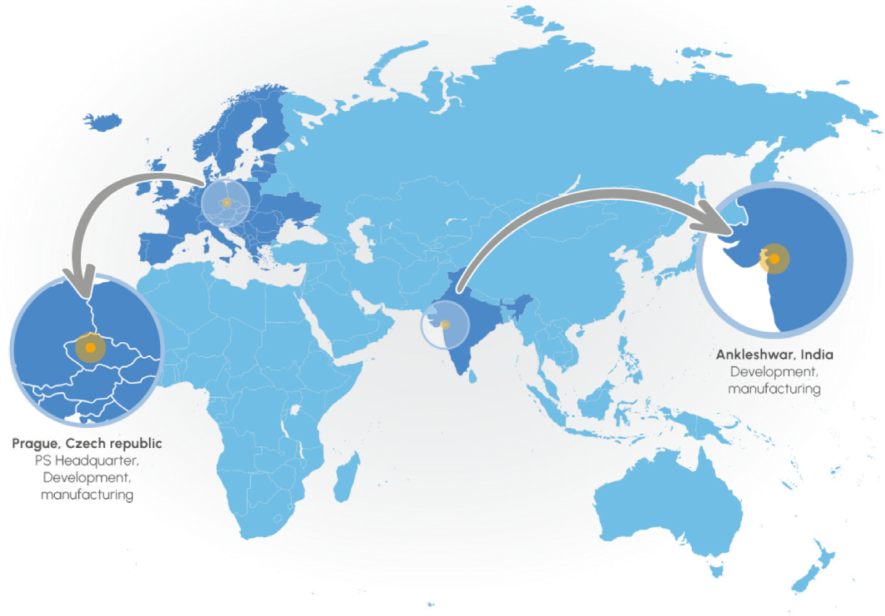
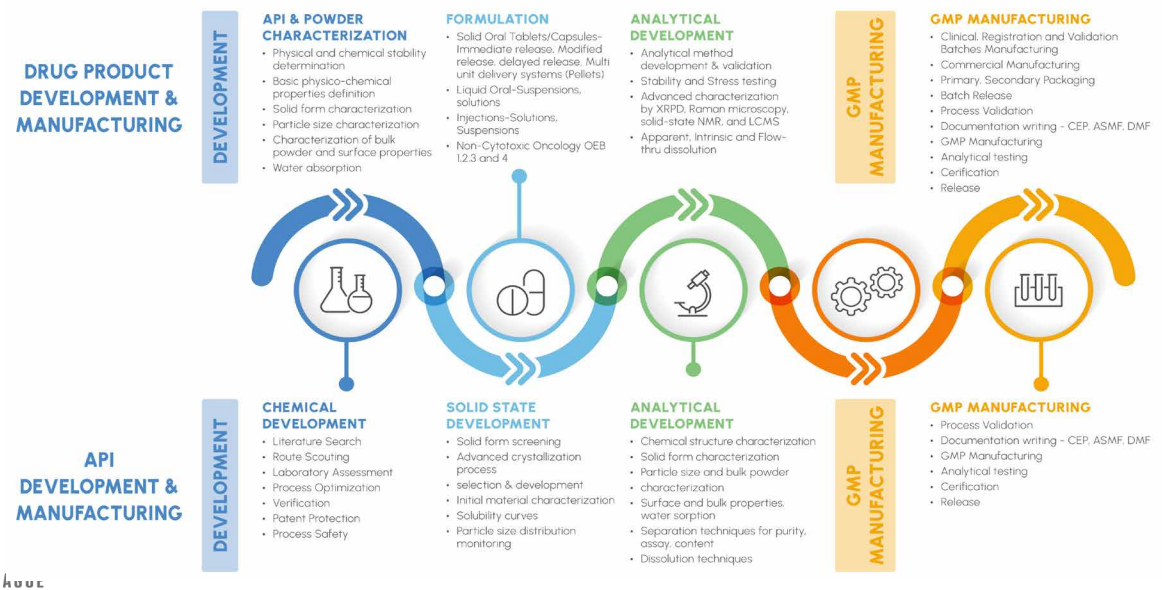
Main Locations



API & Pharmaceutical Development

From development to GMP production



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Technology Platforms

Commercial strategy is focused on six technology platforms, each with its own target profile attribute:

- Small Molecules
- Oligo-Nucleotides
- Oral Solids
- Oral Liquids
- Injectables
- Topical & Opthalmic

Within each platform, Prague Scientific partners with our clients individually to tailor their scope and appropriate technology application, facilitates the development and scale-up of the product, establishes pricing and budget alongside the sales team, and oversees the alignment with operations and project management teams to deliver a customized execution plan for the project journey.

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powered by Zentiva

API & Pharmaceutical Development

Prague Scientific performs the full scope of development services. From API Development & Manufacturing and through Formulation development to Drug product registration, GMP-Manufacturing and Pharmacovigilance.

Our comprehensive involvement in every stage of API and drug product development provides you a smooth, one-stop solution delivered by a trusted partner.

We have experts and modern equipment which enable us to participate in pre-clinical, clinical as well as post-launch stage of the development, safety testing and commercialization.

Our outstanding R&D Team, which consists of more than 200 experts and modern technologies will allow you to achieve great results within short timelines.

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API Manufacturing

GMP operations, Prague Pilot Plant, Ankleshwar Pilot Plant and Full-Scale Plant

- GMP batches for clinical trials.
- Process validation.
- Commercial Manufacturing.
- The facilities comply with cGMP and HSE requirements
- 50+ CEP, ASMF and US DMF were developed, compiled, and used for DP registrations.

Equipment available: Reactors 25-6000L, Autoclaves 20-2500L, Isolation and Drying Units, Sieving and Milling equipment.

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powered by Zentiva

API Development: Special Chemistry

Oligonucleotides, Prague

- Non-GMP custom synthesis of various oligonucleotides (up to 18-25 nucleotides) possible up to a gram scale
- Experience with LC purification and desalting/lyophilization
- Characterization of the products by HPLC/LR LCMS/NMR available
- Crude Oligo up to 80% purity and Purified Oligo up to 95 %
- Post synthetic modification-based on experience in Organic Chemistry

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powered by Zentiva

API Development: Special Chemistry

Synthesis & Analysis & Characterization of Oligonucleotides, Prague

- **ÄKTA OP100 Synthesizer** -

  Current syntheses scales:
  ca. 42 micromol to 247 micromol
  Higher scales are technically also possible
  8 amidite positions available now

- **Preparative Akta Pure 150 LC System:**

  LC IEX separations up to 1 g of crude oligo
  Desalting by SEC or Tangential Flow Filtration (TFF)
  Lyophilization available

- **Characterization:**
  IP RP HPLC or SAX HPLC analysis

  ^{31}P/^{19}F/^{13}C/^{1}H NMR measurements possible (Bruker NMRs)

  LR LCMS analyses

- **Analytical Shimadzu HPLC System:**
  Analyses of crude and purified fractions by IP RP HPLC or SAX HPLC
  Evaluation of mock fractions pooling to maximize purified oligos yields

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Pharma-Development

API and Powder Characterization

- **Physical and chemical stability**
- **Basic phys-chem properties**
- **Solid form characterization**
- **Particle size characterization**
- **Characterization** of **bulk powder properties** and **optimization** of tablet composition based on **powder rheology**
- **Troubleshooting** and **investigation** of tablet hardening, softening, poor tablet disintegration, chemical degradation and solid form conversion
- **Powder bulk and surface properties**
- **Water absorption:** dynamic water sorption, thermo-gravimetric analysis

Formulation

- **Excipients and Process selection**
- **Delivery Dosage Form**
- **Technology**

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Analytical Development

Our team of **80 highly skilled analytical chemists** can offer the following services:

- Analytical **method development**
- Analytical **method validation**
- Specification setting
- Analytical method transfers
- **Stability and Stress testing**
- **Reference standard characterization** by MS, NMR, IR
- **Solid state NMR Analysis**, Polymorph Characterization and Purity
- Preparation of CMC part of ASMF

Equipment available: *40+ HPLC and UPLC systems, GC, CE, IC, 12 Dissolution apparatuses, 2 NMRs for liquid and 1 NMR for solid phase measurements, GC/MS, LC/MS, Titrators, Stability chambers, LIMS system*

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Scientific Affairs

Prague Scientific provides a full scope of pharmacovigilance and regulatory consulting services to support pharmaceutical companies.

Our highly skilled and experienced consultants will help you to set-up the best practices for your products in order to meet the global and local regulatory requirements and ensure the drug safety.

Benefits of outsourcing our services:

- Lower costs and risks than entering the markets by yourself
- Flexible resource allocation according to your needs
- Up-to-date knowledge of the local regulatory requirements
- More focus on your core business activities

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Scientific Affairs: Regulatory

PRE-APPROVAL

- **Regulatory dossier compilation** all modules
- **Regulatory due diligence** and strategy incl., **scientific advice** meetings
- Product information preparation **SPC, PIL** and labelling
- **Cooperation with EU agencies** for pre-submission activities
- Support for local specific requirements
- **eCTD publication** services

SUBMISSION

- **Dossier dispatch, submission of applications, deficiencies management**, translation of product information text
- **DTP services** i.e. mock-ups preparation and updates
- **RIM data services**

POST-APPROVAL

- Portfolio management
- MA maintenance: variations(Type IA, Type IB, Type II), renewal, and MA transfer, 'sunset clause' exemptions package, withdrawal
- RMS transfers, Industrial transfers support, MAs harmonization strategy proposal and execution, MA duplication procedure
- Certificate of Pharmaceutical Product (CPP)

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Scientific Affairs: Pharmacovigilance (PV)

Prague Scientific offers complete and compliant solutions for pharmacovigilance activities related to the detection, assessment, understanding and prevention of adverse events or any other possible drug-related problems. Our consulting services cover all aspects of local pharmacovigilance in respective territories, which is compliant with GVP (Good Vigilance Practices).

We offer the following PV services:

- Local Pharmacovigilance contact points
- Management of safety information reports
- Local literature screening and regulatory intelligence monitoring
- Submissions and communication with local regulatory authorities
- Local adaptation and implementation of risk minimization measures
- Auditing of pharmacovigilance processes, auditing

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Academic Cooperation

Prague Scientific closely collaborates with The Parc (Pharmaceutical Applied Research Centre), which is a platform offering a post-graduate program that is based on collaboration between academic and industrial partners (https://www.theparc.eu).

The scientific scope of The Parc consortium covers a broad range of pharmaceutical expertise such as Chemical Engineering, Physical Chemistry, Materials Science, Analytical Chemistry, Computational Chemistry, Pharmaceutical Technology, or Clinical Research.

The cooperation with The Parc provides an opportunity to gain a support of top experts and researchers as well as access to a wide range of technologies and state-of-the-art equipment that are available at partnering universities and institutes.

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PRAGUE SCIENTIFIC
powered by Zentiva

OTHERS

6

PROFARMA-PRODUKT, S.R.O.

Profarma – Produkt, s.r.o.

Authorised Manufacturer of Medicinal products and Food supplements

Introduction

- Profarma is a company with a long-term tradition.
- Company **PROFARMA-PRODUKT, s.r.o.** was established on June,5th 1995 as a company manufacturing pharmaceutical raw, intermediate and ready to use materials for use in pharmacies such as solutions, ointment basis and other products etc.
- Very important step in development of company was a purchase of marketing authorization of antiseptic medicinal product AJATIN® Profarma tinktura.
- Profarma is a small family company employing 14 people with adequate qualification and knowledge and long-term experience in GMP.
- Our site is in an old historical building which was extended according to company´s requirements. At the moment we use some 1000 m^2 where you can find separeted manufacturing, laboratory and stock premisses.

Our range:

- Medicinal products
- API´s
- Food supplements
- Biocidal products

Quality control

- We have our own physical-chemical laboratory to provide testing of our products and raw materials.
- We perform microbiological testing of finished products and raw materials.
- We secure the quality of requirements necessary for compliance of GMP and manufacturing premisses.

Medicinal products: Manufacturer´s Authorization and GMP certificate

Production of medicinal products for human use and API

Part 1 – Manufacturing operations

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms)

1.2.1.5 Liquids for external use

1.2.2 Batch certification

1.5 Packaging

1.5.1 Primary packaging

1.5.1.5 Liquids for external use

1.5.2 Secondary packaging

1.6 Quality control testing

1.6.2 Microbiological: non-sterility

1.6.3 Chemical/Physical

Medicinal products: Profarma – Produkt is MAH and manufacturer of following products

- Ajatin is Medicinal product used for wound treatment and surgical fields
- Yellow colour as indication of treated area
- Authorised nationally in Czechia and Slovakia

Ajatin® Profarma tinktura – Cutaneous solution 50 ml, 1000 ml

AJATIN ® Profarma tinktura with mechanical dispenser - Cutaneous spray, solution 25 ml, 50 ml

Medicinal products: Contract manufacturing

- We are manufacturer of medicinal products authorized by another MAH
- We offer our services as a GMP contract manufacturer of authorised medicinal forms.
- Available capacities:
  - Vials 10 – 100 ml: approximately 4000 pcs/day
  - Bottles 100 – 1000 ml: approximately 1000 – 3000 pcs/day

Possibility to extend the certifications according to contractors requirements

API manufacturing

- We manufacture our own API for our products and some customer´s products
- We synthetize API Benzododecinium bromide by neuthralisation reaction

Food supplements - Contract manufacturing

We offer and provide contract production of food supplements:

- manufacture of powder mixes, premixes and their filling into bottles
- manufacture of powder mixes, premixes and their filling into hard gelatin capsules
- adjustment of hard capsules, pills, tablets etc. into doses, blisters and sachets
- manufacture and filling of liquids into bottles from 10 to 5000 ml
- manufacture of gels, emulsions, suspensions

Expert collaboration:

- University of Chemistry and Technology, Prague
- Charles University, Faculty of Pharmacy, Hradec Králové
- Research Institute of Organic Synthesis, Rybitví
- University of South Bohemia in České Budějovice

Our business partners and clients:

- Zakłady Farmaceutyczne POLPHARMA S.A.
- ICN Polfa Rzeszów S.A.
- ENEO Pharmaceuticals s.r.o.
- Teva Pharmaceuticals CR, s.r.o.
- Biopol GN, s.r.o division Pharma United Inc. Canada
- APOTEX INC., Ontario, Canada
- Interpharma Praha a.s.
- Bioveta, a.s.

We look forward to our co-operation

CONTACT INFORMATION:

PROFARMA-PRODUKT s.r.o.

Liberecká 801/20
460 01 Jablonec nad Nisou

Czech Republic

Telephone:

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Business department: +420 483 100 308

Quality control: +420 483 100 314

E-mail: l.kucera@profarma.cz
profarma@profarma.cz

Web: www.profarma.cz

Map: Scan the QR code

7

OTHERS

ZENT2U BY ZENTIVA

Presenting Zent2U

Zent2U
YOUR EUROPEAN PHARMA PARTNER

August 2024

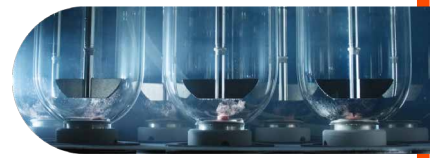
Zent2U, part of Zentiva

A strong and reliable partner

2 R&D centres in Prague & Ankleshwar
supporting pipeline development, driving ~3.5x ROI on new product launches

4 wholly-owned flagships sites
in the Czech Republic, Romania & India with best-in-class conversion costs

A dynamic and diverse team of
5000+ people



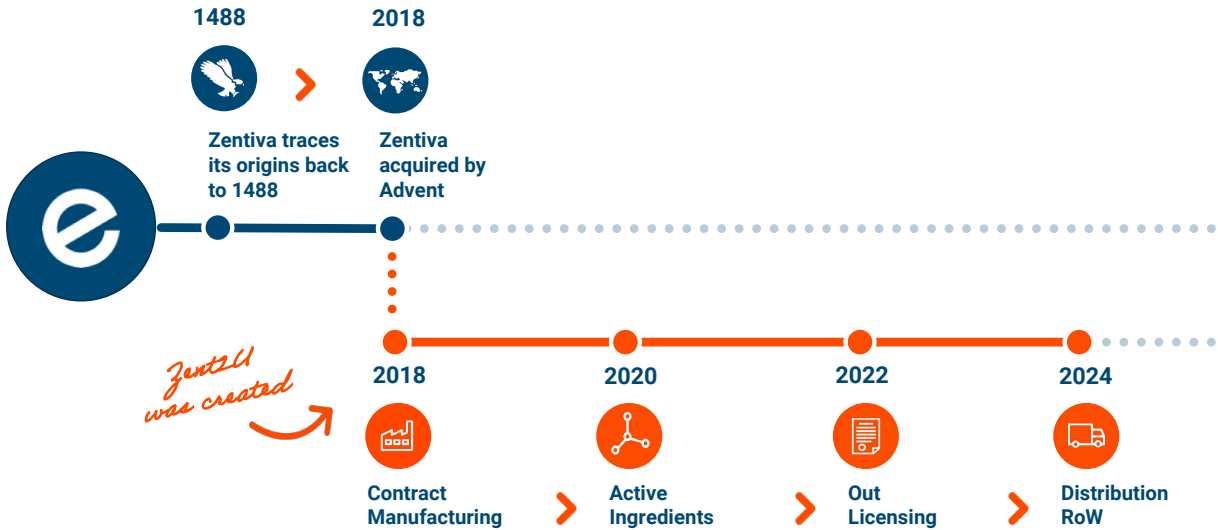
1.5 billion sales
* Year end results 2023

0 We have committed to achieve Carbon Neutrality in Scopes 1 and 2 by 2030

Zent2U
YOUR EUROPEAN PHARMA PARTNER

Zent2U powered by Zentiva's strong heritage

A B2B Business Unit



Zent2U
YOUR EUROPEAN PHARMA PARTNER

Zent2U footprint

We supply our products to 5 continents

Serving patients in **50+** countries

An International Team...

75 satisfied customers

Large & diversified portfolio **100+** products

...with the ability to meet business requirements

Zent2U
YOUR EUROPEAN PHARMA PARTNER

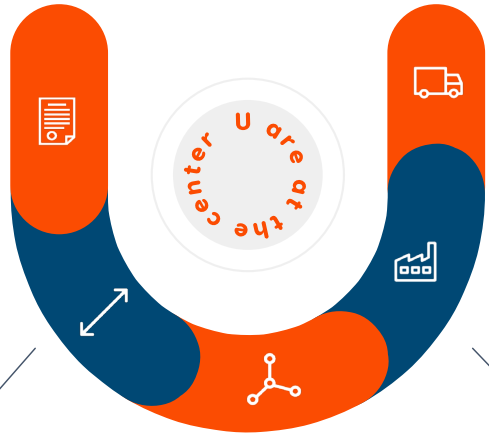
Zent2U has 5 business activities

Out-Licensing

High- quality EU dossiers and Value-Added medicines

Distribution

Bringing Zentiva' strong brand and high-quality product in new markets



Contract Development

Full scope of high-quality development services

Contract Manufacturing

Tailored services for specialized technologies in state-of-the-art European facilities

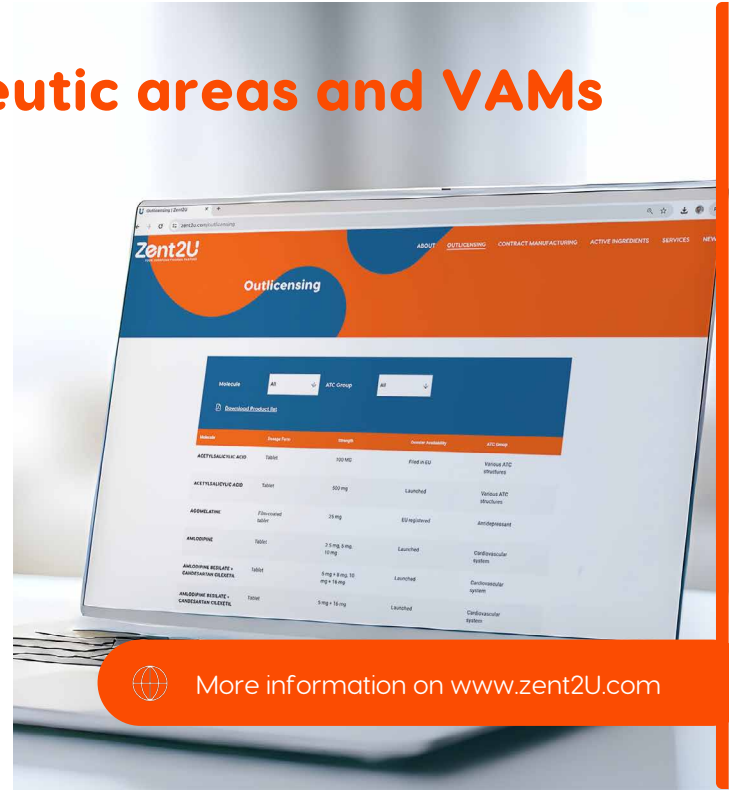
Active Pharmaceutical Ingredients

Focused portfolio of high-quality APIs

Zent2U
YOUR EUROPEAN PHARMA PARTNER

Focused on 5 therapeutic areas and VAMs

- **Cardiology**
- **Alimentary tract and metabolism**
- **CNS**
- **Anti-infective**
- **Blood and blood forming organs**



Zent2U
YOUR EUROPEAN PHARMA PARTNER

Meet our Team:

Dynamic & Diverse!

Thomas Koene
Head of Zent2U

Katerina Mala
Head of Customer Service and Supply Chain

Theodorian Zainea
Head of API and Contract Manufacturing

Yuliyana Manolova
Head of Distribution and Clinical Trials

Julius Petřík
Operations Manager

Martina Andrlová
Customer Service and Supply Chain Specialist

Jan Zajíc
Portfolio Manager

Anca-Oana Croitoru
Contract Manufacturing Manager

Madalina Racaru
Customer Service and Supply Chain Specialist

Martina Vrzalová
Executive Assistant

Rahul Padhye
Head of B2B International

Nina Fuentes
Key Account Manager

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