Argent BioPharma

Facilities in Slovenia

June 2024

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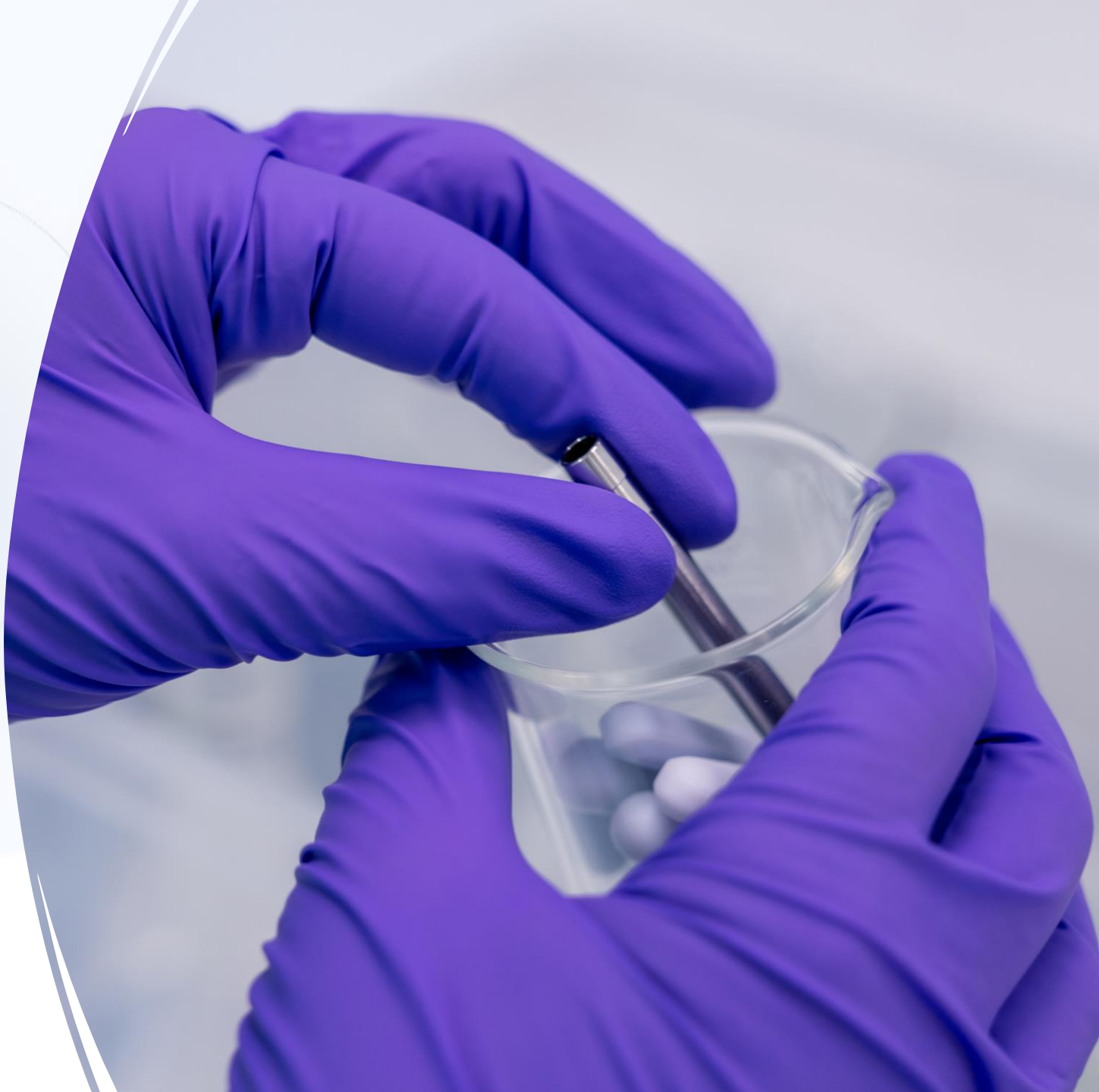


Slovenian Facilities

Research and Development center located on two locations:

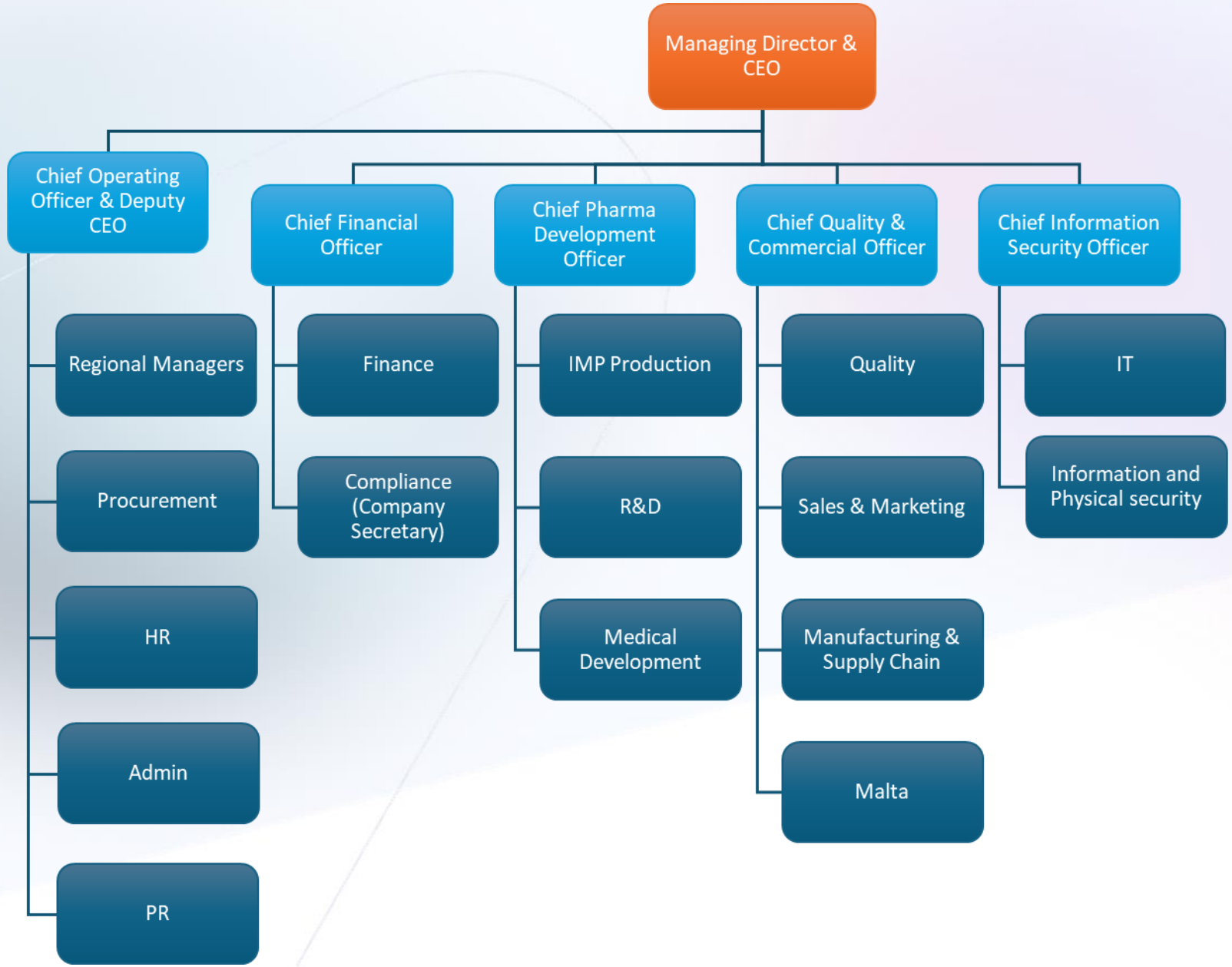
- **Emonska cesta 8, 1000 Ljubljana**

(Operations – HR, Admin, Finance, R&D, Medical Development, Quality and Commercial, Security and IT)

- **Kamniška ulica 29, 1000 Ljubljana**

(IMP production department and Quality control)

Departments on both locations:



Main Activities - Departments at Emonska

- **Pharma Development Department - R&D, Medical Development**

- The Pharma Development Department focuses on innovative liquid products and serves markets in Australia, Ireland, and the UK with a range of non-sterile liquid dosage forms and bulk products. We also supply Active Pharmaceutical Ingredients to various EU markets. Our operations include a licensed research lab for cannabinoids and psilocybin and an acclaimed IMP production facility. Accredited with EU GMP certification from the Slovenian Agency (JAZMP), we ensure top-quality standards. Our expert teams in medical innovation, Regulatory Affairs, and project management drive efficient development from concept to market, securing our competitive edge.

Main Activities - Departments at Emonska

Quality and Commercial Department

The Quality Division consists of Quality Control and Quality Assurance. It is responsible for ensuring that all products meet the highest standards of quality and comply with regulatory requirements.

Quality Assurance is responsible for ensuring compliance with guidelines, requirements, and the law; managing the documentation system; managing deviations, changes, complaints, risks, recalls, contractors, and training; participating in internal audits, external audits, and inspections; and maintaining the GMP environment.

Quality Control is responsible for performing quality control procedures for raw materials, materials and finished products (sampling, sending for analysis, checking results and suitability), supervising stability studies, supervising production, and participating in internal audits and inspections.

Commercial Department

The Commercial Department is responsible for implementing strategic business plans that align with market opportunities and customer needs. The primary focus is on expanding the pharmaceutical market with Argent BioPharma's innovative products. This involves navigating the regulatory landscape and adhering to health and pharmaceutical regulations to successfully launch our products in different markets. Additionally, we meet with healthcare professionals to inform them about our products, enhancing their knowledge and expertise while providing ongoing support.
Other key roles include driving sales to exceed targets, maintaining client relationships, and increasing market share. The department also seeks new business opportunities, partnerships, and markets to promote growth and diversification. Through these efforts, the Commercial Department ensures that Argent BioPharma's products reach those who need them most.

Main Activities - Departments at Emonska

Operations Department – HR & Admin

The Operations Department is dedicated to ensuring the seamless functioning of the company's core activities by managing both human resources and administrative functions. The HR focuses on talent acquisition, employee relations, and development, ensuring a motivated and skilled workforce. Meanwhile, the Administration handles the facilities management, and daily operational tasks, enabling a productive and efficient work environment.

Finance Department

The Finance Department is pivotal in ensuring compliance with accounting and financial standards specific to our industry, strategic planning for research and development funding, monitoring regulatory requirements for clinical trials and drug approvals, analyzing market trends, managing investor relations, financial disclosures, securities regulations compliance, and all crucial for sustaining the financial health and success of the organization.

Security Department / *"Connecting Argent BioPharma – Security Meets Technology and Collaboration."*

The Security Department is responsible for the company's Physical and digital security and IT needs. We are handling all IT support, planning and infrastructure, information systems, cyber security, and physical security procedures and systems. Our mission statement: To enable the company to realize its tasks to research and lead the development of innovative medicines aimed at addressing unmet medical needs on a global scale while carrying out actions to secure employees, facilities, and information systems.

Main Activities - Kamniška

At our production location, we meticulously manage several key processes to ensure efficient operations. We receive and store all incoming materials and raw materials necessary for production, and handle the receipt and storage of Active Pharmaceutical Ingredients (API) designated for distribution.

For both production and research and development purposes, we sample raw materials, materials, and finished products. We then release these raw materials and materials for production. Our manufacturing authorization covers the production of Investigational Medicinal Products (IMPs) - non-sterile liquids for internal use, including primary and secondary packaging and batch certification.

We manage the storage, dispatch, and waste related to IMPs. Additionally, we clean all production glassware and materials to maintain high standards of hygiene. We also handle the sampling and storage of reference and analysis samples of raw materials, materials, and finished products.

Emonska cesta 8, 1000 Ljubljana

Operations – HR, Admin, Finance, R&D, Medical Development, Quality and Commercial, Security and IT

Ground Floor Overview:

As you step into our building at Emonska cesta in Ljubljana, you're greeted by a spacious hallway leading to various essential areas:

- To the left, you'll find two well-appointed office spaces where the Finance department is located.

- Adjacent is a convenient small kitchen area.

- To the right, you'll discover our laboratory, equipped for innovative research and development.

- Alongside the lab are additional office and storage spaces, ensuring organization and efficiency throughout our operations.

First Floor Overview:

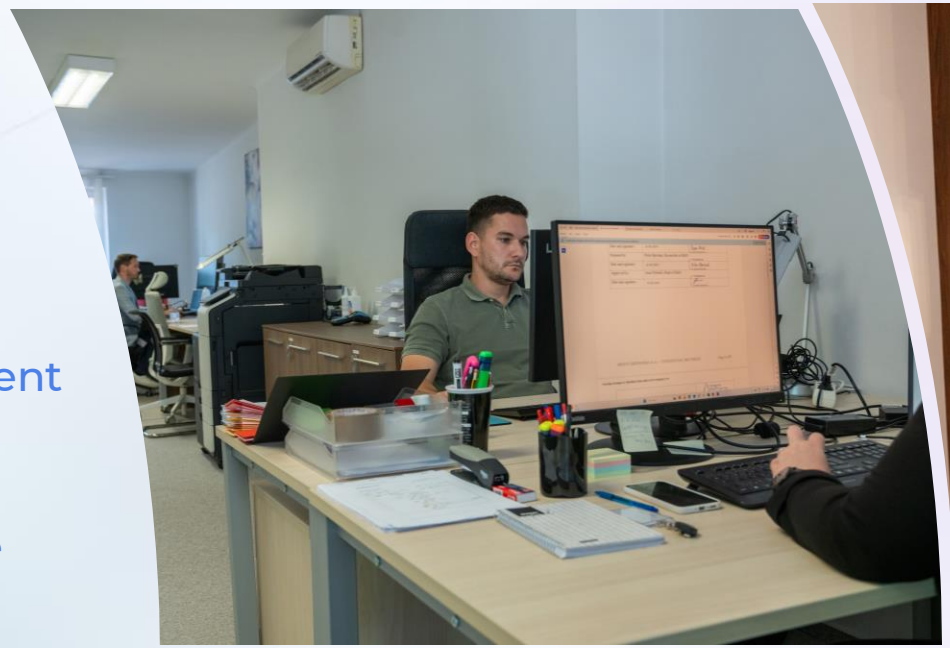
- Upon ascending the stairs in our building, you'll encounter a small hallway leading to key areas:

- On the right, you'll find a convenient kitchen area.

- Straight ahead, you'll arrive at the reception office, the central hub for welcoming guests and managing inquiries.

- Adjacent to the reception, you'll discover a well-appointed meeting room, equipped for productive discussions and presentations, alongside three individual offices.

- To the left of the hallway, you'll find three offices dedicated to our Quality department.



Second Floor Overview:

Upon ascending to the second floor of our building at Emonska cesta 8 in Ljubljana, you'll find a layout tailored for managerial functions and team gatherings:

• The second floor hosts six spacious offices primarily designated for managerial staff.

• Adjacent to the offices, you'll discover a generously sized meeting room. This room is equipped to accommodate team meetings, presentations, and discussions.

• Accessible from the meeting room or adjacent areas, a terrace offers a refreshing outdoor space.

• Completing the floor layout, a well-equipped kitchen area ensures convenience for our team members.

Security at Emonska Building

Visitors to Emonska facilities

- **Notified and registered** with Administration in advance by the hosting employee.
- Met at the facility **main entrance** by the hosting employee / Administration
- **First stop > reception**
  (Fill and sign visitors form).
- **Accompanied at all times!**

Meetings in Emonska facilities

- Held in **meeting rooms**.
- Meeting rooms are **booked in advance** with administration.

Incident response entry of unauthorized persons

Order of immediate action

- **Call any employee nearby** and update them on the event.
- Ensure **room doors** around you are closed.
- **Ask directly to verify the unauthorized person's identity** and the purpose of their arrival.
- Try to get as many **personal details** as possible (name surname, if possible, ask for an ID).
- Politely **ask them to accompany you to the company's main entrance**.
- At the same time and as quickly as possible, **a report must be made to the office manager, and any manager you can reach in the moment.**
- In a life-threatening situation, the employees **must lock themselves in the offices, lock the doors, call the emergency services and notify any manager possible.**

Key Personnel for new employees

Operations Department

Chief Operations Officer & Deputy CEO

Yifat Steuer (phone: +44 7572 781289, yifat.steuer@argentbiopharma.com)

- **Human Resource**

  Maša Oblak, HR Manager (phone: +386 51 668 315, masa.oblak@argentbiopharma.com)

- **Administration**

  Sanja Cacovich, Administrative Manager (phone: + 386 41 418904, sanja.cacovich@argentbiopharma.com)

- **Regional Management**

  Yishai Shoshani, Junior Regional Manager (phone: +386 70 510548, yishai.shoshani@argentbiopharma.com)

Security Department

Chief Information Security Officer

Yair Tal (phone: +972 509319913, yair.tal@argentbiopharma.com)

- **Information Security & IT**

  Bala Railla Krishna, IT Administrator (phone: + 386 51369346, bala.railla@argentbiopharma.com)

  Alexandria Friedman, Head of Information Systems (phone: +386 31 705611, sasha.friedman@argentbiopharma.com)

Kamniška ulica 29, 1000 Ljubljana

IMP production department and Quality control

Initial Entry and Production Areas

- Upon entering our production facility, you'll first encounter an entrance area that leads to the gowning area on the left, where personnel prepare for work in controlled environments.

- Moving forward, there's an interspace or area designated for receipt of raw materials, an area for secondary packaging tasks, and a dispatch area for finished products.

- To the right, you'll find clean rooms divided into a personal lock, a production room, and a sampling room for quality control measures.

Additional Facility Areas

- Continuing straight ahead, you'll come across the lavatory, kitchen, office space, and the Quality Control (QC) room.

- On the left side, there are 3 storage areas. 2 of them allocated for finished products and waste, and one for incoming materials, and raw materials. This organized layout ensures efficiency in production operations and proper management of resources throughout the facility.

Licenses and authorizations of Emonska & Kamniška

Slovenian EU-GMP certified facility

At RTG, we meet the requirements of the EU Good Manufacturing Practice (EU GMP) and Good Distribution Practice (EU GDP) guidelines

Manufacturing authorisation for production of medicinal products in clinical trials (no. 800-15/2024-3) and GMP certificate (no. 450-8/2023-1)

- Manufacturing of non-sterile products
- Manufacturing of liquids for internal use
- Primary packaging
- Secondary packaging
- Batch certification

Certificate of GDP compliance of a distributor of active substances for use as starting materials (no. 455-9/2023-1)

Certificate of registration in the register of importers of active substances (no. 806-7/2023-8)

Certificate of registration in the register of wholesalers of active substances (no. 805-6/2023-9)

Certificate of registration in the register of brokers selling medicinal products and active substances (no. 807-1/2024-3)

Authorisation for the possession of illicit drugs (cannabinoids) (no. 187-386/2020/15)

Authorisation for possession of illicit drugs (psilocybin) for scientific and research purposes (no. 187-40/2018/7)

Practices in Facility Management

- Access control,
- Interlock system in the clean area,
- Hygiene procedures for premise, equipment and personnel,
- Active production of 3 Investigational medicinal products (IMPs) – established technological procedures (TPs) and batch manufacturing records (BMR),
- Pest control,
- Environmental monitoring and control,
- Secondary packaging and blinding of IMPs for clinical trials.

Production capacity of our products

CannEpil 30 ml

In 4 years, we produced altogether **16 batches** of CannEpil 30 ml, which resulted in **1401 pieces** of produced finished products.

We can produce 2 batches per week, which gives us a **production capacity** of **97 batches per year - approx. 8827 pcs** (considering all the holidays through the year).

CannEpil placebo, 30 ml

In 4 years, we produced altogether **12 batches** of CannEpil placebo, 30 ml, which resulted in **351 pieces** of produced finished products.

We can produce 4 batches per week, which gives us a **production capacity** of **201 batches per year - approx. 5226 pcs** (considering all the holidays throughout the year).

CannEpil 50 ml

In 4 years, we produced altogether **33 batches** of CannEpil 50 ml, which resulted in **1876 pieces** of produced finished products.

We can produce 2 batches per week, which gives us a **production capacity** of **97 batches per year - approx. 5141 pcs** (considering all the holidays throughout the year).

Production capacity of our products

CogniCann

In 4 years, we produced altogether 5 **batches** of CogniCann, which resulted in **889 pieces** of produced finished products.

We can produce 2 batches per week, which gives us a **production capacity** of **97 batches per year - approx. 17460 pcs** (considering all the holidays throughout the year).

CogniCann Placebo

In 4 years, we produced altogether 3 **batches** of CogniCann, which resulted in **253 pieces** of produced finished products.

We can produce 4 batches per week, which gives us a **production capacity** of **201 batches per year - approx. 16884 pcs** (considering all the holidays throughout the year).

Production capacity of our products

CimetrA

In 4 years, we produced altogether **21 batches** of CimetrA, which resulted in **4891 pieces** of produced finished products.

We can produce 2 batches per week, which gives us a **production capacity** of **97 batches per year - approx. 20855 pcs**

CimetrA placebo

In 4 years, we produced altogether **5 batches** of CimetrA placebo, which resulted in **891 pieces** of produced finished products.

We can produce 2 batches per week, which gives us a **production capacity** of **97 batches per year - approx. 24056 pcs**

Key Performance Indicators (KPI) and Management Review

KPI

- Provide an overview of the company's performance to ensure continuous improvement,
- Monitored monthly, and the results are evaluated once a year at a management review,
- Monitor in different areas (e.g. production, QC, R&D and QA) that support the production process.

The defined targets lead to improvements in the company's performance.

Management Review

- The ultimate objective is the continuous improvement of the quality system,
- Performed annually and presented to management,
- Ensuring that processes are effectively implemented,
- Ensuring that all levels of management are informed of changes, updates, revisions and issues,
- Ensuring the quality of finished products is assured throughout the finished product lifecycle.

Improvements in efficiency lead to increased performance and process improvements.

Argent BioPharma

Thank you for your attention!

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