



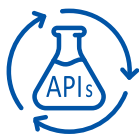
Polpharma is the largest manufacturer of medicines and active pharmaceutical ingredients (APIs) in Poland and one of the largest pharmaceutical groups in Central and Eastern Europe

EUROPEAN CDMO PARTNER AND API MANUFACTURER SINCE 1951

 Supporting customers with development and manufacturing of APIs

 FDA-approved site integrating R&D, pilot and large scale commercial production

 Development and manufacturing services from early clinical phases to full life cycle management



**ACTIVELY SELLING APIs GLOBALLY IN THE HIGHLY
REGULATED MARKETS IN THE WORLD**



STRATEGIC INVESTMENTS IN HP API

COMPLETE HPAPI STRATEGY EXECUTION AND GRAND OPENING OF NEW R&D AND PRODUCTION FACILITY IS PLANNED **FOR Q3 2024**



Aiming at the continuous development of Polpharma and caring for the future of patients, business partners and our employees, we have launched an investment in a specialized facility for the **Research and Development and Production** of highly active substances.

With an **OEL value down to 10 ng/m³ (OEB 6)**, the HP API investment includes separate process laboratories (**PDL**), analytical laboratories (**ADL**) with the possibility of performing **Quality Control** analysis, and a **GMP kilo-lab production** line with volume up to 1.5 kg with potential volume increase.



PDL

- ▲ 4x Isolators (Dispensing unit, 2x Wet units and Dry unit)
- ▲ 2x Reactor 1000ml
- ▲ 2x Reactor 250ml
- ▲ 4x Reactor 100ml
- ▲ 2x Tray Dryer



ADL/QC

- ▲ 5x Isolators
- ▲ 12x Fume Hoods
- ▲ 5x Ventilated Enclosures
- ▲ HPLC with detectors: UV-Vis (PDA), RI
- ▲ UPLC with detectors: UV-Vis (PDA), RI, MS, FLR
- ▲ GC (also GC-MS)
- ▲ IC
- ▲ Titration
- ▲ IR, XRPD
- ▲ DSC, TGA
- ▲ PSD
- ▲ Forced Degradation Study



KILO-LAB

- ▲ Combined Isolator (Dispensing area, Wet area and Dry area)
- ▲ Reactor 35l
- ▲ Reactor 15l
- ▲ Reactor 5l
- ▲ Nutsche Filter
- ▲ Tray Dryer
- ▲ Mill

HPAPI R&D AND KILO-LAB GMP

- Products: **OEL: ≥ 10 ng/m³**
- Reactor capacity range: **5 to 35 dm³**
- Operational temperature range: **-20°C to 200°C**



KL isolator

DEVELOPMENT AND COMMERCIAL MANUFACTURING

Polpharma offers a full range of services since initial development (for early stages of NCE's), process development, validation and commercial manufacturing of API's



Full development from initial stage to fully industrial process



Tech tranfer to industrial scale based on risk assessment



Process scale-up and validation, including definition of NOR's, PAR's

WE OFFER



Analytical method development and validation



Impurities identification and characterization (including GTx and nitrosamine assessment)

API MANUFACTURING SITE

STAROGARD GDANSKI

- ▲ 350 employees
- ▲ > 50 products in the portfolio
- ▲ sales on 6 continents, to 65 countries

STAROGARD PRODUCTION: **6,2 ha**

Warehousing 3,0 ha

(Tank Farm and Solid Raw Materials)

Wastewater Treatment Plant 4,1 ha

33,1 ha

EQUIPMENT TYPE:

- ▲ GL/SST/HST
- ▲ Columns
- ▲ Crystallizers
- ▲ Centrifuges
- ▲ Dryers
- ▲ Filter-dryers
- ▲ Mills
- ▲ Micronizers
- ▲ Lyophilizer

OPERATING RANGES PILOT & COMMERCIAL SCALE:

- ▲ Temp. -80°C to +200°C
- ▲ Pressure -1 to +10 bars
- ▲ pH in the full range

KILO-LAB:

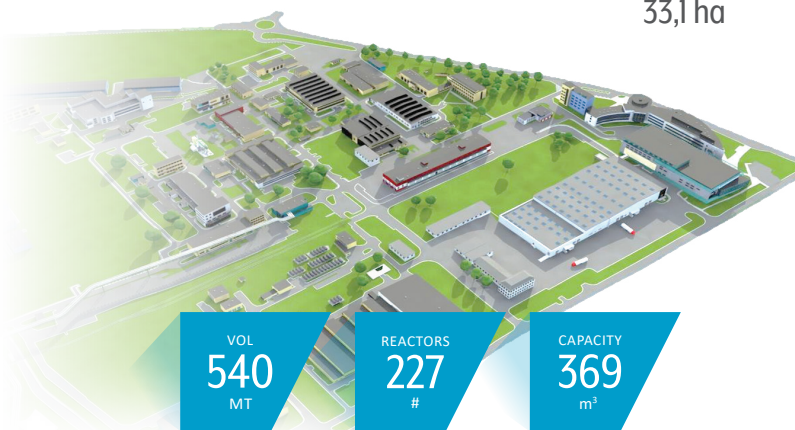
- Products: **OEL ≥ 200 ng/m³**
- Reactor capacity range: **25 to 63 dm³**
- Operational temperature range: **(-80)°C to 200°C**

PILOT PLANT:

- Products: **OEL ≥ 1 µg/m³**
- Reactor capacity range: **63 to 6300 dm³**
- Operational temperature range: **(-80)°C to 200°C**

COMMERCIAL SCALE:

- Products: **OEL ≥ 1 µg/m³**
- Reactor capacity range: **150 to 6300 dm³**
- Operational temperature range: **(-80)°C to 200°C**



*Available from H2 2023, pending Cryogenic Capabilities extension up to 6000L.

R&D

Strong R&D management team with a great experience in development of chemical processes and complex projects, provide a wide range of solutions to our customers. Our R&D facility is about 1 000 sqm and includes 10 laboratories, 30 fume hoods with state of the art instruments to support chemical and analytical development projects.

We have extensive expertise in particle design, crystallization and bi-phosphonate compounds.

20  process development

27  analytical development

15  regulatory affairs and customer technical services



REGULATORY

Our APIs are exported to over 60 countries, including the highly developed markets of the United States, Europe, Japan, Korea, Brasil among many others.

Last PAI for NCE in 2015.

QUALITY

We have an experienced team of more than 100 people that are committed to provide an excellent service. From QC and QA operations to a Customer Service/Technical Service teams that provide our customers with the highest level of Quality.

EHS

We have implemented Environmental Policy in response to the fast-evolving requirements of the European Union in terms of taking action for the climate and circular economy, such as the European Green Deal.

The four core areas of Polpharma's new Environmental Policy are:

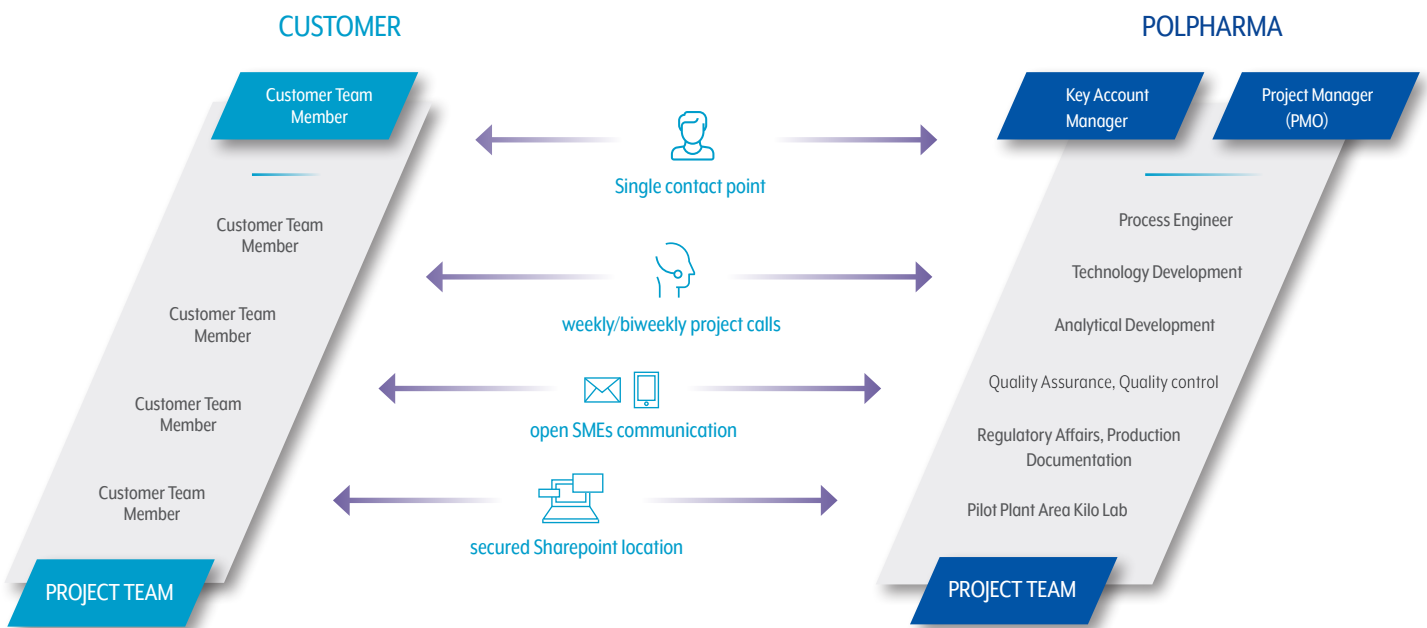
- ▲ minimisation of impact on climate change
- ▲ water protection
- ▲ transition to circular economy
- ▲ minimisation of impacts along the entire value chain



PROJECT MANAGEMENT

- ▲ Dedicated single contact person, face-to-face relationships, and rapid response to customer needs, with the goal of identifying the optimal, customized solution
- ▲ Dedicated Project Management Office assuring the highest level of governance
- ▲ Management standards based on best practices and lessons learned approach
- ▲ Project Managers with average >10 years' experience and technical background in R&D
- ▲ Customized reporting and communication for project updates

CORE INTERFACE BETWEEN THE CUSTOMER AND POLPHARMA TEAM



WE ACT

WITH OWNERSHIP

AS ONE

WITH OPENNESS





CUSTOMER EXPERIENCE



*“Deep knowledge and technical support provided by Regulatory, analytical and chemistry in determining a strategy for potential genotoxic and elemental impurities as well as the experimental data needed to back it up. Finally, **I have found Polpharma’s quality systems and people to be among the best that I have experienced.**”*

CMC Consultant



*“One of the most important benefits I see in working with Polpharma is **the relationship of teamwork and transparency. I have never seen this with another CMO.**”*

CMC Expert



*“The relationship we have with Polpharma represents **a true partnership...** demonstrated by Polpharma’s collaborative approach, their flexibility, their proactiveness in identifying opportunities, and their technical competence.*

The partnership that we have with Polpharma is a model that we aspire to developing with all our suppliers.”

Senior Director Commercial Supply Chain

CONTACT US

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