



# CDMO

**EU-BASED CDMO and API manufacturer,  
trusted by customers and business  
partners since 70 years**

Polpharma is the largest manufacturer of pharmaceuticals and APIs in Poland and one of the major pharmaceutical groups in Central and Eastern Europe

## API MAIN TECHNOLOGIES

### HIGH POTENT

- ▲ **R&D:** OEB  $\leq 6$  (OEL  $> 10 \text{ ng/m}^3$ )
- ▲ **GMP PP/KL:** OEB  $\leq 5$  (OEL  $> 200 \text{ ng/m}^3$ )
- ▲ **GMP Commercial:** OEB  $\leq 6$  (OEL  $> 10 \text{ ng/m}^3$ )

### CRYOGENIC

- ▲ **PP:** Reactor capacity range: 0.1 to 0.5 m<sup>3</sup>  
Operational temperature: down to -80°C
- ▲ **COMMERCIAL:** Reactor capacity range: 2.5 to 6.3 m<sup>3</sup>  
Total reactors vol: 23.5 m<sup>3</sup>

### BROAD TYPE OF CHEMISTRY

#### R&D, Kilo Lab, Pilot, Commercial

- ▲ Highly reactive compounds, organometallic, organophosphorus
- ▲ Powder handling (PSD adjustment) by milling and micronization & Solid State Chemistry

### OLIGONUCLEOTIDES

- ▲ Development and GMP small scale production line by Q3 2024
- ▲ First product validated by Q2 2025

## API MANUFACTURING SITE

### STAROGARD GDANSKI

#### EQUIPMENT TYPE:

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

#### OPERATING RANGES PILOT & COMMERCIAL SCALE:

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

#### KILO-LAB:

- ▲ Containments: OEL  $\geq 200 \text{ ng/m}^3$
- ▲ Reactor capacity range: 25 to 63 dm<sup>3</sup>
- ▲ Operational temperature range: (-80)°C to 200°C

#### PILOT PLANT:

- ▲ Containments: OEL  $\geq 1 \mu\text{g/m}^3$
- ▲ Reactor capacity range: 63 to 630 dm<sup>3</sup>
- ▲ Operational temperature range: (-80)°C to 200°C

#### COMMERCIAL SCALE:

- ▲ Containments: OEL  $\geq 1 \mu\text{g/m}^3$
- ▲ Reactor capacity range: 150 to 6300 dm<sup>3</sup>
- ▲ Operational temperature range: (-80)°C to 200°C

## POLPHARMA HP API EXPANSION



We have invested a total of EUR 24 million into a specialized facility for the R&D and Production of highly active substances with an OEL value down to 10 ng/m<sup>3</sup> (OEB 6). Our new facility includes a separate process development laboratory (PDL), analytical development laboratory (ADL) with QC analysis capabilities and a GMP kilo-lab scale production line with approximately 1.5 kg max batch capacity.

The design of the assumes best in class isolator technology to be used for personnel and product safety.



**PDL**

**4** Isolators  
(Dispensing unit,  
2 x Wet units and Dry unit)

### REACTORS

**100 - 200 ml**  
**250 - 1000 ml**

### TEMPERATURE RANGE

**(-20°C) - 140°C**  
**(-80°C) - 160°C**

**2** VacumTray Dryers



**ADL/QC**

**5** Isolators  
Ability to perform essential  
analyses for method  
development and product  
optimizaion and release.

**12** Fume Hoods  
**5** 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)

### REACTORS

**5 dm<sup>3</sup>**  
**15 dm<sup>3</sup>**  
**35 dm<sup>3</sup>**

### TEMPERATURE RANGE

**(-80°C) - 200°C**

**2** VacumTray Dryers

Nutsche Filter  
Mill

## CDMO OFFERING

### TECHNOLOGIES

- ▲ Broad type of chemistry (highly reactive compounds, organometallic, organophosphorus)
- ▲ Powder handling (PSD adjustment) by milling and micronization & Solid State Chemistry

### QUALITY

Extremely positive track record of compliance audits (authorities & customers)

### REGULATORY

Fast, flexible, proactive & diligent regulatory service support, filing experience in 60+ countries

### COMPETITIVENESS

Labor and operation cost structure more competitive compared to West EU

## KEY FACTS



**>70**  
Countries



**~455** (R&D ~70, ~16 PHD)  
Employees



### Regulatory



### Full value chain

R&D, production commercial, supply chain, PMO

## HYBRID BUSINESS MODEL

- ▲ **>70 years of experience in API business**

- ▲ **Global market presence**

- ▲ **Generics and CDMO**

From development to commercial

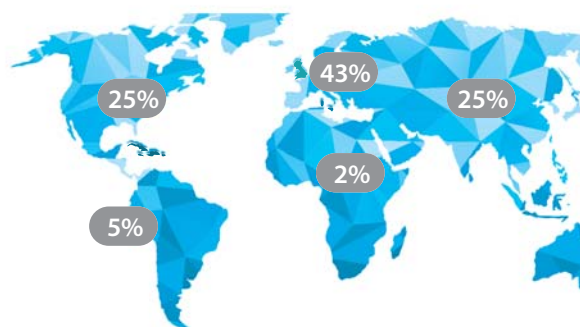
- ▲ **European location**

R&D and 2 manufacturing plants

- ▲ **Agile organisation**

Fast decision making, top execution

- ▲ **Project management excellence**



## ESG

Polpharma has been awarded the EcoVadis Silver Medal for our commitment to sustainability and CSR. This recognition places us among the top companies evaluated by EcoVadis, a globally trusted rating platform for environmental, social, and ethical performance. Receiving the EcoVadis Silver Medal is a testament to our dedication to improving our sustainability efforts and driving positive change within our industry. We are proud of this achievement and remain committed to further enhancing our practices to achieve even higher standards in the future.



## 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.

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process development

39 

analytical development

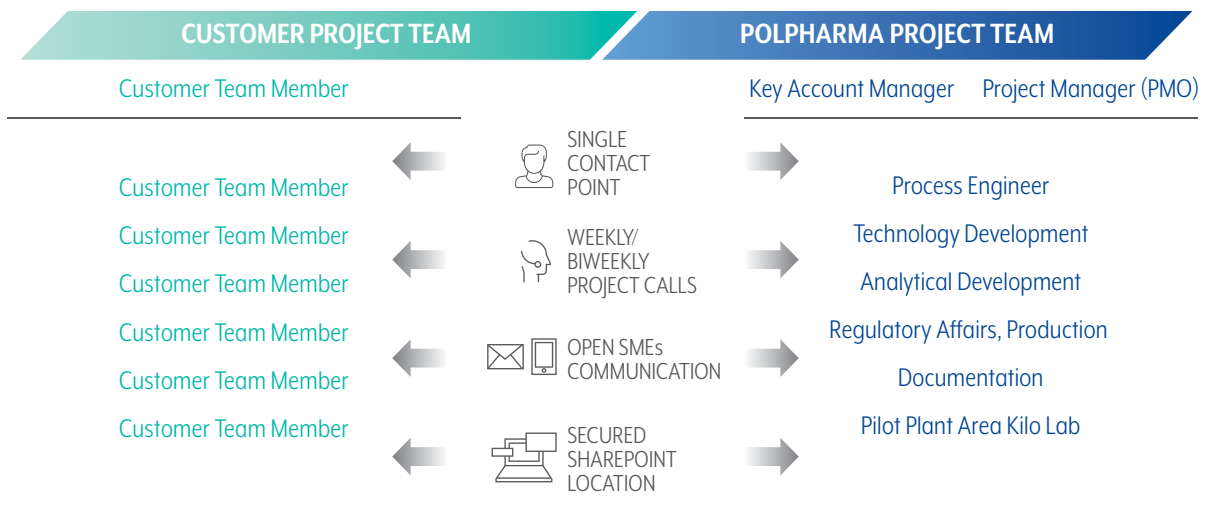
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regulatory affairs and customer technical support

## CDMO 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
- ▲ 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



## CDMO PROJECT IMPLEMENTATION

WHAT ARE THE KEY SUCCESS FACTORS OF A LEADING CDMO ORGANIZATION TODAY:

SPEED

FLEXIBILITY

DELIVER ON PROMISES

BASIC AND UNNEGOTIABLE ENABLERS:

- ▲ Technology capability required by the project (equipment and knowledge, experience)
- ▲ Robust quality system
- ▲ Performing supply chain and project management organization



*"We aspire to be your partner of choice who is reliable, authentic and delivers solutions"*

Let's join forces on your upcoming project with our passionate and dedicated team, who are excited to work together to achieve exceptional results!

## OUR CDMO TEAM



**Manuel Lourenco**

Head of CDMO API

*"The objective of a CDMO is to provide a service in all stages of development that allows its customers to be fast to market. This is our commitment.*

*We also assume the commitment to provide solutions from a supply chain perspective that would allow our customers to have a sustainable solution for the long term."*



**Dawid Ignatowicz**

Head of CDMO API Europe

*"After 15 years at Polpharma, every day reassures me that the greatest assets we have are our committed, skilled scientists and the strong relationships we have built over the years with our Customers and Business Partners.*

*The trust we have been granted and our customers' satisfaction is the engine that always empowers us to strive for better service. "*



**Jolanta Pawłowska**

Advisor for Technical Support, Business Development and CDMO API

*"Collaboration and communication between R&D, production and the customers involve a wide range of interdisciplinary skills that are offered to the customers and are critical to the successful development of drug substance and drug product."*

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Pharmaceutical Works**

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**LinkedIn**

<https://www.linkedin.com/showcase/polpharma-api/>

THE FUTURE IS  
**NOW** >>>



**CDMO BROCHURE**