polpharma CDMO

What We Promise, We Deliver

From development to commercial launch, we work as part of your team – guiding development, scaling processes, and staying fully accountable from first touch to final batch.

CDMO

One Team. One Site. From Start to Scale.

Ph1 - Ph2	Phase 3	Registration	Commercial
Process Development, Technology Transfer & cGMP batches	cGMP Batches & Process Validation	Regulatory Submission & Approval	Commercial Production & Constant Improvements

- ✓ **Phase-appropriate method** validation and full CMC support
- ✓ **Risk-managed tech transfer** to industrial scale — built for consistency and speed
- ✓ **Solid-state expertise:** Powder handling, PSD control via milling, micronization, and crystallization
- ✓ **Impurity profiling:** Genotoxins, nitrosamines, unknowns — identified, tracked, and managed
- ✓ **Flexible scaling:** Adapting to your evolving clinical and commercial needs, from kilograms to multi-ton
- ✓ **Adaptive method strategy:** Full development / efficent tech transfer of existing methods

Our Pillars

Compliance
Unshakable Foundation

Global regulatory excellence isn't optional, it's where we begin

Quality
Zero-error Culture

A shared mindset built into every process and interaction

Collaboration
Biotech Advantage

We collaborate with your team, keeping you informed all the time

People
Driving Edge

Our people lead with initiative from first conversation to final batch

Technology
Enabling Power

Advanced capabilities for complex molecules and seamless scale-up

Selectivity
Partnership Focus

Quality over quantity so you get full attention, real availability, and results

API Main Technologies

High potent	✓ **R&D:** OEB ≤ 6 (OEL>10ng/m³) ✓ **GMP PP/KL:** OEB ≤ 5 (OEL > 200ng/m³) ✓ **GMP Commercial:** OEB ≤ 6 (OEL > 10ng/m³)
Cryogenic	✓ **PP:** Reactor capacity range: 0.1 to 0.5 m³ Operational temperature: down to -80 °C ✓ Commercial: Reactor capacity range: 2.5 to 6.3m³ Total reactors vol: 23.5m³
Oligonucleotides	✓ GMP small scale production line by Q2 2025 ✓ First product validated by Q4 2025

API Manufacturing Site

Starogard Gdański

Equipment type:

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

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 ≥ 200 ng/m³** ✓ Reactor capacity range: **25 to 63 dm³** ✓ Operational temperature range: **(-80)°C to 200°C**
Pilot Plant:	✓ Containments: **OEL ≥ 1 µg/m³** ✓ Reactor capacity range: **63 to 630 dm³** ✓ Operational temperature range: **(-80)°C to 200°C**
Commercial Scale:	✓ Containments: **OEL ≥ 1 µg/m³** ✓ Reactor capacity range: **150 to 6300 dm³** ✓ Operational temperature range: **(-80)°C to 200°C**

Starogard Gdański

VOL '24 MT	REACTORS #	CAPACITY m³
424	227	369

Strong R&D management team:

- ✓ ~ **30** ppl. process development
- ✓ ~ **40** ppl. analytical development
- ✓ ~ **20** ppl. regulatory affairs and customer technical support

Benefits:

- ✓ Streamlined development
- ✓ Faster problem resolution
- ✓ Consistent quality oversight
- ✓ Shortened timelines
- ✓ Seamless knowledge transfer

Sales on 6 continents to 70 countries:

- ✓ 34 ha
- ✓ 450 employees
- ✓ Access to sea
- ✓ 60 products in the portfolio
- ✓ Competitive cost structure

People are our Edge

You're not hiring a facility, you're partnering with a highly qualified team

Expertise Meets Commitment

~500
Highly skilled employees

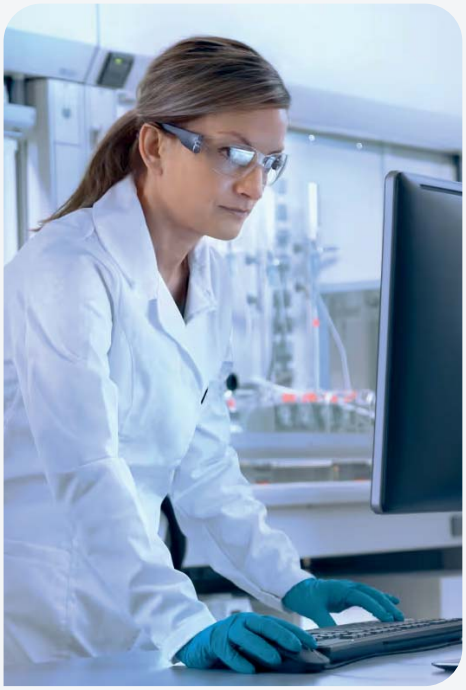
85
Specialists in R&D

16
PhDs across functions

- Engaged
- Well educated
- Accountable

5 Project Managers

With average 10 years of experience and background in chemistry, science or R&D



Compliance is our Foundation

Non-negotiable, it's our starting point

Regulatory Approvals

Filing Experience across

60+

Countries

Regulatory **Support**

Fast, flexible, proactive & diligent

EU GMP certificates for all departments and API products

Rigorous data standards across operations

Full visibility with audit-ready documentation and raw data access

Multi-layered systems: TrackWise, LIMS, EDMS, DCS and more

Collaboration is our Difference

We keep you fully informed – no surprises and no decisions made without you

Single POC

Dedicated Project Manager & Business Lead

Direct Access to Experts

Speak directly with our scientists and technical leads whenever needed

Site Visits

See the systems behind the promise

Clear scopes, costs, roles and workflows: You'll know what, who and when

Weekly updates are standard, immediate notification if things shift

Flexibility to accommodate change requests

Shared workspace: for easy document sharing and progress tracking

Why Work With Us

	Polpharma CDMO	Industry Standard
Dedicated Project Manager	✓	Varies
Direct Access to R&D Team	✓	Limited
Change Request Flexibility	High	Low-Medium
Raw Data Accessibility	✓	Limited
Bilingual Documentation	✓	Limited
High-Potency Capabilities	OEL ≥ 10 ng/m³	Varies

Zero-error Thinking. Powered by People.

Our CDMO Team

Dawid Ignatowicz
Head of CDMO API

"After over 15 years at Polpharma, every day reassures me that our greatest assets are our skilled scientists and the strong relationships built with our Customers and Business Partners. As a CDMO, we act as an extension of customer resources, taking full ownership and always striving to deliver trust, satisfaction, and better service."

Peter Mondolfi
Head of US CDMO Business Development

"With over twenty years in the biotech/pharma space, I've learned that trust is key to building strong, lasting relationships. Clients must feel confident that when they place their trust in a CDMO partner, that partner will not only execute but truly own the project as if it were theirs, acting as a true collaborator. Polpharma CDMO API is that partner. "

Jolanta Pawłowska
Advisor of 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. Together, these combined capabilities ensure a smoother, more efficient path from concept to high-quality commercial reality."

Connect & Collaborate

Talk to us — Get access to our specialists

Visit our site — Experience our integrated capabilities firsthand

Get the proposal — Tailored, comprehensive and straightforward

Feel the difference — Move forward with confidence, clarity, and momentum

Polpharma Pharmaceutical Works

Pelplinska 19
83-200 Starogard Gdański
Poland

Contact:

cdmo@polpharma.com
api@polpharma.com
+48 58 563 16 00

Find:

www.linkedin.com/showcase/polpharma-api

www.api.polpharma.com

Download brochure