YOUR MODULAR ONE-STOP-SHOP
for biopharmaceuticals

www.polpharmabiologics.com
From idea to global market

Polpharma Biologics is a rapidly expanding biopharmaceutical company dedicated to improving patients’ lives by providing affordable, high-quality biologics.

Since 2013, we have built a modern and fully-integrated environment for the development and production of biological medicines using mammalian and microbial expression systems.

We provide an integrated value chain

- Cell Line Development
- Analytical Development
- Process Development and Characterization (eTPP and GMP)
- Formulation Development
- Process Scale-up
- Clinical DS and DP Manufacturing
- Process Validation and Commercial DS Manufacturing
- Fill & Finish (vials, PFS, cartridges, liquid and lyophilized formulations)

Just a few months ahead of submission of our first biosimilar product to the US FDA, we are well positioned to efficiently and expertly support your entire project at all stages of biopharmaceutical development, from cell line generation through process development to biopharmaceutical cGMP manufacturing. Our dedicated team strives to tailor unique, customized solutions that fit our clients’ needs, bringing their products to market faster.

Through working on our own biosimilars and new biological entities pipeline, we have gained invaluable expertise, insights and experience.

What makes Polpharma Biologics special is the unique mix of people and technology. In our team, seasoned industry veterans work with highly trained and passionate young specialists. Equipped with cutting-edge, no-compromise technologies this team will never settle for second-best. They uncompromisingly strive to meet customer expectations by delivering products and services with precision, quality and flexibility.

Dr Joerg Windisch
Chief Executive Officer
and President of the Management Board
Polpharma Biologics

As one of the most modern and truly integrated CDMO’s we are best positioned to take over biological projects at any given development stage and take them forward from there, be it mammalian or microbial drug substances or drug products, both in liquid or lyophilized form. We produce clinical and commercial quantities for the global markets and are passionate about providing reliable services, applying strict technological and quality standards and delivering on-time.

Hannes Teissl
Supervisory Board Member, Polpharma Biologics
Chairman of the Board, Polpharma Biologics Switzerland AG

Well balanced pipeline of biosimilars and new biological entities

<table>
<thead>
<tr>
<th>Project</th>
<th>Originator</th>
<th>Therapeutic area</th>
<th>Research</th>
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Integrated biotech network

**UTRECHT**

**NL**

**GDAŃSK**

**PL**

**BIOCEROS – ANTIBODY DISCOVERY AND CELL LINE DEVELOPMENT**

- Founded in 2013 and a member of Polpharma Biologics since 2016
- Outstanding track record of generating high yield production cell lines for both biosimilar and innovative proteins based on its proprietary CHO<sup>®</sup> platform technology
- Highly experienced in generating innovative monoclonal antibodies, intended to provide novel treatment options
- Highly innovative team of international scientists

**DEVELOPMENT AND cGMP MANUFACTURING CENTER**

- One of the most modern biotech laboratories in Europe, delivering optimization, upscaling of processes and formulation development up to cGMP-grade clinical material for biosimilar and innovative programs
- Full product quality control, beginning in the early stages of development, through comparability studies, up to the production of cGMP batch
- State of the art equipment and modern technologies - fully single use platforms in mammalian facility - hybrid system of stainless steel and disposable technologies in microbial
- International team combining experience and long track work record of top professionals with passion of young scientists

**DUCHNICE / Warsaw area**

**PL**

**Zurich**

**CHE**

**LARGE SCALE FACILITY FOR DRUG SUBSTANCE MANUFACTURING AND STERILE FILL & FINISH**

- Polpharma Biologics’ CMO partner
- One of the biggest biotechnology plants in Central and Eastern Europe
- Over 30,000 m² of commercial scale cGMP production facility for Drug Substance and sterile Fill and Finish in vials and pre-filled syringes
- Fully operational in 2021
- Team experienced in sterile manufacturing, maintenance, QA and QC

**CLINICAL DEVELOPMENT, REGULATORY AFFAIRS AND INTELLECTUAL PROPERTY CENTER**

- Established in 2019
- Development of clinical strategies and execution of clinical trials
- Regulatory affairs activities including interactions with health authorities (FDA, EMA, ANVISA) and marketing authorization applications submission
- IP landscaping and assessment of freedom to operate
- Prosecution and enforcement of IP rights
- Planning and management of IP related litigation
- Highly experienced team composed of seasoned industry veterans
The magic in the cell

Bioceros, Utrecht, The Netherlands
Cell line development center

Bioceros is a member of Polpharma Biologics that complements our services by adding an outstanding track record of generating high-yield production cell lines for new biologic entities and biosimilars based on its proprietary CHO rundown platform technology.

This platform is complemented by a comprehensive process toolbox for targeted process modulation that helps accomplish fingerprint biosimilarity, which in turn can be analysed by Bioceros robust in-house bio- and analytical assays.

Bioceros proprietary technologies

**CHO Rundown**

Our cell line development platform covers all stages from transfection to high-yield producing CHO cell lines and is completely animal component free. CHO cell lines grow in chemically defined media, which is a crucial requirement in modern biopharmaceutical manufacturing practice. Furthermore, our CHO cell lines have been successfully scaled up to 1000 L and similar scaling up of a biosimilar-producing CHO cell line is ongoing.

**SPOT**

We developed the SPOT™ technology that ensures the highest specific productivity while minimising undesired species and reducing waste in downstream processing.

**SLIM**

Our innovative metabolic SLIM™ technology reduces feed consumption at much lower power input, eliminating process hardware limitations.

**CASH**

We developed CASH™ technology for faster screening and selection of novel therapeutic candidates.

Having worked for over 25 years on the preclinical development of therapeutic antibodies, we have done it all – from innovative monoclonal antibodies to biosimilars. However, directing complex mammalian expression systems towards the desired behaviour, which is to produce enormously high levels of a given target protein with the right level of required post translational modifications, can be considered a scientific art. We utilise the full range of cutting-edge high-throughput technologies, but in the end, extensive experience of our professional team makes the difference and enables us to boost the productivity.

Dr Louis Beem
Chief Scientific Officer and Managing Director
Bioceros

Know-how you can rely on

Polpharma Biologics, Gdańsk, Poland
R&D center

Our Gdańsk facility is one of the most modern biotechnological R&D laboratories in Europe. Our highly skilled and motivated team operates state-of-the-art equipment.

The facility supports development and optimisation of analytical and production methods for novel biological medicines and biosimilars up to good manufacturing practice (GMP) grade.

Customised formulations for both drug substance and drug product can also be developed in-house and subsequently tested for stability according to international conference on harmonisation standards.

Working with a team of highly motivated, experienced and dedicated professionals does make all the difference. Here at Polpharma Biologics we strive to develop integrated programs, analytics and respective documentation for our customers resulting in robust, efficient and economical processes to the highest Biotech standards and conforming to industry requirements. Our experience and understanding of the issues at hand at all steps in the project can make all of the difference to the outcome of your project.

Dr Nicholas Hunt
Director Technical Research and Development
Polpharma Biologics
From tech transfer to continuous supply

Polpharma Biologics, Gdańsk, Poland
Clinical and commercial manufacturing center

Our state-of-the-art biopharmaceutical cGMP production facility in Gdańsk is run by highly qualified and experienced personnel.

We are fully enabled to deliver clinical material and furthermore secure on-time commercial launch and subsequent supply at economically attractive conditions by leveraging our cost-effective footprint.

Intense cross-functional collaboration between our analytical, process development, formulation and manufacturing departments drive fast and successful technological transfers and process upscaling. We have chosen cutting-edge disposable technologies run by qualified and experienced personal to guarantee reliable supply while maintaining a high degree of flexibility and scalability.

Dr Adriana Kiedziarska-Mencfeld
Technical Operations Director
Polpharma Biologics

Quality Assurance is a core of all we do – starting from development, through manufacturing, testing and release until delivery to the patients. Our quality system was designed to meet the highest international standards. However, the greatest value of our company are our employees, who everyday work in compliant way, as they fully understand their responsibility for people’s health and life.

Marlena Nowak
Quality Director
Polpharma Biologics

Our manufacturing capabilities at a glance:

- cGMP disposable cell culture drug substance production at up to 2000 L scale for clinical and commercial supply
- cGMP stainless steel microbial drug substance production at up to 350 L scale for clinical and commercial supply
- Downstream process in single-use technology for fast changeover and zero cross-contamination risk
- Liquid fill & finish combi-line for vials, syringes and cartridges (throughout of up to 3000 units per hour)
- Lyophilizer 5 m²
- State-of-the-art quality control laboratory
- Drug substance and drug product testing and release

Reliable supply for your success

Polpharma Biologics’ CMO partner,
Duchnice (Warsaw area), Poland
Large scale facility for drug substance manufacturing and sterile fill & finish

To serve the growing global demand for biopharmaceuticals, we have included into our network the new Polpharma’s commercial-scale cGMP production facility for drug substance manufacturing and sterile fill & finish.

<table>
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<tr>
<th>Feature</th>
<th>Value</th>
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<tbody>
<tr>
<td>Square meters</td>
<td>over 30,000</td>
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<tr>
<td>Single-use bioreactors</td>
<td>starting with 4 x 2000 L</td>
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<tr>
<td>In the second stage</td>
<td>extension to 12 x 2000 L</td>
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<tr>
<td>Vials and syringes F&amp;P</td>
<td>up to 30 MLN</td>
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Marlena Nowak
Quality Director
Polpharma Biologics
Integrated value chain

Polpharma Biologics offers a truly integrated biopharmaceutical one-stop-shop approach. Our fully integrated solutions encompass all required services for biopharmaceutical development and production value chain.

Our contract development and manufacturing services for innovative biological medicines and biosimilars are tailored to suit unique customer needs. Our world-class multinational team of scientists and engineers provides invaluable expertise and insightful advice. At the same time, our project management team ensures transparency and provides you with access to all the information you may require to drive your project forward on your terms.

We offer a truly integrated biopharmaceutical one-stop-shop, which encompasses all required services from cell line development all the way to sterile fill & finish, thereby shortening your time to market, reducing managerial complexity and eradicating risky handovers between multiple service providers.

Tomasz Góralczyk
Business Development & Alliances Director
Polpharma Biologics

Selection of the right people with appropriate competencies for a specific task is crucial for delivering successful projects. We have built our Project Management Team with people that are not only business-oriented and have strong scientific backgrounds, but, more importantly, have great communication and leadership skills, allowing them to build relations with all stakeholders in order to drive the project towards the finish line.

Dr Rafał Derlacz
Program Head
Polpharma Biologics
Polpharma Biologics

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