



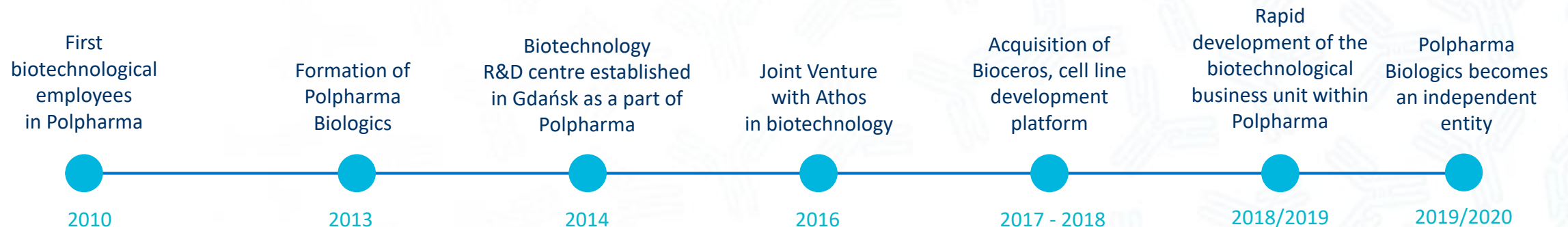
World class solutions for the
development and manufacture
of biologics

Polpharma Biologics – Enabling Your Success

Polpharma Biologics provides world-class solutions for the development and manufacture of biologics in both mammalian and microbial expression systems.

From Cell Line Development to Fill Finish, we provide a truly integrated platform for the cost-effective and rapid delivery of novel biologics and biosimilars at pre-clinical, clinical and commercial scale.

- **European footprint** and **experienced team of 400+ professionals**
- **International track record** in biotechnological development and manufacturing of novel biologics and biosimilars
- **Integrated services offering** from discovery to commercial supply
- **GMP drug substance and drug product** production in both mammalian and microbial systems
- **Sterile GMP fill & finish** of liquid and lyophilized formats





Key Capabilities



Discovery, Development and Manufacture of Novel Biologics

- All the component to take your product from DNA, through IND, through clinical trials and to support your global commercial supply
 - Antibody Discovery & Optimization
 - Antibody Humanization
 - Cell Line Development
 - Process Development
 - cGMP Manufacturing
 - Extensive Analytics & Bioassays



Development and Manufacture of Biosimilars

- Exceptional technologies and capabilities deliver fingerprint like similarity, smoothing your route to market
- High Quality Analytics: Deeply characterize the protein of interest and identify its core quality attributes
- Reducing Cost of Goods: Technologies to significantly reduce manufacturing costs
- Quick to Clinic: Our integrated capabilities reduce development time significantly



Formulation Development Drug Product & Fill Finish

- Drug product development and cGMP manufacturing of sterile biologicals in liquid and lyophilized forms at lab and large-scale
- Operate a state-of-the-art biopharmaceutical cGMP fill & finish plant in Europe
- Equipped with disposable liquid filling technologies, lyophilization and freeze-drying capabilities
- Clinical and Commercial Supply

Regulatory and IP Support

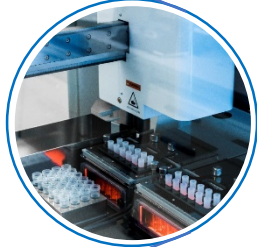
Discovery, Optimization, Development and Manufacture

Extensive tools for the discovery, optimization and evaluation of new biologics and biosimilars in both mammalian and microbial.



Monoclonal Antibody Discovery & Humanization

- Extensive antibody discovery platform (CASH™) for novel therapeutics
- Antibody humanization utilizing best in class technology
- Bioassay and analytical toolbox for extensive characterization and evaluation



Industry Leading Cell Line Development

- Development of high quality, high titer manufacturing cell lines
- Utilize our own proprietary CHO-K1 derived cell line, CHO^{BC}®
- Deploy our SPOT™ and SLIM™ technology to reach titers upwards of 9 g/L



Upstream and Downstream Process Development

- Utilize our extensive knowledge and our process modulation toolbox
- Quickly establish processes that will yield the optimal outcome at the highest level of efficiency
- Apply quality-by-design (QbD) principles to guarantee the quality, safety and efficacy of your products



cGMP Manufacturing

- State-of-the-art manufacturing facilities that utilizes the latest single use technology
- SUBs include 2 x 50 L, 1 x 250 L, 1 x 1000 L and 4 x 2000 L with a further 6 x 2000 L planned plus 1 x 500 L stainless steel
- Produce drug substance and drug product for pre-clinical, clinical and commercial supply
- Separate suits for mammalian (up to 2000 L) and microbial (up to 500 L) production

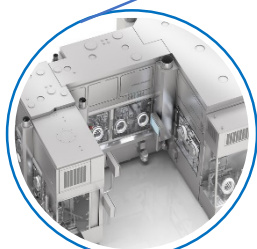
Drug Product Manufacturing for Clinical and Commercial Supply

Polpharma Biologics provides drug product development and cGMP manufacturing of sterile biologics in liquid and lyophilized forms at lab and large-scale.



Formulation Development

- Apply a broad array of high-throughput technologies to provide rapid formulation development
- Simultaneous real-time and accelerated stability testing according to ICH standards
- Semi-automatic filling machine to determine critical process parameters



Drug Product Manufacturing

- State-of-the-art biopharmaceutical drug product manufacturing plant
- Range of volumes from 4 L up to 200 L with SU Technology to transfer product to filling line
- Bioburden reduction filtration and Class A redundant sterile filtration



Fill Finish

- Operate a state-of-the-art biopharmaceutical cGMP fill & finish plant in Europe.
- Equipped with disposable liquid filling technologies, lyophilization and freeze drying capabilities
- Syringes from 0.5 ml up to 10 ml, cartridges: up to 10ml, vials 2R up to 30R, up to 60 pcs/min



Analytical Development & QC Services

- Development, qualification and validation of analytics for late stage development
- Robust control strategy required to manufacture and commercialize biologic molecules

State-of-the-art Facilities

By continuously investing in state-of-the-art infrastructure and personnel, we achieve and maintain the highest level of quality while securing competitive prices for our customers.

Utrecht, Netherlands

Center of excellence for the development of mammalian cell lines for monoclonal antibodies (mAbs) and other therapeutic proteins with a strong focus on CQA modulation and titer optimization

Gdańsk, Poland

Our integrated biopharmaceutical development and GMP drug substance manufacturing facility in Gdańsk is one of the most modern in Europe, employing both microbial and mammalian systems, as well as aseptic fill & finish of final drug product

Warsaw, Poland

A new commercial-scale GMP production facility for drug substance, the site is built in a modular design to allow for rapid expansion to meet customer commercial supply requirements



Working with Polpharma Biologics

Polpharma Biologics is led by a team of industry experts with decades of international experience spanning the full spectrum of biopharmaceutical development

Project Management

- For set up and continuous on-site project management and coordination Polpharma Biologics will dedicate an experienced project manager, who will be the primary contact for the duration of the project
- As one of the few truly integrated CDMOs supporting the development and manufacture of biosimilars and novel biologics, Polpharma Biologics has the equipment, technology and expertise to be fully flexible to your needs at all stages of your development programs
- We are fully focused on executing project on-time to the highest of standards

Experience

We have extensive experience of taking new therapeutics and biosimilars through development and can support you on individual projects or use our experience not only in development but also in regulatory, quality and IP to accelerate your product to the clinic

- Experienced staff at Polpharma Biologics have worked on hundreds of projects at every level of development across the globe





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