



PORTON
BIOPHARMA



**DEVELOPING & MANUFACTURING
LIFE-SAVING PRODUCTS**

www.portonbiopharma.com



WHAT WE OFFER

Porton Biopharma Limited (PBL) is a UK-based company experienced in developing, manufacturing and bringing life-saving biopharmaceutical therapeutics and vaccines to market globally. The company's expertise lies in taking concepts from the research laboratory, progressing them through various stages of process development and scale-up to manufactured product at pilot scale.

With the experience of having marketed products and facilities licensed by the MHRA and FDA, PBL is able to leverage experience of regulatory compliance and quality systems to develop new biotherapeutics be they native or recombinant proteins, products from micro-organisms requiring containment, enzymes for diagnostics, or other biomolecules.

PBL's experience, spans collaborations and partnerships, from UK and US government customers through to start-up biotech and mid/large pharmaceutical organisations.

With a rolling programme of investment, the site already has the infrastructure, capacity and land available to develop and build new facilities for companies keen to tap into its expertise.

With a flexible approach, PBL is open and willing to consider various business models to assist in getting products to market. Coupled with office/laboratory facilities closely located on the secure Porton Science Park, Porton Down, Salisbury provides the ideal location for start-up biotech/biopharma companies to develop and progress products through clinical assessment and eventual licensure.

PRODUCTS

Anthrax Vaccine

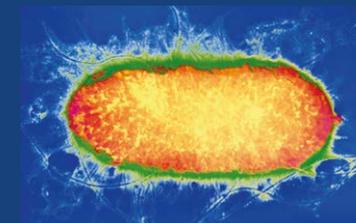
PBL is the sole manufacturer of the UK's licensed anthrax vaccine. The vaccine is manufactured for, and on behalf of, the UK Government. It is supplied to the Department of Health for occupational health purposes and to the Ministry of Defence as a strategic biodefence medical countermeasure.

Erwinase®

PBL is the sole manufacturer of Erwinase® which is indicated for the treatment of Acute Lymphoblastic Leukaemia (ALL), the most common form of cancer in children.

The product is manufactured in PBL licensed pharmaceutical manufacturing facility. Since its first registration in the UK in 1985 Erwinase® has been registered in approximately 20 countries and commercialised in up to 80 countries world-wide, including approval in the USA by the FDA in November 2011 under the name Erwinaze®.

Erwinase® is an L-asparaginase enzyme derived from the bacterium *Erwinia chrysanthemi* that is used as part of the treatment protocols in conjunction with radiotherapy or chemotherapy. Erwinase® is used when patients demonstrate an allergic reaction to L-asparaginase enzymes from other sources. In those aged 14 or younger, more than 90% will survive their leukaemia for 5 years or more after they are diagnosed*

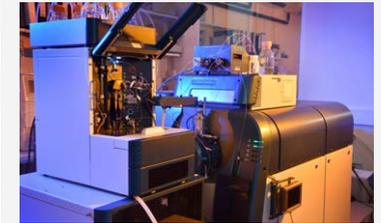
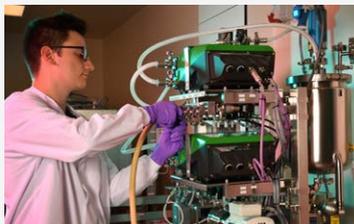


*Cancer Research UK www.cancerresearchuk.org/about-cancer/type/all/treatment/statistics-and-outlook-for-acute-lymphoblastic-leukaemia

OUR CAPABILITIES

Having significantly invested in new development facilities and equipment recently, PBL is able to offer services which include:

- Development fermentation studies in a range of production platforms including WAVE Bioreactors™ and stirred-tank bioreactors from 1L through 15L to 50L scale at biocontainment level 2 in pre-GMP facilities
- Flexible film isolator capability for growth of organisms at biocontainment level 3 in a range of bench-top fermenters and WAVE Bioreactors, plus stirred tank bioreactor capacity of up to 60L also at biocontainment level 3
- Product purification including preparative chromatography and Tangential Flow Filtration (TFF) from laboratory-scale models to 1000L
- Protein Modification & Formulation – Our extensive in-house capabilities include chemical modifications of proteins (e.g., antibody labelling and conjugation) and formulation development. The group can perform high-throughput formulation screening using our cutting-edge equipment and knowledge.



- Analytical method development and qualification to demonstrate process reproducibility and in-process and final product analysis, with methods including LC-Mass Spectrometry, HPLC, UPLC, 1-D and 2-D electrophoresis, capillary electrophoresis, ELISA and dynamic light scattering
- High-throughput formulation screening and product stability assessments using a range of cutting-edge equipment
- Molecular biology services, including cell bank establishment, full proteomic analyses, gene synthesis (via an outsourced partner) and cloning into a range of expression vectors designed for various host cell platforms

The Development Group offers these services utilising a systematic Quality by Design approach, driven by predefined customer-agreed objectives that emphasise product understanding and process robustness.

We would be delighted to discuss how we can help you!

WHO WE ARE

Our mission is to protect patients' health through the quality-assured development and production of biopharmaceuticals whilst maximising revenues through worldwide sales.

Porton Biopharma's strategy as a company with a distinguished heritage is to grow the existing business, develop our product pipelines and build relationships across the industry. PBL were corporatised from Public Health England on 1 April 2015 to enable growth of the business by developing and manufacturing life-saving products.

The company is built upon decades of biopharmaceutical experience, including the successful licensure of many therapies that now save thousands of lives every year and generate revenues from worldwide sales. We have state-of-the-art cGMP manufacturing facilities which are licensed by the MHRA and FDA, where we manufacture biopharmaceutical products and are investing in new capabilities and capacity. With a multi-skilled workforce of approximately 350 and an ongoing programme of investing in our facilities, we are focused on continual improvement and the delivery of products that make a real difference to patients' lives.

At PBL we offer expertise and scalability in the developmental production of biologicals, including product characterisation, process and analytical validation. Allied with experience of regulatory compliance gained from the licensure of our own products, this puts us in an ideal position to offer expertise and enable you to successfully develop your products.



GET IN TOUCH

**We are located on the
Porton Down Campus near Salisbury:**

Porton Biopharma Limited
Manor Farm Road, Porton Down
Salisbury, Wiltshire UK
SP4 0JG

Telephone: +44 (0)1980 612100
Fax: +44 (0) 1980 612500
business@portonbiopharma.com
www.portonbiopharma.com

