a thousand smiles. in one celebration.

Life.
a thousand milestones. in one journey. Life.

Established in 1953, Biological E Limited (BE) is a leading, world-class Pharmaceutical and Biologics company with an impressive range of healthcare products.

We are a company driven by knowledge – a huge pool of talent that gives us the competitive advantage to make an impact in the global markets. Our unequalled values and a quality customer-centric policy forms the basis of our investments in systems and infrastructure.

BE is the ‘first private sector biological products company’ and a pioneer in the vaccine industry in India. We take pride in our historical and on-going partnership with the Government of India in the National Immunization Program of the country. This enables us to provide affordable access to critical vaccines for millions of children in India.

In addition to our efforts in Biologics, BE has built expertise in the areas of novel delivery systems, strategic bulk actives and formulations.

The BE business model has three core dimensions comprising of Biologics, Pharmaceuticals and Bulk Actives. Through these strategic divisions, the company is able to address the needs of the domestic markets as well as international markets in Asia, the CIS countries, the USA, and Latin America.
Biologics

From its maiden products in classical biologics such as Heparin, BE continues to innovate and develop new age genetically engineered biologics. BE produces and markets a range of paediatric and adult vaccines and has a significant market share in the Indian vaccine market. In just a span of a decade, the company has delivered over 1.5 billion doses of vaccine towards the immunization needs in India.

BE brings an enormous breadth of biologics ranging from bacterial vaccines – toxoids to polysaccharide conjugates and cell-culture viral vaccines to recombinant proteins. Our current research focus comprises of developing low molecular weight heparins (LMWH), conjugate vaccines and a portfolio of flavivirus vaccines for unmet needs.
Pharmaceuticals

BE has a broad range of pharmaceutical formulations – oral dosages as well as injectables. This range of branded formulations encompass therapeutic segments of

- Non-Narcotic Cough Preparations
- Digestive Enzymes and Vitamins
- Anticoagulants and Liver extracts
- Anti-Infectives and Antibiotics
- Haematemesis

Active Pharmaceutical Ingredients (API)

Strategically, the API division of BE supports the captive consumption needs of the company. Specializing in alkaloids such as Noscapine and its derivatives and biologics such as Heparin, LMWH and PSGAG (Chondroitin Sulphate), BE has committed significant investments to ensure a sustainable quality supply for the global markets.
In 2006, BE commissioned a state-of-the-art cGMP manufacturing facility at SP Biotech Park in Andhra Pradesh to produce vaccines and biologics meeting international standards. This facility will enable BE to enhance capacities for its existing vaccines, create large-scale manufacturing capacities for new vaccines that are in the R&D pipeline and most importantly, create access for its products across the world – especially in regulated markets.

Be it world-class manufacturing, sales or distribution, BE, through its investments, is in a unique position today to meet the opportunities for global demands in biologics as well as in pharmaceuticals.

**Quality Operations**

BE has a commitment to the philosophy of total quality which has been implemented through a well-defined and evolved quality management system. Quality Operations at BE are controlled by an independent Quality Assurance department.

The Quality Operations are supported by an independent and robust Quality Control and Analytical Development in addition to Assurance.

In addition to WHO GMP certifications, BE is currently in the process of WHO Prequalification and filing with other regulatory agencies such as the USFDA, MHRA and EMEA.
Research & Development

BE’s expertise ranges from formulation development in small molecules, development of polysaccharides and conjugate vaccines, cell-culture viral vaccines to recombinant proteins. The current focus of BE’s research is primarily on process development and large-scale manufacturing. This development is carried out at our well equipped research facilities with cGMP, pilot facility and analytical development labs. These facilities have been designed to handle organisms requiring a BL2 level of containment.

Clinical & Regulatory Affairs

The Clinical and Regulatory Affairs engages in conducting Phase II to Phase IV clinical research programs for international markets, in compliance with ICH-Good Clinical Practice (GCP) guidelines. BE conducts its own extensive pre-clinical research to support its R&D and regulatory programmes. This research focuses on efficacy and toxicity models involving small animals. Our pre-clinical testing facilities are designed to meet GMP regulations and provide for the containment of individual experiments.

Partnerships

BE currently is engaged in partnerships with several global companies and well respected Institutions and Public Health Organizations world-wide. Some of our strategic partners are:

- Netherlands Vaccine Institute (NVI), Netherlands
- Intercell AG, Austria
- National Institute of Health (NIH), U.S.A
- Indian Institute of Science (IISc), Bangalore - India
- International Centre for Diarrhoeal Disease Research (ICDDR), Bangladesh
Biological E is committed to the societies we operate in and to the environments we inhabit. We believe in equal employment, transparency and responsible business and community practices that allow us to deliver quality products and services to people across the world.

For more information please be invited to

www.biologicale.com
a thousand creations. one recreation. Life.