Biotechnology and products manufactured from biological materials continue to grow at an unprecedented pace. In every corner of the world, men and women are engaged in cutting edge research to find new and better ways to diagnose and treat human and animal diseases and advance health conditions.

Largely fueled by TSE (Transmissible Spongiform Encephalopathy) concerns, the use of animal sourced materials in the production of these products is becoming increasingly regulated. Consequently, the need for safe and reliable sources of key components has grown proportionately. This is particularly evident in global, pharmaceutical markets.

Selborne Biological Services is a leading supplier of specialized products of animal origin for the biotech, pharmaceutical, veterinary, and diagnostics industries. Selborne strives to provide its clients with the highest level of product confidence by adhering to the following principles:

- **100% sourcing from non-BSE countries** (Australia and New Zealand)
- Flexibility in manufacturing services
- Continuous Improvement
- Strict compliance with cGMP guidelines and Quality Systems
- Maintaining core values of honesty, integrity, trust, and customer satisfaction

Australia is one of few countries in the world with the highest rating (lowest risk) for potential BSE contamination as rated by the EU Scientific Steering Committee on the Geographical Risk of BSE. Accordingly, it is Selborne’s policy that all products derived from animal sources with TSE concerns (bovine, ovine and caprine), be limited to collection from countries considered to be TSE free, namely Australia and New Zealand.

Selborne holds EDQM Certificates of Suitability with respect to TSE safety for all bovine products.

Selborne sources its starting materials from closed, dedicated donor groups of animals from licensed and inspected abattoirs only.

**COMPANY HISTORY**

Selborne’s company origins and namesake derive from the historic village of Selborne, England, in East Hampshire. One of the most celebrated villages in all of England, Selborne owes its renown to Gilbert White (author of the much acclaimed "The Natural History and Antiquities of Selborne"), an 18th century curate and naturalist who was born and lived here throughout his life. Hampshire was also home to and inspiration for heralded novelist, Jane Austen, where she wrote some of her most famous and enduring works (Pride & Prejudice, Emma, Mansfield Park) of the early 19th century. The quiet splendor and setting of this tranquil countryside village is marvelously unspoiled and remains much as it was during their lifetimes.

The widespread use of tissue cultures in the production of viral vaccines during the 1960’s brought to the fore the need for high quality serum as a component of cell culture medium. A small operation was started in 1974 to address this need, later moving to a 100 acre isolation farm in Selborne, England. The company name was changed at that time to Selborne Biological Services to reflect the new home and service orientation. From that beginning, Selborne Biological Services Ltd. (Selborne) has grown to become a leading specialist in the production of blood-based products, protein fractions, and other animal related products and services for the biotech, pharmaceutical, diagnostic and veterinary industries.
Move to Southern Hemisphere

In the late 1980’s, the outbreak of Bovine Spongiform Encephalopathy (BSE), combined with Sheep Scrapie disease in the United Kingdom posed significant problems for manufacturers of biological medicines utilizing serum. This realisation prompted Selborne to turn its attention to the Southern Hemisphere, to countries known to be free of BSE and Sheep Scrapie. Australia and New Zealand were ideal, having economies based heavily on agriculture, an animal health status which was excellent, and importation of animals strictly monitored. Operations were quickly established at Tauranga, New Zealand, followed in 1992 by a manufacturing site in Longford, Tasmania, Australia.

Conveniently located near Launceston airport, Longford is ideally situated as a biologics manufacturing site. With increasing concerns over the safety of biological products and pharmaceuticals manufactured using animal derived materials, Tasmania offers a safe haven from both a sourcing and manufacturing viewpoint.

Located some 150 miles across the Bass Strait, south of Australia’s mainland, Tasmania offers the added benefit of further isolation, having no common borders.

In 1997, Selborne sold the Tauranga, New Zealand site to focus its manufacturing operations in Tasmania. By 1998, the GMP manufacturing facility was commissioned and is now the main manufacturing site for Selborne’s global operations. The UK site continues to produce a small range of gamma globulins and other intermediate proteins in addition to maintaining a sales, marketing and distribution centre for our European clients.

U.S. Presence

Because Selborne has no manufacturing operations within the USA, sales functions within North America were traditionally handled through Distribution partners. Due to the preeminence of the U.S. pharmaceutical and biotech markets and to better serve its partners and customers alike, Selborne determined that a direct presence within the U.S. was essential. Accordingly, Selborne Biological Services (USA) LLC was formed in the spring of 2005, based in Logan, Utah. Selborne’s USA affiliate is the global center for its Marketing operations. From this location and through its network of partners, Selborne offers warehouse and logistical support, as well as technical and analytical services.

AUSTRALIAN FACILITIES

One of the competitive advantages Selborne offers to its customers is remarkable flexibility in manufacturing operations. Selborne can accommodate a wide array of formats, volumes and packaging to suit your research or production needs. Selborne’s manufacturing operations include the following general capabilities:

- Over 500 square metres of laboratory and temperature controlled storage;
- Large and small volume serum protein separation/purification facilities;
- Multiple Class 10,000 clean rooms;
- Serial filtration from 0.45µm to triple 0.1µm;
- True pool batch sizes from 500 to 2500 litres;
- Packaging options ranging from small volume bottles to customised large volume flexible containers;
- Isolated filtration for non bovine material;
- Segregated bovine products manufacturing utilizing disposable production technologies;
- Customised sera processing including IgG depletion, Gamma Irradiation, and Heat Inactivation.

Additional facilities upgrades and expansions are currently under way in both Australia and the UK with completion expected near the end of 2007.
It is Selborne’s policy to manufacture and supply products that meet or exceed customer expectations in terms of quality and compliance with pertinent regulatory requirements.

Quality Systems

Selborne applies the principles of cGMP to all manufacturing activities as defined in the ICH Q7A guidelines (International Conference on Harmonisation - Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients) and other National/International codes as may be relevant.

To maintain compliance with cGMP and regulatory requirements, Selborne maintains an independent QA/QC department with the following responsibilities:

Quality Control (QC) is responsible for the testing of raw materials, components, intermediates and finished products. QC also has responsibility and authority for the release or rejection of raw materials and components for use in manufacturing. The environmental monitoring program in the production facility is conducted and evaluated by QC.

Quality Assurance (QA) has responsibility and authority in all matters relating to quality control, documentation, internal and external auditing and the release or rejection of finished product.
QA monitors all aspects of the Quality System to ensure that activities are conducted in accordance with standards specified in cGMP codes of practice. QA also ensures that products comply with prescribed specifications at all stages of manufacture.

**Regulatory Licensing**

Selborne is licensed by the Australian Therapeutic Goods Administration (TGA) for the manufacture of certain APIs (Active Pharmaceutical Ingredients).

The principles that pertain to the manufacture of APIs are integral to all areas of production at Selborne. Selborne also has experience in the submission of applications with other regulatory authorities as applicable to the country of end use.

**Traceability**

The increasing incidence of diseases such as BSE (Bovine Spongiform Encephalopathy) as well as elevated levels of chemical residues have consumers progressively alarmed at the safety of animal-sourced products. In consequence of these concerns and in order to protect the integrity of their supply chain, many countries which import animal products are enacting policies of strict regulation.

Australia is the leading exporter to many of the world’s top markets. All around the globe, Australian beef and animal-derived products are recognized for their exceptional quality and safety. No where is this reputation more valued than among the world’s leading pharmaceutical manufacturers.
To protect this enviable position, the National Livestock Identification System (NLIS) was adopted in October 2003 by all Australian state and territory governments. The NLIS is a whole-of-life tracking system which incorporates RFID (Radio Frequency Identification) technology to provide unprecedented levels of a livestock traceability. The identification of livestock begins on the property of birth through the placement of low frequency, passive RFID tag that remains with the animal until it is processed. The NLIS is recognized as one of the world’s foremost livestock, traceability and integrity systems in force.

The NLIS integrates Australia’s regulatory bodies, farmers/ranchers, suppliers, and processors (including abattoirs) and extends along the entire supply chain. Australian abattoirs are subject to strict federal government controls that include ante and post mortem inspections of 100% of all animals by on-site AQIS (Australian Quarantine & Inspection Service) veterinarians. These factories are licensed by AQIS, who are responsible for export health certification. All cattle presented for slaughter must be matched with a National Vendor Declaration Form. The Vendor Declaration System is fully auditable.

Selborne sources all their Australian derived raw materials including blood and blood products from export registered abattoirs. Selborne’s animal-derived products can be traced back to the abattoirs daily production record. This system together with the NLIS allows traceability back to the property of birth.

Blood from which products are manufactured is derived only from animals that meet the following criteria:

- pass as being fit for human consumption
- meet the requirements for export to overseas destinations
- passed by the AQIS onsite veterinarian
- are not injured
- do not present with any pathological conditions
- are grazed only on foods such as pasture grass or grains
- are not within specified withholding periods for veterinary or agricultural treatments

**PRODUCTS & SERVICES**

Selborne’s core area of product and service expertise rests principally within its capacity as a biologics manufacturer. Selborne has been producing quality biological products for more than 30 years. Its family of products fall within two main divisions:

- Animal Blood Products, including a family of sera, plasma and microbiological reagents
- Protein Fractions, grouped into products for cell culture, diagnostic applications, and therapeutic proteins

For specific product inquiries or to request a sample or to obtain a listing of current products and services, see our corporate website at www.selbornebiological.com or contact your nearest Selborne office or sales representative.

Selborne. No worries.
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NOTE: The Australia facility is a manufacturing site only. Product inquiries should be directed to either the U.S., UK, or Japan distributor offices.

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NOTE: SB Trading Co., Ltd. is the sole distributor of Selborne products in Japan. Based in Tokyo, SB Trading has a long and successful history in the supply of materials to the Pharmaceutical and Biotechnology Industries.