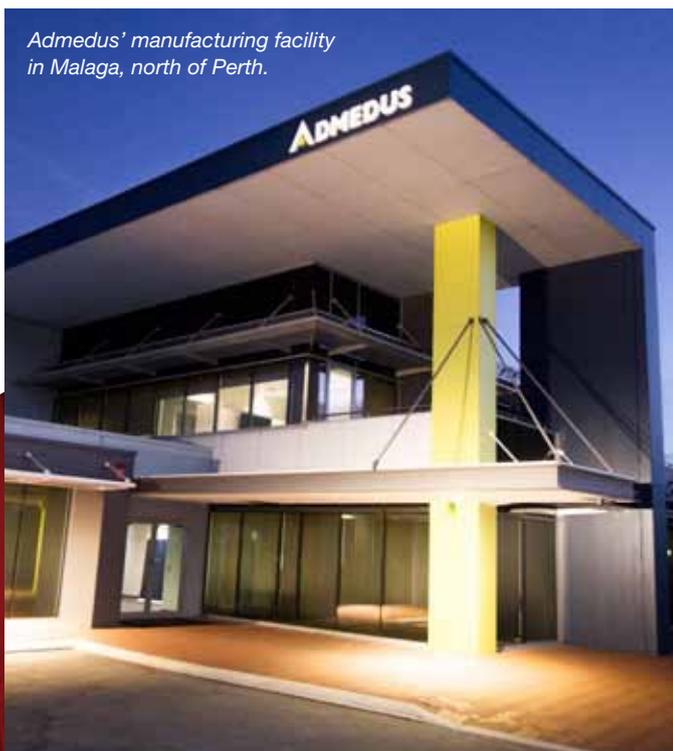


MEDICAL DEVICES GAINING A GLOBAL EDGE

Australian manufacturers of medical devices technology are exporting their products globally. These companies are at the cutting edge of innovation, and they're calling on Government to do more to support a sector that could represent the future of manufacturing in this country. By Carole Goldsmith.



Admedus' manufacturing facility in Malaga, north of Perth.

The Medical Technology Association of Australia (MTAA) published the 2013 fact book *Medical Technology in Australia: Key Facts and Figures in 2013*. The report analyses the Australian medical technology industry, which includes medical devices, diagnostics and medical imaging equipment. These therapeutic goods are all regulated by the Therapeutic Goods Administration (TGA).

The fact book revealed that the Australian medical technology industry had a turnover of approximately \$10bn in 2012, generated by over 500 companies who employed more than 19,000 people. The industry was responsible for 41,292 medical devices being listed on the Australian Register of Therapeutic Goods (ARTG) in 2013. Globally the medical technology market was valued at US\$325bn in 2011.

AusBiotech represents 3000 members in the life sciences sphere, including therapeutics, food technology, agricultural, environmental and industrial sectors. Medical technology (devices and diagnostics) also make up a large proportion of AusBiotech's members.

"Among AusBiotech's membership there are around 50 high-technology medical devices manufacturers and hundreds more that produce simpler devices," says AusBiotech's Chief Operating Officer, Glenn Cross

Cross highlights two AusBiotech members, Admedus and Universal Biosensors, who are innovators and global leaders in their field.

Admedus – Engineering implantable tissue

Diversified healthcare group Admedus is expanding operations with its recent acquisition of an established manufacturing site in Malaga, northern Perth. With a fully operational infrastructure, this facility will

Manufacturing CardioCel from Admedus' ADAPT Technology.



CardioCel is a breakthrough treatment for cardiovascular defects.

support Admedus' global marketing of CardioCel, a breakthrough new treatment for the repair and reconstruction of cardiovascular defects such as congenital heart disease. It will also generate an additional 12 production jobs for the company, bringing the total number of employees to 55, some of whom are based in EU and the USA.

Currently Admedus is using the Ray and Bill Dobney Cell & Tissue Therapies WA (CTTWA) bio-therapeutic manufacturing facility at the Royal Perth Hospital to undertake small-scale production. The manufacturing of CardioCel is undertaken in clean rooms, with CTTWA licenced by the TGA to undertake core tissue and cell therapy work.

"CardioCel is the first of a suite of implantable tissues that our scientists are developing from our patented ADAPT tissue engineering process," says Admedus Chief Operating Officer, Dr Julian Chick. "Now on the market in the EU and USA for congenital heart disease and cardiovascular repair in adults and children, CardioCel to date has shown no calcification or other complications.

Admedus received an \$1.9m Commercialisation Australia grant in 2013 to assist with R&D during the development of CardioCel and the process of getting FDA approval. All patients from the Phase II study who have been followed up through the extension study continue to show no signs of calcification or no required follow up surgeries, after three to six years. The company anticipates continued data from the ongoing monitoring of these patients.

"The first patient implanted in the Phase II study had a complex cardiac reconstruction using CardioCel when they were only three weeks old," adds Dr Chick. "The patient who is now six years of age, has no detectable calcification (using electrocardiograph imagery) in the implant. The literature indicates that other products on the market typically show detectable macro-calcification – or calcium build-up on body tissues – within a six-to-12-month period of cardiac reconstruction."

Tissue engineering is the creation of an implantable tissue used to support or replace a diseased or injured body part. Admedus scientists have developed a technique that completely re-engineers xenograft tissue (a graft of tissue taken from a donor from one species and grafted into a recipient within another species). Harvested bovine tissue is initially used, and then during the manufacturing process, all bovine remnants are removed.

The tissue is then stripped of all intracellular contents, which when exposed to the ADAPT process, produces a bio-prosthetic scaffold. The resulting bio-implant bears no resemblance to its origins and has none of its previous characteristics. Once implanted, tissue produced by the ADAPT process has no cytotoxicity and studies indicate it becomes repopulated with the patient's own cells.

Each 4cm-by-4cm sized CardioCel tissue is produced and stored in a jar with sterilisation solution. During cardiac reconstructive surgery, the surgeon removes the tissue from the jar, cuts it to the required size and stitches it to the patient's heart.

"At full capacity we estimate that the new manufacturing site will produce over 100,000 units per year within five years," says Dr Chick. "In Europe alone, there are approximately 100,000 cardiovascular surgical procedures in adults and children, in which our tissue patch could be successfully applied."

Admedus scientists are also working with Professor Ian Frazer – widely known for his work on the development of Gardasil, the first prophylactic cervical cancer vaccine – on the development of therapeutic vaccines that combat infectious diseases and cancers, such as the herpes simplex virus and human papillomavirus.

"These programs are currently in clinical development with a recently reported positive outcome from the Phase I clinical trial," says Dr Chick.

Universal Biosensors – partnering with global leaders

Medical diagnostics company Universal Biosensors (UBI) focuses on the research, development and manufacture of diagnostic test systems for point-of-care (POC) professional and home use. The UBI group, which is incorporated in both Australia and the USA, has been very successful in partnering with international health leaders in product R&D and global distribution.

A biosensor is a device that collects data about a biological or physiological process or parameter such as blood glucose testing and blood coagulation. UBI's first product, a blood glucose monitoring device, is being commercialised globally by LifeScan, a Johnson & Johnson company. A second range of products for the point-of-care coagulation testing market is in development with partner Siemens Healthcare Diagnostics.

Located in Rowville, east of Melbourne, UBI employs around 80 people. With an ISO-13485-accredited facility and quality system in place, the company's state-of-the-art manufacturing operation is able to produce a variety of biosensors on a large commercial scale. ISO-13485 is an international standard specifically for the design and manufacture of medical devices.

UBI CEO Paul Wright describes the company's manufacturing site: "Our facilities are unique, and we designed the biosensor technology and manufacturing process together. The biosensors have to be low-cost and reliable, as millions need to be produced and used every day. The optimal way to produce these sensors was to create a custom-built and highly automated manufacturing process.

Continued next page