



Marine Biomedical

Discovering the oceans' potential

MEDIA RELEASE

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Unique Biotech Manufacturing Facility Opens in Broome

- **First medical device manufacturing facility established in north Australia**
- **Essential for US and Australian regulatory approval for new medical products**
- **Enables manufacture of PearlBone™ for patient use**
- **Pioneering biotech investment in north Australia**

Marine Biomedical has officially opened a Broome biotech manufacturing facility essential for transforming local pearl shell into life-changing PearlBone™ medical products for global use in patients with trauma and reconstructive surgery.

Western Australian Minister for Innovation and the Digital Economy; Science: Medical Research, Hon. Stephen Dawson MLC formally opened the company's pioneering investment in a regional biotech capability, comprising a state-of-the-art medical device cleanroom, analytical laboratory, packaging area and offices.

Establishing the biotech manufacturing facility is an essential next step in Marine Biomedical's steady progress toward obtaining regulatory approvals for the use of PearlBone™ in medical applications, particularly orthopaedics, following its success in pre-clinical trials.

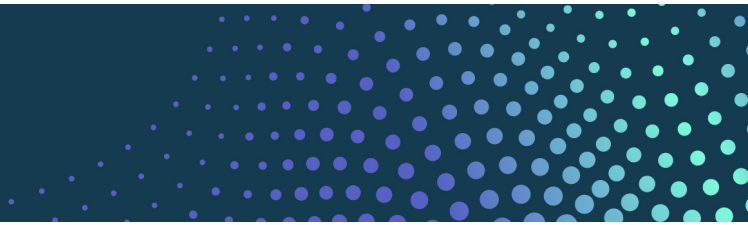
The Good Manufacturing Practice (GMP) cleanroom enables Marine Biomedical to manufacture PearlBone™ to the highest quality standards required for approval from the US Food and Drug Administration (FDA) and the Australian Therapeutic Goods Administration (TGA).

PearlBone™ is a patented bone substitute originally developed by Professor Minghao Zheng and Dr Rui Ruan at the University of Western Australia. Derived from the nacre (mother of pearl) of Broome's silver-lipped pearl oyster, the innovative technology harnesses the natural process of mollusc biomineralization to encourage bone formation in humans.

As well as providing a sustainable source of bone grafting material, PearlBone™ could help address the global shortage of implant materials for a range of orthopaedic conditions, partially resulting from humans living longer. More than 2 million bone grafts are performed globally each year.

Locating the facility in Broome ensures proximity to the sustainable pearl shell resources grown in the pristine waters of the Indian Ocean. Marine Biomedical's long-term goal is to commercialise medical products sourced entirely from the by-products of sustainably certified fisheries.

Five specialist staff are now working at the facility, with the initial focus being on producing batches of PearlBone™ to undergo quality and safety assessment and eventually use for treatment of patients with fractures. "The full-scale batch production during the remainder of 2023 will enable a formal submission to the US FDA for use in humans" said the CEO of Marine Biomedical Pty Ltd, Mr Patrick Moase.



Opening the biotech manufacturing facility, the Hon. Stephen Dawson said its presence in Broome would elevate regional research and innovation capabilities and demonstrate the opportunities available in the Kimberley.

“This manufacturing facility will not only position Marine Biomedical and Broome as an international trailblazer in the marine-derived biomedical sector, but the State Government believes it will inspire other businesses and investors to pursue the many opportunities available in our regional areas,” said Minister Dawson.

“We are completely focused on our pathway to regulatory approval for this remarkable medical product, which has been proven to support new bone growth and has the potential to deliver extraordinary long-term benefits across a range of orthopaedic applications,” said Mr Moase.

Marine Biomedical’s commitment to the manufacturing facility has been supported by Western Australian and Federal Government grants that have expedited the establishment of the Broome operation.

The company is particularly appreciative of the support and encouragement of both Governments in establishing manufacturing capacity in a regional community and their combined interest in our pathway for obtaining regulatory approval for PearlBone™.

MEDIA ENQUIRIES

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