YOUR REGULATORY PARTNER IN AUSTRALIA, NEW ZEALAND & ASIA

BRANDWOOD : BIOMEDICAL

securing your compliance

Regulatory, Technical and Quality Services for Medical Devices & IVDs

- Global Regulatory strategy
- Worldwide Regulatory Submissions and reviews
- Quality Systems
- Labeling and IFU
- Clinical Trials
- Post-market compliance
- Authorized Representation and Sponsorship

> "Our Chinese application for a Class III medical device had been stalled and was in danger of rejection by CFDA. Brandwood Biomedical were able to resolve the impasse and take us forward to approval. We were delighted with their ability to understand our product, communicate effectively with CFDA at the right level and achieve a positive and timely outcome."
>
> **European Device Manufacturer**

Experts in Market Access and Compliance

Market Entry Strategy | International Regulatory Submissions | Clinical Trials | Reimbursement
Technical File Preparation | ISO 13485 and 21CFR 820 Quality Systems | Vendor Accreditation
Risk Assessments | Product Requirements and Technical Standards | Postmarket Compliance

SYSTEM CERTIFICATION ISO 9001 SGS

www.**brandwoodbiomedical**.com

Who We Are:

Brandwood Biomedical provides technical, regulatory and commercial advisory services to support the whole product life cycle in medical devices and in vitro diagnostics.

We support regulatory approval and market access in global markets, with particular expertise in Australia, New Zealand and the Asia Pacific.

How We Assist You:

Premarket Submissions

- Regulatory Strategy and pathways in international jurisdictions including Australia, New Zealand, China, Taiwan, Japan, ASEAN, Europe and North America.
- Preparation of technical dossiers for premarket submissions.
- Management of filings and reviews.

Standards and Risk Management

- Expert advice on ISO 14971 Risk Management and on standards compliance, pre-clinical testing, and clinical trial protocols, including selection and supervision of service providers in international jurisdictions.

Quality Systems

- Implementation or upgrade of systems to compliance with: - GMP ISO 13485, FDA 21 CFR 820 - GLP ISO 17025, FDA 21 CFR 58
- Assistance with facility inspections including internal pre-audit and attendance at external audit.
- Supplier audits.

Postmarket

- Implementation of systems for continued compliance.
- Management of emerging issues to minimise disruption.

Our Capabilities:

Recent projects include:

- Successful registration of Class III endoprosthesis on the Australian Register of Therapeutic Goods (ARTG).
- Asian regulatory strategy for companion diagnostic.
- Negotiation of China standards compliance exemption and regulatory approval for imaging device.
- FDA IDE clinical trials submission and management of Australian trial arm for implantable heart assist.
- Negotiation of single certificate Taiwan QSD for multi-site global manufacturer.

> "Brandwood Biomedical's global expertise and direct approach are what we were looking for in a regulatory consultant. The personal relationships we have since developed make it a pleasure working with them."
>
> **Multinational IVD manufacturer**

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