

## Dr Arthur Brandwood



*As Managing Director of Brandwood Biomedical, Arthur Brandwood has provided a decade of expert consultancy services, delivering effective regulatory and quality strategies and outcomes to support the profitable life cycle of medical devices and in vitro diagnostics in international markets.*

### Business Profile

Clients of Arthur benefit from his unique combination of academic, industrial, competent authority and business experience in medical devices and *in vitro* diagnostics.

Easy to understand regulatory pathways are delivered in which competent authority preferences are used to optimize input for technical documentation including risk management, design documentation and clinical evaluation reports. The resulting dossiers are 'reviewer friendly', supporting fast approval and prompt time to market.

His expertise enables clients to create and execute meaningful quality systems that not only deliver compliance but also provide clear instructions for all employees so they understand their role in their organisation and the value they add to it.

Clients are of all sizes, from multinationals to start-ups. Approvals in the major global jurisdictions are delivered, including US FDA 510K, PMA, CE Marks and Australian TGA.

### Professional Experience

Arthur Brandwood has over 25 years experience in the medical technology field in industry, academia and government. He has lived and worked in Europe, Australia and South East Asia. Combined with his senior competent authority expertise and international relationships, this provides a truly global perspective.

He is a visiting Professor in Biomedical engineering at the University of Sydney and lectures widely on regulatory affairs and medical device testing and development across the world.

Arthur currently serves on the Asian Harmonisation Working Party on medical devices regulations. He has served as the accredited Australian expert to ISO, taking a leading role in preparation of medical device standards including standards for medical implants, ISO 10993 Biocompatibility and ISO 14155 Medical Devices Clinical Trials. He has chaired ISO Working Groups on Tissue Engineered Medical Products and on Implant Tracking.

Arthur is an active senior member of AusBiotech and National Chair of AusMedtech.

*Leads major regulatory affairs, quality systems and CRO consultancy services for the medical device and in vitro diagnostics industry.*

*Clients benefit from experience gained as Director of Devices Registration and Director of the Biomaterials and Engineering laboratories at the Australian Therapeutic Goods Administration (TGA).*

*An extensive network of relationships with regulators in international competent authorities provides global access to technical knowledge needed for effective and safe product registrations and practical quality management systems.*

### Qualifications

*BSc, PhD, MIMMM, CEng, AIMM*