BRANDWOOD:BIOMEDICAL
securing your compliance

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enquiries@brandwoodbiomedical.com

Dr Arthur Brandwood

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

As CEO of Brandwood Biomedical, Arthur Brandwood has provided more than 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. Operations are expanding into Asia, including direct representation in China.

Professional Experience Summary

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.

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博德 亚瑟 博士

作为博德生物医学公司的总裁，博德阿瑟提供专家咨询服务的十年来，以高效率的产品认证和战略性的质量管理，支撑医疗器械和体外诊断设备在国际市场上有最佳的产品盈利寿命周期。

领导医疗器械和体外诊断设备的大型产品认证事务，质量体系和临床试验咨询服务。

客户们从他在澳大利亚治疗物品管理局（TGA）担任设备登记主管和生物材料及工程实验室主管的经验中受益匪浅。

他与国际主管部门的审批员有密切联系，为有效和安全的产品注册和实用的质量管理系统提供全球性技术知识。

技术资格

生物博士
利兹大学

认证材料工程师，材料，矿物和矿业研究所

教授
悉尼大学

业务简介

亚瑟在客户中极高的口碑得益于他在医疗器械和体外诊断设备上集学术界，产业界，商业界和主管机关的知识经验于一身。

他有一套简单明了的产品认证捷径：采用主管机关的偏好来优化产品技术报告，包括风险管理，设计文件和临床试验报告，由此整理出让审批部门容易阅读的档案，从而达到迅速的审批及缩短进入市场的等待时间。

亚瑟的专业知识帮助客户创建及执行优越的质量体系，不仅仅符合审核标准，而且阐明所有雇员的职责范围，使他们了解对公司贡献和为公司增加的价值。

亚瑟的客户涵盖跨国公司到初创企业。覆盖全球各主要地区的审批，包括美国 FDA 的 510K，PMA，欧盟 CE 标志和澳大利亚 TGA 批准认证。亚洲的业务范围正在迅速增长中，公司在中国建立直线联系的代表。

专业经验

博德亚瑟在医疗技术领域拥有超二十五年的工作经验，从工业界到学术界和政府主管机关。他在欧洲，澳洲和东南亚都有工作和生活经历。他曾在政府主管机关任要职，获取了精深的专业知识及广博的国际关系网，结合以上，亚瑟提供给客户一个真正全球性的视野。

亚瑟是悉尼大学生物医学工程系的访问教授，主讲产品认证事务、医疗器械检测和它们在全球各地的发展。

亚瑟现任亚洲协调工作组（AHWP）成员，积极于国际医疗器械法规的协调工作。他曾担任国际标准化组织（ISO）澳大利亚的认可专家，是医疗设备标准的主要起草者，包括医疗植入物标准，生物相容性（ISO 10993）和医疗器械临床试验（ISO 14155）。他主持了 ISO 关于组织工程（Tissue Engieering）医疗产品和种植物追踪的工作组。

亚瑟现任全国医疗器械行业协会主席（Ausmedtech）。