



www.archeremery.com.au

The company

Archer Emery & Associates was established in September 2006. We have offices in Canberra, Perth and Melbourne. Together we have over 70 years of experience within TGA and the pharmaceutical industry. **Our aim is to provide reliable and cost effective services to assist clients to develop, manufacture and market medicines and therapeutic devices of the highest quality, safety and efficacy.**

Key benefits

Archer Emery & Associates will provide you with:

- Advice on best practice (our team's experience is second to none);
- A realistic assessment of the likelihood of success of a submission or regulatory agency audit;
- Reliable, specialist advice that will save you time and money.

We are committed to excellence and ensure we remain at the forefront of new regulatory developments by being actively involved in peak industry groups.

Regulatory advice

Archer Emery & Associates can assist with:

- Strategic regulatory advice for new and existing products / brands
- Skilled regulatory problem solving
- Expert assessment of registration submissions and assistance with gaps
- Guidance on product labelling
- Rescheduling applications and advice
- TGA liaison and communication
- Customised staff training

GMP / manufacturing advice

Archer Emery & Associates can assist with:

- GMP Auditing
- Marketing authorization / release for sale compliance
- Tamper Evident Packaging advice
- Customised GMP Training
- Documentation systems
- Validation programs (e.g. cleaning, process and analytical method)
- Stability program design
- Supplier qualification programs
- Quality management systems

Our people

Paul Archer - Director

B Pharm

Paul is qualified in Pharmacy and specialises in regulatory and strategic advice, medicines scheduling and problem solving.

Paul has 17 years of senior TGA experience, principally as Head of OTC Medicines but also as Head of Poisons Scheduling and Traditional Medicines and as Secretary of several national committees. He was responsible for developing much TGA policy including legislation and guidelines for the proposed Joint Agency with New Zealand. He has conducted training courses for Australian industry and overseas regulatory agencies.

Julie Emery– Director

BSc(Hons) LLB GDipMgt(TechMgt) MASM

Julie is qualified in Microbiology, Law and Management (Technology Management). She specialises in TGA systems, applications, legislation, labelling and staff training.

Julie has 10 years TGA experience as Manager of the Client Services and Secretariat Unit in OTC Medicines and Manager of the Australian Register of Therapeutic Goods as well as 4 years industry experience. She was responsible for developing technical terminology and label warning statements for the ANZTPA. Julie made a significant contribution to the development of the TGA's Online Systems and conducted training workshops for Australian industry and overseas regulatory personnel visiting the TGA.

Alan Duff– Senior Associate

MSc FRACI C Chem

Alan is qualified in Chemistry and Business Administration. He specialises in GMP auditing in Australia and overseas, GMP training and technical advice on quality of medicines.

Alan has 21 years TGA and 13 years industry experience. He was a Senior GMP Auditor within TGA, responsible for auditing many manufacturing plants in Australia and around the world. He has worked closely with regulatory agencies in other countries including many South East Asian countries and the US FDA. More recently he was Head of Post-Market Review for OTC Medicines. He has conducted GMP training in Australia and overseas.

Ruby Campbell– Senior Associate

BAppSc(Hons) PhD MRACI C Chem

Ruby is qualified in Chemistry and Marketing. She specialises in technical affairs and has joined AEA to assist with business development, and the marketing of AEA's services.

Ruby has 25 years experience in the pharmaceutical industry in Australia and overseas. Most recently she was Director of Quality & Regulatory Affairs for a leading global contract manufacturer. She was also Regulatory & Technical Manager (OTC) for the Australian Self-Medication Industry Inc, New Product Development Project Manager for a leading UK based healthcare company and Business Development Manager for a US based pharmaceutical contract manufacturer.

Our team

Our strength is our people. We work closely together to ensure the best results for our clients. Every report is reviewed and signed off by at least 2 team members.

Why choose AEA?

Archer Emery & Associates is one of Australia's leading pharmaceutical consulting companies. Since September 2006 we have helped clients across Australia, NZ, the USA, Europe and Asia. We measure our clients' satisfaction by the achievement of their outcomes and have had an outstanding success rate to date.

Contact us

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