



# Archer Emery & Associates

## Advanced Training Client focussed workshop

[www.archeremery.com.au](http://www.archeremery.com.au)

### *Workshop Objective*

Up to 25% of applications to register OTC medicines are withdrawn or rejected. Many more applications are delayed because they don't meet the TGA's requirements. This represents a wasted resource for many sponsors.

The objective of this course is to improve the client's overall success rate and minimise the time from lodgement to approval.

### *Duration and venue*

- 2 sessions of 3 hours, preferably on the same day
- **Venue** - To be provided by the client (preferably at the client's workplace)

### *Intended for*

- Companies with extensive experience in submitting OTC medicine applications.
- Senior staff involved in planning, preparation and management of OTC registration applications (e.g. regulatory affairs, marketing). Individuals or small groups.

### *Key features*

- For individuals or small groups
- Tailored to meet your needs within the broad outline described below
- Led by consultants with extensive TGA regulatory/evaluation experience in OTC medicines
- Conducted in-house for your convenience
- **Sessions are highly interactive** - the key information is presented in a form that is easily understood and assimilated.
- Participants are encouraged to discuss examples from their own experience.
- Copies of all presentation material will be provided after the course.
- **All participants will be given a personal certificate**

### *Information to be provided to the consultant*

Copies of a completed company application including the covering letter, TGA evaluation report, MEC minutes and the approval / rejection letter at least 2 weeks prior to the session). All information will be held in the strictest confidence.

## *Description*

The consultant leads the group in analysing a finished application to:

- identify factors behind its success or failure; and
- formulate strategies for improving the success rate and decreasing time to approval.

Topics for discussion could include:

- Preparation of the application and data;
- Pre-submission contact with TGA;
- Presentation of data;
- Anticipating problems and addressing them upfront;
- Surviving TGA screening;
- What the TGA expects from the company contact person;
- The role of the TGA evaluator and supervisors;
- Strategies for dealing successfully with TGA personnel at different levels;
- The importance of peer review;
- Maximising the value of your response to the evaluation report;
- The MEC minutes – responding effectively to questions and issues;

- Responding to a proposal to reject;
- Appearing before the MEC;
- Dealing with the Delegate of the Secretary;
- Dealing with the Delegate of the Minister;
- Appeal to the AAT – when is it worthwhile?
- Learning from past mistakes.

## *Preparation required*

- Each participant will need to review a completed company application including the covering letter, TGA evaluation report, MEC minutes and the approval / rejection letter.
- Estimated preparation time: 4 hours

## *Follow up*

A report of the outcomes of the discussion can be prepared by the consultant. Further sessions may be arranged at the discretion of the client.

## *Why choose AEA?*

Archer Emery & Associates aims to give a broad understanding of the regulatory context in which pharmaceutical companies operate with emphasis on areas of relevance to the client.

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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