

Objective

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

Key features

- For individuals or small groups.
- Tailored to meet your needs.
- Led by consultants with extensive TGA regulatory/evaluation experience.
- **Each module lasts from 2 – 3 hours**
- **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.
- Preparation time for participants will be 2 – 4 hours per course.
- Required reading will be provided 2 weeks before the course.
- Copies of all presentation material will be provided after the course.
- **All participants will be given a personal certificate.**

Modules

Introduction to medicines regulation 1

- What are therapeutic goods / products?
- What is a medicine / medical device?
- Exempt, listed / class 1, registered / class II medicines and how to differentiate
- Commonwealth / State legislation
- Medicines classification – the poisons schedules

Introduction to medicines regulation 2

- Medicines / foods interface
- Medicines / cosmetics interface
- Medicines / medical devices interface
- Prescription / OTC / complementary medicine
- Advertising regulation
- Expert committees
- Appeals

Medicines classification (scheduling) 1

- Commonwealth and State roles
- The NDPSC
- The SUSDP
- State drugs and poisons legislation
- New Zealand classification
- Trans-Tasman harmonisation of scheduling

Medicines classification (scheduling) 2

- Applications to NDPSC
- Switch - factors influencing success

Labelling of medicines 1

- Australia and New Zealand – current labelling legislation
- ANZTPA Labelling Order
- Guidelines – ARGOM, ARGCM
- SUSDP
- RASML
- Assessment of labelling – non-prescription medicines

Labelling of medicines 2

- 'Presentation' of medicines
- Naming of medicines
- Brand extension and differentiation between products
- Common problems in labels
- Consumer focused labelling

Preparation of OTC submissions 1

- The application
- Labels, PI and CMI
- Manufacturing information
- Formulation
- Starting Material Specifications
- Finished Product Specifications
- Stability

Preparation of OTC submissions 2

- Establishing safety and efficacy – no data, standard references, literature-based submission, bioequivalence data or clinical trials?
- Is too much data never enough? Getting the balance right.
- Dealing with the evaluator – anticipating problems.

Appeals

- Appearance before the MEC
- Dealing with the Delegate
- Appeals to the Minister
- Appeals to the AAT
- Other legal options

Why choose AEA?

Archer Emery & Associates is one of Australia's leading pharmaceutical consulting companies. Since September 2006 we have helped many 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.

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