



## Welcome to the AEA client newsletter

What a lot has changed in the last few months! The long-awaited ANZTPA has disappeared from view and we await the new Government to see what the future will hold. In this issue we reflect on our first 12 months as consultants, on staff training and peer review, cosmetics regulation and an update on some key TGA documents.

### *The first 12 months*

Over the last 12 months we have helped many clients achieve their goals in terms of regulatory compliance, new product applications, medicines scheduling and GMP. In addition we have delivered targeted training to company staff and conducted 'pre-audit' GMP audits in India, Hong Kong, China and New Zealand.

### *Our role as consultants*

Many medicine applications are rejected or withdrawn because of problems that could have been addressed before the application was submitted. We see our role as adding value to what companies already do by helping them get things right the first time around and in helping to resolve problems when they arise.

### *On staff training*

We all know that good staff are a great asset and how difficult and costly it is to recruit, train and retain good people. We take staff training to the next level by presenting flexible modules, each of 2 to 3 hours duration, delivered by an experienced consultant to individuals or small groups in the workplace. Each module is tailored to meet the needs of individual clients. Our preference is to base the training around actual issues being dealt with by the trainee at the time. Our consultants remain available for follow-up and consultation (either in person or by phone) to help with any questions or difficulties that may arise. The aim is to develop your staff to the point where they can successfully handle product applications and regulatory problems on their own.

Click here for our training brochures: [AEA training](#); [AEA Advanced Training](#).

### *On GMP*

In our first 12 months we have conducted 'pre-audit audits' in India, Hong Kong, China and New Zealand to help manufacturers prepare for audits from the TGA and US FDA. In all cases our consultants have been able to use their extensive knowledge and experience to successfully identify and address problems before the actual audit takes place.

### *Overseas manufacturers*

The TGA document 'Guidance on the clearance of overseas manufacturers' (August 2007) has now been updated to the 15th Edition. The main change is in relation to New Zealand. The new document no longer treats New Zealand as 'equivalent to an MRA country' for the purpose of audits within New Zealand; it is now treated in the same way as PIC/S members and the US FDA. That is, sponsors now need to provide key supporting documentation in addition to GMP certification (previously GMP certification alone was sufficient).

### *Cosmetics changes*

The new *Industrial Chemicals (Notification and Assessment) Amendment (Cosmetics) Act 2007* came into effect on 17 September 2007, completing a process that began in 2005. Under the new arrangements, certain antibacterial skin products, secondary sunscreens, anti-acne products, anti-dandruff products and antiperspirants are now regulated as cosmetics rather than therapeutic goods. The rules that apply to the classification of products as cosmetic or therapeutic are very specific. Interim NICNAS permits are no longer required and the process is now based on self-assessment. Further information is available on the NICNAS website at [www.nicnas.gov.au](http://www.nicnas.gov.au). Great care is needed to ensure that all criteria are met. AEA consultants are very familiar with these rules and are available to help you get it right.

### *New web site*

We now have a new website to celebrate our first anniversary. Have a look at [www.archeremery.com.au](http://www.archeremery.com.au).

### *Contact us:*

Phone: 1300 786 477  
E-mail: [info@archeremery.com.au](mailto:info@archeremery.com.au)  
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### *AEA Newsletter No. 2, December 2007*

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### *Holiday times:*

*Our office will be closed from 24 Dec to 7 Jan.*

*For urgent issues please call 02 62813873 and leave a message*

*Our very best wishes for Christmas and the New Year from all at AEA*





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