



AEA client newsletter - GMP edition

The TGA recently announced that the turnaround time for overseas manufacturer desktop audits is now **8.5 months** (as against a target time of 30 working days to March 2008) with a rejection rate of **15 to 20%**. This means that sponsors who are dependent on a single overseas manufacturer requiring a desktop audit run a significant risk of a) not getting a new clearance before the old one expires and b) having their product cancelled if the audit results in a rejection.

Until March 2008, the target time for desktop audits was 30 working days. While the TGA intends to increase auditor numbers, it will take time and resources to recruit and train new people so the increase in turnaround time may have a way to go. **We currently recommend allowing at least 12 months for a clearance application requiring a desktop audit.**

In this newsletter, we highlight some of the factors that can lead to a rejection, give a list of the major changes in the latest TGA '*Guidance on the GMP Clearance of Overseas Manufacturers*' and **details of our new pre-clearance service to increase your chance of success.**



GMP desktop audits - problem areas

Some of the **factors that can lead to rejection** were outlined by TGA officers at an ARCS seminar held in Sydney in March. These included:

- | Failure to provide a complete set of documents as specified in the TGA Guidance;
- | The product is outside the scope of the GMP certificate provided;
- | The GMP certificate is not notarised;
- | The audit conducted by an overseas regulator was not relevant to the product or too limited in scope;
- | The audit report is heavily redacted (edited to block out information);
- | The GMP contract / agreement does not include all products or steps;
- | The release for supply step is requested in the clearance but is not the responsibility of the manufacturer under the contract;
- | Compliance with Australian marketing authorisation is not addressed;
- | The validation master plan is too brief to provide assurance that validation requirements have been met;
- | The procedure for handling deviations and out of specification (OOS) test results is not covered in the documentation;
- | The release for supply procedure is inadequately documented;
- | The release for supply procedure does not include certification that the batch complies with the marketing authorisation.

Overseas complementary medicine manufacturers

Of concern to complementary medicine sponsors, the TGA has indicated that where a country does not regulate complementary medicines to a medicine standard, an audit conducted by the regulatory agency in that country cannot be considered in lieu of a TGA audit. This applies to inspections within MRA partner countries as well as other countries where the desktop audit process applies.

The TGA has not issued details of which countries it regards as being in which category. In these circumstances **we recommend checking that the particular product is regulated as a medicine in that country and asking the TGA before submitting the application as their views on regulation may differ from yours.**

New TGA GMP guidance document

The TGA issued the 16th edition of the '*Guidance on the GMP Clearance of Overseas Medicine Manufacturers*' in March. Unfortunately they did not identify the changes, of which there are many. For the benefit of our clients and newsletter subscribers, **the major changes are flagged below.**

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- | Desktop audits are not considered for high risk products including blood and biological products;
- | Desktop audits are not considered for complementary medicines where a country does not regulate complementary medicines to a medicine standard (see above);
- | The expiry of GMP clearances will depend on the type of product manufactured and the outcome of the desktop audit;
- | Audits by the US FDA for complementary medicine manufacturers (either inside or outside the US) will not be considered for a GMP clearance;
- | Documentary evidence for non-MRA based GMP clearance can be provided within 30 working days after receipt of the application fee - this gives some relief in terms of turnaround time where documents are not immediately available;
- | The target time of 30 working days has been removed (the target time is now "as soon as possible").



New service - application review

We have introduced a pre-clearance service where our senior consultants review your GMP preclearance documentation to optimise your chances of success. This service is managed by Mr Alan Duff - a qualified organic chemist with high-level industry experience and 19 years as a senior TGA auditor.

With an 8 month plus turnaround time and a rejection rate of up to 20%, you want to make sure that your application for GMP preclearance is in the best possible shape. If the application is rejected you may be faced with an expensive TGA audit or a new application and further long delays. In the meantime, your product may be under real threat of cancellation from the ARTG. **We can optimise your chances of a successful outcome.**

Contact Paul Archer (02 6281 3873) for more details.

Web site

For further information on Archer Emery & Associates and the services we offer go to: www.archeremery.com.au.

Contact us:

Phone: 1300 786 477
E-mail: info@archeremery.com.au
Web: www.archeremery.com.au

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