Technical Alert

TGA Adoption of PIC/S Guide to GMP PE009-13

Upcoming Revision of Manufacturing Fees & Charges

TGA Adoption of PIC/S Guide to GMP PE009-13

The TGA recently published on its website further information regarding its intention to adopt as its manufacturing principles the current version of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products, PE009-13, which will be active from 1 January. CMA representatives attended the TGA-Industry Working Group on Good Manufacturing Practice (TIWGG) on Thursday 23 November where the process was further discussed.

Background

The manufacturing principles were last updated in 2010, as the 2009 PIC/S version PE009-8. Since that time the PIC/s guide has been updated a number of times. Although many updates are clarifications, some manufacturers may need to modify operational procedures to maintain compliance. It is expected that the formal legal adoption of the new Manufacturing Principles will occur in mid-December.

Resources

A summary of new and changed requirements is available on the TGA website here and by PDF.

A history of revisions between the last adopted code and the new code is here.

The full PIC/S documents are available here.

GMP Guidance Documents: TGA will honour all existing guidance documents until they are amended.

Guidance for Complementary Medicines: If there are specific issues identified with implementation of the new code, please advise both gmp@tga.gov.au and technical@cmaustralia.org.au . Issues can be raised at the Complementary Medicine Technical Working Group (CM-TWG) and where required the TGA can develop local guidance.

As audits occur under the new code, the TGA encourage feedback on the interpretation of the new code by using the "Audit feedback form – Interpretation of requirements."

Frequently Asked Questions: The TGA are expecting to publish in January.

Transition plans

During the transitional period, auditors will be aiming to assist and encourage implementation of the new requirements. They will expect that actions are progressing in a timely manner in order for full compliance to be achieved by 1 January 2019. They will not cite a deficiency when companies demonstrate they are meeting the minimum expectations in this period. They will report an "other" deficiency if the company has not undertaken an appropriate approach to implementing the new requirements. Major deficiencies will generally only be cited where a manufacturer has not commenced, or is not appropriately progressing, action to implement the new PIC/S Guide to GMP requirements. Accordingly, audits undertaken in the second half of 2018 will have higher expectations than the first half. A major deficiency may also be cited where a manufacturer's implemented procedures and systems do not meet the requirements of the PIC/S Guide to GMP.

In recognition of the complexity and impact of the change, the following timeframes are proposed by the TGA for implementation.

1 Jan 2018 to 30 Jun 2018

Manufacturer processes:

- Assess impact of new manufacturing principles on operations;
- Start updating quality systems documentation;
- Work towards implementing revised practices.

Audits:

- Auditors are not expecting all changes will have been implemented, but they will be seeking that manufacturers can demonstrate how they are transitioning. For example, discussing with staff, raising change controls. Comments will be included in reports. A deficiency may be recorded if it appears that no actions have been initiated.

1 Jul 2018 to 31 Dec 2018:

Manufacturer processes:

- Assessments of impacts are complete (or well advanced);
- Approved quality systems documentation in place;
- Revised practices and quality policy/procedures are implemented;
- Staff awareness training complete;
- Trending critical parameters commenced;
- Amending/drafting new contracts in process.

Audits:

- A major deficiency will be recorded if no attempt to become compliant has been made by this time.

1 Jan 2019: Full compliance expected.

Upcoming Revision of Manufacturing Fees & Charges

There is a significant overhaul of manufacturing fees and charges flagged by the TGA. Engagement will open in December and end around early March.

TGA GMP area is currently under-recovering significantly. Manufacturing license charge is adequately cost recovered but all others under-recovered. There will be a review of the fees for alignment with the current business model, including business improvements so that new fees and charges will be set against the more efficient business model. *E.g.* E-Signatures when issuing licences, and the new GMP Clearance system.

The new fee model will include a matrix based on risk based re-inspection frequencies. There will be lower fees for more compliant manufacturers, creating a more accurate reflection of costs of auditing individual manufacturers, as well as creating a financial incentive to be compliant.

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