Technical Alert

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

Now Active: Updated *Uniform Procedure for the Recall of Therapeutic Goods*

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

On 1 January 2018 the TGA adopted the current version of the *PIC/S Guide to Good Manufacturing Practice for Medicinal Products PE009-13*, excluding Annexes 4, 5 and 14, as the mandatory manufacturing principles for medicines and active pharmaceutical ingredients. This will supersede the PIC/S Guide to Good Manufacturing Practice for Medicinal Products PE009-8. The TGA has expectations of full compliance by **1 January 2019**, with transition arrangements during 2018.

The main changes introduced by PE009-13

To aid manufactures in achieving compliance the TGA has published a guideline: '*PE009-13, the PIC/S guide to GMP for medicinal products - TGA interpretation and expectations for demonstrating compliance*' on the TGA website here or by PDF.

A summary of new and amended GMP requirements for manufacturers is available on the TGA website here, the transition plan here and both are available together by PDF.

The TGA's expectation is that by 1 July 2018, manufacturers will have: completed their assessment of the impact of the new manufacturing principles on their operations completed; or be well advanced, towards updating quality systems documentation and implementing revised practices.

Transition - Implications of PE009-13 adoption for TGA guidance

In the interim period, TGA auditors will accept compliance with existing guidance documentation published on the TGA website. However, manufacturers are expected to understand the requirements of PE009-13 and to appraise the modifications to their own Pharmaceutical Quality Systems and to implement changes in line with the transition plan.

CMA activity

The TGA plan on working with industry to update documentation to reflect any new requirements. CMA's Manufacturing & GMP Committee has been elevated to a Board level committee and will be meeting this year to discuss any issues relating to complementary medicines in the application of the new GMP guide, including guidance documents that will require updating.

Members are encouraged to forward any identified issues to technical@cmaustralia.org.au for attention by the Committee Secretariat.

Complementary Medicines Australia
PO Box 450 Mawson ACT 2607 | Tel: +61 (0)2 6260 4022 | Website: www.cmaustralia.org.au

Uniform recall procedure for therapeutic goods (URPTG)

The NEW Uniform Recall Procedure for Therapeutic Goods (URPTG) will take effect from today, **Monday, 15 January 2018**. The previous URPTG has now been archived.

The new URPTG, templates, and FAQ about the new document can be found on the TGA website here and by PDF.

The URPTG has undergone its first update since 2004, with changes that align with regulatory best practice. It has been available since October 2017 for a 3 month familiarisation period. This guidance on the Uniform Recall Procedure for Therapeutic Goods (URPTG) provides a consistent approach for undertaking recall and non-recall actions of therapeutic goods supplied, imported into or exported from Australia.

Notable changes

- The new document clearly delineates the roles and responsibilities of the different parties who can be involved in a recall.

- Step-by-step instructions and supporting information for sponsors to follow when conducting a recall.

- New terminology and classification for some items:
    - The term 'recall for product correction' will no longer be used to categorise recall actions and has been replaced with new introduced terms are 'product defect correction' and 'product defect alert' (when discontinuation of treatment is considered riskier than continued use of the deficient product).
    - For non-recall items, the new term is 'quarantine' has replaced 'recovery'.
    - Minor amendments have been made to the terms, 'recall' and 'hazard alert'.

ENDS

Complementary Medicines Australia
PO Box 450 Mawson ACT 2607 | Tel: +61 (0)2 6260 4022 | Website: www.cmaustralia.org.au