

Technical Alert

### Call for comment - Consultation on PICS GMP Guide

Dear member,

The EU has revised Chapter 1, 2, 6 and 7 of the EU GMP Guide on "Quality Systems", "Quality Control" and "Outsourced Activities", respectively.

As the PIC/S and EU GMP Guides must remain aligned, and requirements should be equivalent, comments from industry on the revisions should only aim at clarifying those requirements which may be unclear or confusing.

The PIC/S Secretariat has prepared a revision of the same chapters of the PIC/S GMP Guide (see PS/INF 69/2014, PS/INF 70/2014 & PS/INF 71/2014). This revision is based on the EU text and shows the amendments in track changes. Where these changes are not relevant for PIC/S (e.g. reference to EU specific legislation), the PIC/S Secretariat has proposed alternate wording (highlighted in yellow).

The PIC/S Secretariat requested that non-EEA members provide comments by the end of August 2015. Given the September meeting proposed for the TGA-Industry Working Group on GMP (TIWGG), of which CMA is a member of, the TGA has managed to seek an extension for feedback by one month to the end of September 2015.

CMA therefore invites members to consider the proposed changes and identify where any revisions may be inappropriate for the complementary medicines sector, so that we may flag these with our CM technical working group in consideration of developing specific Australian guidance documentation as required.

Attachments provided for information and comments include:

- **PIC/S Sub-committee on harmonisation of GMP** – Recommendations to Comments Received from Australia and other Participating Authorities for Revised PIC/S Chapters 1, 2, 6, and 7.
- **Revised chapter 1** – Pharmaceutical quality systems, quality control, product quality review and quality risk management (track changed)
- **Revised chapter 2** – Personnel, key personnel, training, hygiene and consultants (track changed)
- **Revised chapter 6** – Quality control, good quality control laboratory practice, On-going stability programme and technical transfer of testing methods (track changed)
- **Revised chapter 7** – Outsourced activities.

[Click here](#) to download the full set of documents.

Please send your comments to [submissions@cmaustralia.org.au](mailto:submissions@cmaustralia.org.au) by **Friday 31, July 2015**.

If you have any questions or require further information please contact Emma Burchell on (ph.) 02 6260 4022 or email: [emma.burchell@cmaustralia.org.au](mailto:emma.burchell@cmaustralia.org.au)

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