



## 2018 brings change to our GMP code and the BP

2018 is nearly upon us and there are some important updates in the Australian Pharmaceutical Industry. The biggest being the TGA's adoption of the current version of the PIC/S guide to GMP. In addition, as with every year, we have a new British Pharmacopoeia. So what's changed?

### TGA to adopt the new PIC/S guide to GMP

The TGA intends to adopt the current version of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products (PE009-13) as the Manufacturing Principles for medicines, active pharmaceutical ingredients and sunscreens. The initial adoption is scheduled to commence on 31 December 2017.

#### What does this mean for an Australian GMP manufacturer?

1. GMP inspectors will use the new guide to GMP during inspections
2. Compliance with the new requirements will be expected from this adoption date
3. GMP inspectors, will however take a pragmatic approach to discussing and reporting deficiencies
4. A 12 month graduated adoption plan has been developed to highlight the increasing expectations for compliance through this period

[Click here to visit the TGA website for more information.](#)

### British Pharmacopoeia 2018 – what's changed?

The new version of the British Pharmacopoeia is effective on 1st January 2018.

This edition incorporates all the monographs of the 9th Edition of the European Pharmacopoeia, as amended by Supplements 9.1 and 9.2.

A snapshot of the changes are listed below:

1. 35 new monographs of national origin.
2. 39 new monographs from the European Pharmacopoeia.
3. 102 technical and a further 83 editorial revisions to monographs.
4. There are a number of herbal additions including Horse-chestnut Fruit and Liquorice Liquid Extract

Keep up to date with the changes at [pharmacopoeia.com](http://pharmacopoeia.com)

To check the upcoming changes and its effect on your materials and products, email us at [ServiceAustralia@ALSglobal.com](mailto:ServiceAustralia@ALSglobal.com).

#### So what is different? Here is a flavour of the changes:

1. Chapters 1, 2 and 7 have been revised to align with the current version of ICH Q10
2. Chapter 2 (Personnel) has a new section on consultants, specifically stating that they have adequate education, training and experience.
3. Chapter 2 (Personnel) includes more detail on Senior Management being ultimately responsible and ensuring they are involved through management review.
4. Chapter 4 (Documentation) provides more clarity on the retention of documents
5. In Chapter 6 (Quality Control), all the sections have been revised.

### TGA: Complementary medicine reforms – commencing in 2018

There was excitement at the recent CMA conference in Sydney, with the TGA presenting on the upcoming reforms to the regulation of complementary medicines.

The implementation of this new framework will:

- > Introduce a new product assessment pathway sitting between the existing listed medicine (low risk) and registered medicine (high risk) pathways.
- > Include a list of permitted indications
- > Reward innovation with exclusivity for newly approved ingredients

In preparation for the changes the TGA are running information sessions throughout Australia. Visit [www.tga.gov.au/complementary-medicine-reforms-information-sessions](http://www.tga.gov.au/complementary-medicine-reforms-information-sessions) for more information.

