

Technical Alert

Manufacturing Call for Comment: Release for Supply

Dear member,

The CHC invites you to comment on the TGA's Office of Manufacturing Quality - Draft Release for Supply Technical Guidance document [Part 1](#) General Guidance and Responsibilities.

Submissions are welcome to the [CHC](#) by **COB Friday, 23 August** for submission to the TGA by the 6 September 2013.

This guidance will consist of two parts:

- **Part 1** will describe the general requirements and responsibilities relating to release for supply by an Authorised Person applicable to all TGA licensed and/or certified manufacturers and to Australian sponsors and;
- **Part 2** will outline specific considerations on how the general requirements in Part 1 can be met for specific areas of manufacture, for example for complementary medicines or for different supply chains.

Action

The consultation calls for suggested improvements to Part 1, as well as for suggested topics to be addressed in Part 2.

Please take advantage of the long consultation period to consider Part 1 of the technical guidance document, noting any suggestions for amendment and more importantly allowing yourself time to consider any specific situations within the Australian environment and how the intent of the general requirements might be met in a proposal for Part 2. For example, please consider your audit experiences etc.

The Manufacturing & GMP Working Group will discuss and finalise the details of the CHC's response to the consultation at an upcoming meeting proposed for **Thursday, 28 August**. A call for confirmation of attendees for the meeting will be issued closer to the date. In addition, comments can be provided to emma.burchell@chc.org.au by COB Friday 23 August 2013.

Note also that the OMQ will be presenting sessions on the draft Release for Supply Technical Guidance Document - [PDA](#) (Melbourne) will host a seminar on 25 June and [RACI's Pharmaceutical Science Group](#) (Sydney) on 11 July 2013.

For further information contact:

CHC Head of Regulatory Affairs
Emma.Burchell@chc.org.au

Emma Burchell

0451 681 663