

Dear Members of GMP/GDP Inspectors Working Group

Greetings from Singapore / Health Sciences Authority.

We are sorry for this late response with regard to comments on revised Chapter 5 of EU GMP Guide.

We would like to suggest to amend (*in blue colour and italic font*) the proposed revised 5.17 for the following purposes:

- improve clarity; and
- eliminate redundancy

“Prevention of cross-contamination in production

5.17 Normally, the production of non-medicinal products should be avoided in *production* areas ~~and with equipment destined for the production of medicinal products~~ but in exceptional circumstances could be allowed where the measures to prevent cross contamination with medicinal products described below and in Chapter 3 can be applied. The production of technical poisons, such as pesticides and herbicides, should not be allowed in premises used for the manufacture of medicinal products.”

Best regards and have a nice day, please.

Boon

Boon Meow Hoe | Dy Director / Senior GMP Auditor | Overseas Audit Unit – Audit Branch | Audit & Licensing Division | Health Products Regulation Group
((65) 68663507 | 6 (65) 64789068 | 150 Cantonment Road, Cantonment Centre, Blk A, #01-02, Singapore 089762 | Visit us at <http://www.hsa.gov.sg>

Health Sciences Authority | Singapore | To be the leading innovative authority protecting & advancing national health & safety

To wisely regulate health products < To serve the administration of justice < To secure the nation's blood supply < To safeguard public health

Please consider the environment before printing this e-mail

"**Confidentiality Caution:** This message is intended only for the use of the addressee and may contain information that is privileged and confidential. You should not use, copy or disseminate it for any purpose, or otherwise disclose its contents to any other person. Thank you."