PDA Europe
Adalbertstr. 9
16548 Glienicke/ Berlin
Germany

General Manager:
Georg Roessling, PhD
Senior Vice President

Tel: + 49 33056 2377-10
Fax: + 49 33056 2377-77
Email: info-europe@pda.org
www.pda.org

31 October 2008

David Cockburn
Inspections Sector
European Medicines Agency
7 Westferry Circus
London E14 4HB
United Kingdom
GMP@emea.europa.eu

Sabine Atzor
Pharmaceuticals Unit
Enterprise and Industry DG
European Commission, BREY 10/069
B-1049 Brussels
Belgium
entr-gmp@ec.europa.eu

Ref: EU Guidelines to GMP,
Medicinal Products for Human and Veterinary Use,
Draft Chapter 4, Documentation
(08 April 2008, comments due 31 Oct 2008)

Dear Sabine and David:

PDA is pleased to have the opportunity to provide comments on the revisions to EU GMP Chapter 4, Documentation. Our comments were prepared by a group of member experts in this field after considerable discussion. Our comments are attached in the requested EMEA format.

In general the proposed revisions are acceptable and helpful. We have proposed some changes in order to clarify and further improve the Chapter.

If I can be of further assistance, please feel free to contact me, or our Director of Regulatory Affairs, Jim Lyda at: *lyda@pda.org.*

With very best regards,

Georg Roessling, PhD
Senior Vice President
PDA Europe

Cc: Corbin, Levy, Dana, Lyda

PDA COMMENTS ON
GUIDELINES TO GMP
MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE
DRAFT EU GMP CHAPTER 4

Section #	Existing Wording	Proposed Change	Rationale
§ 4.1 (b), paragraph 4	See also GMP Annex 11, Clause 5	This reference should be to Clause 4.2, based on the companion draft of GMP Annex 11.	Correct the reference.
§ 4.7	Changes made to electronic records should be visible both on-screen and on printouts.	Delete the sentence beginning with "Changes made to ,,," and replace with "It should be possible to view changes as an attached history record or in a detail panel on screen or in the printed record".	Considering the number of changes that may be made to a record over its life, the screens/printouts with changes right next to the item changed could be almost impossible to read or interpret. Also, there is not any CDS software we are aware of that shows this kind of information on a printed form. Audit trail only shows the changed entry and what it was and is not necessarily in the same format as the record. Changes made to electronic records should be visible both on-screen and on printouts as a history file as space on a computer screen is limited.
§ 4.8	They should be retained for at least one year after the expiry date of the finished product.	Not all "records" are directly associated with product. The last sentence should be rewritten to read "Allow for an appropriate retention period based on the business activity the record supports."	In some cases the retention period may actually be longer than the period currently stipulated. Records should be made or completed at the time each action is taken and in such a way that all significant activities concerning the manufacture of medicinal products are traceable. They should be retained for at least one year after the expiry date of the finished product.
§ 4.9	For any critical documentation elements …a record of changes and deletions (even at System Administrator level),	Delete the phrase "…(even at System Administrator level)…."	This is a stipulation for the system manufacturer, not the customer. The lack of this (common in many systems today) is a risk assessment factor for the customer
§ 4.18	b) the date(s) and times of the packaging operations.	Add a sentence to read as follows: "There should be a requirement to use a unique time or time zone identifier when the item is part of the log."	Because most companies are global, there may be confusion without including specific time zone references. Date and time zone formats vary depending on the region of the world.