EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 April 2013

Submission of comments on GDP APIs

Comments from:

Name of organisation or individual
The Parenteral Drug Association (PDA)

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	Wherever possible the guideline should reference existing regulations and legislation and only provide additional clarification, where warranted. PDA is concerned that in repeating portions of the text already published in EudraLex Vol 4 Part II, Chapters 7, 10 and 17 there may be confusion and lack of consistency. PDA has prepared a comparison table between the draft guideline and the ICH Q7 document (below).	
	PDA also suggests adding a statement in the introduction clarifying that the guidance is a result of the Falsified Medicines Directive and is based on EudraLex Vol 4 Part II, Chapters 7, 10 and 17. PDA believes this addition will clarify the need for the guideline within the context of existing legislation.	

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A Grid: Draft EU GDP for APIs vs. ICH Q7¶

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2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
1		Comment: Clarify that the term distributor includes agents, brokers and traders	
7		Comment: Modify sentence to read: All personnel involved in the distribution of active substances should have the appropriate ability, training and experience to guarantee that active substances are properly received, stored, handled and delivered, and that the documentation, records and transactions are properly carried out	
8		Comment: For clarity, add a reference to EudraLex Vol 4 Part II	
9		Comment: PDA suggests the following changes: All documentation should be made available on request of competent authorities. The Electronic documentation should comply with EU-GMP Part II, Chapter 5.4 ~~of Part II of Eudralex, the Rules Governing Medicinal Products in the European Union, Volume 4 (*EU Guidelines to Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use* – hereafter 'EU-GMP'),~~ and ~~or~~ the ~~its~~ Annex 11 (~~*Guidelines on Computerised Systems*~~), as applicable	
11		Comment: For clarity, add a reference to EudraLex Vol 4 Part II.	
14		Comment: For clarity, add a reference to EudraLex Vol 4 Part II	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
18 - 22		Comment: For clarity, we suggest adding a reference to each paragraph to EudraLex Vol 4 Part II	
23		*Shortages that requires registered importers to notify relevant customers of any interruption to supply that the importer or distributor becomes aware of.* The meaning of the sentence is not clear as written therefore PDA recommends clarification. If the intent is for an importer to have to notify customers of impending shortages, PDA believes a reference to relevant legislation or guidance is needed.	
25 - 47		Comment: We suggest adding a reference to each paragraph to EudraLex Vol 4 Part II to avoid misinterpretation	
35 a)		Comment: Replace "in good condition" with "meets all specifications and quality attributes"	
44		Comment: We suggest deleting this paragraph or revising to require the API distributor to notify their customers. The API distributor does not know, nor are they required to know, where or when the API is used in Drug Product manufacture. Only the Marketing Authorisation Holder for the Drug Product can comply with this requirement.	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
45/2		Comment: There is an apparent error in the numbering: 45 appears twice. Under the headline 'self-inspection' this should be Number 47	

Please add more rows if needed.