EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 July 2013

Submission of comments on EU-GMP Chapter 8

Comments from:

Name of organisation or individual
PDA (Parenteral Drug Association)

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)*
Name	Comment	Decision to Submit / withdraw comment
	PDA welcomes the opportunity to comment on the proposed changes. The changes reflect current technologies for the control of complaints, quality defects and product recalls and as such they are welcomed.	
	In order to prevent any confusion as regards the nature of a 'complaint' (e.g. relating to quality and/or safety) PDA recommends including a definition. Example: Complaint: Information received by any company employee via electronic, written or verbal means, that indicates potential deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a medicinal product after it has been released for distribution by "the company".	

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)*
Exact Line # (s)	Name (First & Last)	Comment: Proposed change (if any):	Decision to Submit / withdraw comment:
8.7		Comment: For the purpose of clarification, PDA recommends a revised wording. Proposed change (if any): There should be procedures in place to facilitate ~~a request to investigate~~ **the investigation of** the quality ~~of a batch~~ of a medicinal product ~~to support an investigation into a~~ **in the context of an investigation into a** reported suspected adverse event.	
8.8.ii		Comment: The wording of 'extent' of a quality defect needs to be specified. Proposed change (if any): ii. The determination of the **batches affected by** ~~extent of~~ the quality defect.	

8.14		Comment: For the purpose of clarification, PDA recommends to consider the agreements with CMOs. Proposed change (if any): Quality defects should be reported in a timely manner by the manufacturer **in accordance with the quality agreements with any Contract Manufacturing Organization** to the Marketing Authorisation Holder/Sponsor, and all concerned Competent Authorities in cases where the quality defect may result in the recall of the product or in an abnormal restriction in the supply of the product.	
8.16		Comment: 'Special attention' should be given – but what are the measures expected from a defect relating to falsification? Clarification is needed, e.g. by reference to Dir 2001/83/EC Proposed change (if any): Special attention should be given to establishing whether a quality defect relates to falsification **as referenced in Directive 2001/83/EC.**	
8.28		Comment: For the purpose of clarification, PDA recommends to consider a reference to the EU GDP or the WHO 'Guide to good storage practices for pharmaceuticals'. Proposed change (if any): Recalled products should be identified and stored separately in a secure area while awaiting a decision on their fate. **(see appropriate guidance, e.g. GDP or WHO Guide to Good Storage Practices for Pharmaceuticals).**	