18 July 2013

Draft Chapter 8 EU GMP Guide: Complaints, Quality Defects and Product Recalls

Comments from:

Name of organisation or individual
AESGP

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).

1. General comments

Stakeholder number ***(To be completed by the Agency)***	General comment (if any)	Outcome (if applicable) ***(To be completed by the Agency)***

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)***
Principle, 2nd paragraph		Comment: Faulty manufacture is a very general term and should be explained, if used. Critical GMP failures are not referenced, but may be (as well as non-compliance with the marketing authorization) a relevant source for serious quality defects. Proposed change (if any): Delete faulty manufacture or further explain, add critical GMP failures	
Item 8.30		Comment: ”out-of-office hours....”: Availability in out-of-office hours must be clearly defined by the companies and should be checked via Mock recall. However, a blind attempt to reach everybody during out-of-the office hours is not considered productive. Proposed change (if any): Add “Out-of –the office hours are included to check whether the established emergency system works or needs to be improved”.	

Please add more rows if needed.