18 July 2013

# GMP revision: Chapter 6 – Quality Control

## 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<br>*(To be completed by the Agency)* | General comment (if any) | Outcome (if applicable)<br>*(To be completed by the Agency)* |
|---|---|---|
| | | |

## 2. Specific comments on text

| Line number(s) of the relevant text<br>*(e.g. Lines 20-23)* | Stakeholder number<br>*(To be completed by the Agency)* | Comment and rationale; proposed changes<br>*(If changes to the wording are suggested, they should be highlighted using 'track changes')* | Outcome<br>*(To be completed by the Agency)* |
|---|---|---|---|
| Chapter 6<br>6.7, 3rd bullet point | | Comment:<br>Whereas the terms OOS and OOT are defined /well known this does not apply for the term "anomalous"; that gives rise to a lot of confusion.<br>Thus we apply to cancel the words "and anomalous results"<br><br>Proposed change:<br>- a procedure for the investigation of Out Of Specification ~~and anomalous results~~ and Out Of Trend results; | |