EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<July 17, 2013>

Submission of comments on EU-GMP Chapter 6

Comments from:

Name of organisation or individual
PDA (The 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 and controls. The addition of a new section 'Technical transfer of testing methods' (6.37 – 6.41) is highly appreciated.	

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
6.7		Comment: For the purpose of clarification and with regard to the lack of a clear definition on what an 'out-of-trend' exactly is, PDA recommends substituting 'out-of-trend' by 'evaluation of trends'. Proposed change (if any): A procedure for the investigation of Out Of Specification and anomalous results and ~~Out Of Trend results.~~ **the evaluation of trends.**	
6.9		Comment: For the purpose of clarification and with regard to the lack of a clear definition on what an 'out-of-trend' exactly is, PDA recommends deleting the wording 'out-of-trend'. Proposed change (if any): Any ~~out of~~ **atypical** trend or out of specification data should be addressed and subject to investigation.	

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)*
6.15		Comment: For the purpose of clarification, PDA recommends to include a reference to ICH Q4B (EVALUATION AND RECOMMENDATION OF PHARMACOPOEIAL TEXTS FOR USE IN THE ICH REGIONS) Proposed change (if any): add at the end of the sentence: **If reference is made to Ph.Eur. alternative harmonised methods appearing in ICH Q4 and described in USP or JP may be used.**	
6.21		Comment: PDA recommends using a risk based approach and limiting the requirement to those cases, where the verification of the performance of culture media prior to their use is necessary. Proposed change (if any): suggest to add The performance of culture media should be verified prior to use**, if appropriate.**	
6.35		Comment: The wording 'negative' trend is open to misinterpretation since a negative trend does not necessarily result in a negative impact on product quality. PDA therefore suggests deleting the wording 'negative'. Proposed change (if any): **Suspected** out of specification or significant atypical trends should be investigated. Any confirmed out of specification result, or significant ~~negative~~ **atypical** trend, should be reported to the relevant competent authorities.	

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)*
6.37		Comment: PDA agrees that it is appropriate to check the relevance of the original validation. However the level of effort and formality should be left to the company. Proposed change (if any): The original validation of the test method(s) should be reviewed to ensure compliance with current ICH/VICH requirements. **If applicable,** a gap analysis should be performed and documented to...	
6.38		Comment: For the purpose of the use of harmonised wording in the context of a technology transfer, PDA recommends the adoption of wording as specified in the WHO Guidelines on Transfer of Technology in Pharmaceutical Industry; (WHO guideline http://www.who.int/entity/medicines/areas/quality_safety/quality_assurance/TransferTechnologyPharmaceuticalManufacturingTRS961Annex7.pdf). Proposed change (if any): The transfer of test methodology from one laboratory (transferring laboratory) to another laboratory (receiving ~~l~~aboratory) should be described in an ~~written~~ **analytical method transfer** protocol. **The results of the transfer need to be summarized in an analytical method transfer report.**	

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)*
6.39		Comment: See detailed comment to 6.38 as regards harmonised wording. The **analytical method transfer** protocol should include, but not be limited to, the following parameters: (…)	

Please add more rows if needed.