EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2014-05-30

Submission of comments on the draft of revision of EU-GMP Guidelines - Annex 15: Qualification and Validation

Comments from:

Name of organisation or individual
SciencePharma (Poland)

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)*

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)*
Section 4.20		Comment: Minor editorial comment: bullets e) and f) should be combined into one.	
Section 5.2		Comment: It is suggested using the term "verification of transportation" instead of "validation of transportation"; the former is broader and described in other guidelines. It is not clear what kind of information should be defined with regard to transportation routes. It is noted that exact transportation routes often may not be clearly defined (they may be subject to non-essential changes between transportations without any impact to product quality). Taking into account the critical parameters related to transportation it is suggested to change the term "transportation routes" to "transportation modes" which could be clearly defined (e.g. by sea, by air, by road transport).	

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)*
Section 9.11		Comment: It is generally accepted that the number of cleaning procedures to be carried out in the course of cleaning validation should be defined case-by-case based on a risk assessment, however it would be helpful to mention that 3 runs are generally considered acceptable. The same approach is applied in the draft for process validation runs (sections 4.17-4.18). Proposed change: *~~Typically~~ the cleaning procedure should be performed an appropriate number of times based on a risk assessment and meet the acceptance criteria in order to prove that the cleaning method is validated. Without prejudice to the previous sentence, it is generally considered acceptable that a minimum of three consecutive and successful applications of the cleaning procedure would constitute a validation.*	
Section 9.12		Comment: According to section 9.12 for investigational medicinal products or products which are only manufactured infrequently a cleaning verification approach may be acceptable, rather than full cleaning validation. However, in respect to this former approach a reference is made to "principles in this section of the Annex". As the section refers to cleaning validation activities it is not clear which principles should be taken into account regarding cleaning verification. More data on minimum requirements for cleaning verification would be helpful.	