EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 May 2014

Submission of comments on 'Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use Annex 15: Qualification and Validation'

Comments from:

Name of organisation or individual
Norgine Limited

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)*
1.5 g)		Comment: Point g? requires further definition. What does the word 'handling' define? Proposed change (if any): n/a	
1.5 k)		Comment: Need to understand what internal processes are utilised for supplier/vendor management. Validation have a Supplier Assessment For example - Contractor approval Clarification required regarding Materials management: Typically materials will be verified through Qualification protocols. These activities are usually covered outside of the validation plan (VP). It is probably pertinent to identify these activities are required but not necessarily confirmed within the VP. Proposed change (if any): Remove proposal to include material management in the validation plan.	
2.5		Comment: Define the word company. Is this meant to be the third party or the purchasing company. If the latter, this will prove to be difficult to achieve and could lead to project delays and vast cost increases. Proposed change (if any): n/a	

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)*
2.6		Comment: n/a Proposed change (if any): This all encompassing statement should only apply to 'critical' changes (i.e. change to acceptance criteria / operating conditions etc.)	
4.1		Comment: What is meant by the word 'critical' .e.g. Does this refer to product contact materials? Proposed change (if any): n/a	
4.20 f)		Comment: Typo error: f) is part of e) Proposed change (if any): n/a	

Please add more rows if needed.