EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 October 2013

Submission of comments on 'EudraLex - The Rules Governing Medicinal Products in the European Union - Volume 4 - EU Guidelines for Good Manufacturing Practice – Annex 16: Certification by a Qualified Person and Batch Release'

Comments from:

Name of organisation or individual
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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)*
	The EGA welcomes the opportunity to comment on the EMA proposed revised Annex 16. EGA members are generally satisfied with the proposed revision and welcome the proposed changes.	
	We could not find a reference to the requirement for QPs to confirm (according to the amending directive 2011/62/EU) that imported APIs from third countries have the appropriate certification (i.e. written confirmation or EU listing or waiver 2) prior to the API being used in manufacture. These requirements entered into force on 2 July 2013 and should therefore be reflected or referenced in the text of the present annex.	

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 2.2 (page 2)		Comment: It is very difficult for any QP to know the laws in all countries where a pharmaceutical company may export products, unless of course it is within the EU. This is especially important for QPs who release products for many non-EU countries. It is the MAH who should be responsible to at least notify the QP in these cases. Proposed change (if any): "…it is in compliance with the laws in force in the Member State where certification takes place ~~**and of the destination country of the medicinal product**~~, lies with the QP certifying that batch as being suitable for release."	
		Comment: The use of the term equivalent in this section introduces a concept not yet defined explicitly and therefore potentially triggering variable interpretation. "The batch has been manufactured and checked in accordance with the principles and guidelines of EU Good Manufacturing Practice, or ***equivalent***;" Proposed change (if any): We suggest that the term be properly defined in the glossary.	
2.4.3		Comment: See our comment on section 2.2 (page 2) Proposed change (if any):	

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)*
		"Any other relevant legal requirements~~**, e.g. of the destination country,**~~ are taken into account;"	

Please add more rows if needed.