EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

01 November 2013

Submission of comments on 'Draft Annex 16: Certification by a Qualified Person and batch release'

Comments from:

Name of organisation or individual
Pharmaceutical Quality Group (PQG) of the Chartered Quality Institute (CQI)

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)*
	The PQG generally welcomes the revised text of this Annex as an outcome consistent with the Concept Paper. A number of specific comments have been made for your consideration.	

2. Specific comments on text

Line number(s)/section 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)*
2.1/2.2		**Comment** Whilst the MAH is ultimately responsible for the safety, quality and efficacy of an authorised medicinal product, the QP's involvement should not be limited to their responsibilities for a particular batch. QPs should be involved at appropriate stages in the product life cycle in order to ensure that quality is built into the product and that there is an appropriate transfer of product knowledge. This is beyond basic access to the relevant parts of the MA and supports 3.1. **Propose add:** "The MAH should ensure involvement of Qualified Persons at appropriate stages in the product life cycle and ensure that they have access to the relevant details in the MA to enable them to fully discharge their professional duties."	
2.2		**Comment** There should be reference here to the QP operating within a Pharmaceutical Quality System in which other key personnel have operational responsibilities too (ref. EU GMP Chapter 2). **Propose:** "The responsibility within the Pharmaceutical Quality System, within which other key personnel have	

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		responsibilities as defined in Chapter 2, for ensuring that a particular batch...”	
3.2		**Comment** It would be useful to include within a Q&A document some guidance on how the QP is expected to meet the requirement to demonstrate knowledge and to what extent they should have knowledge of stages of manufacture which are contractually the direct responsibility of other Qualified Persons. E.g., where the QP performing the certification of the finished product is at the end of a supply chain where product manufacture has taken place at another site and another QP has provided confirmation that their operations have been undertaken in accordance with GMP and the MA (or CTA).	
3.3		**Comment** It would be useful to include within a Q&A document some clarification regarding where the legal responsibility for the certification of a batch lies in the event that responsibilities are ‘shared’.	
3.4.5		**Comment** This is not fully clear that where an approved Real Time Release Testing programme is in place it may not be	

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		necessary to conduct testing on import to the EU if this is defined in the relevant MA. **Propose:** This testing on import is not required if an approved Real Time Release Testing programme to ensure the quality of medicinal products is in place and the exemption from testing on import is defined in the Marketing Authorisation.	
3.4.8		**Comment** "The bulk product has been stored in similar conditions before completed packaging". "Similar" is vague. It is suggested that this approach is valid provided the bulk has been stored within **defined** conditions before completed packaging.	
3.5.3 and 3.8.1		**Comment** Typically electronic systems are used rather than paper documents to record certifications. **Propose:** 'register or equivalent document' should be 'register or equivalent document/electronic system'.	
3.5.5		**Comment** This is a significant new requirement. Supply chain management is vital and the QP should have well-founded confidence in the Pharmaceutical Quality System elements	

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		supporting this. However, it is excessive to have the entire supply chain from starting materials and components 'documented and available for the QP' and to specify a preferred format for this documentation. **Proposal:** Remove the sentence beginning "The document should preferably..." Change: The requirement from 'is documented and available for the QP' to 'is traceable through the Pharmaceutical Quality System and readily available to the QP on request'.	
4.1		**Comment** It might be useful to add examples of activities in addition to audits for which a QP may rely on contracted parties. For example, the review and approve validation protocols or the management of complaints.	
4.2		**Comment** In addition to the points mentioned, the QP should have: • visibility of the audit schedule • access to CAPA closure reports • access to qualifications of auditors • confirmation that the audit has been conducted to appropriate standards	

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Section 5		**Comment** We agree that QPs should have the ability to assess deviations in line with this section and, subject to a satisfactory outcome to the risk assessment, then perform certification of a batch that meets registered specifications. However, we are concerned that not all Member State competent authorities interpret this section in the same way.	

Please add more rows if needed.