<Date of submission>

Submission of comments on '<Part I Chapter 6 Quality Control>' (EMA/…/…)

Comments from:

Name of organisation or individual
LEEM

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)*
6.7 (bullet point n°3)		**Comment**: typing error **Proposed change (if any)**: " a procedure for the investigation of Out of Specification ~~and~~, anomalous results and Out of Trend results;	
6.12		**Comment**: Guideline should include a more precise definition of an appropriate justification for a sampling plan **Proposed change (if any)**: Samples should be representative of the batch of materials or products from which they are taken. Other samples may also be taken to monitor the most stressed part of a process (e.g. beginning or end of a process). The sampling plan used should be appropriately justified and based on a risk analysis.	
6.17		**Comment:** Equipment used and the status of those equipments should be part of the recorded data for tests performed **Proposed change** (if any): The tests performed should be recorded and the records should include at least the following data: a) name of the material or product and, where	

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		applicable, dosage form; b) batch number and, where appropriate, the manufacturer and/or supplier; c) references to the relevant specifications and testing procedures; d) test results, including observations and calculations, and reference to any certificates of analysis; e) dates of testing; f) initials of the persons who performed the testing; g) initials of the persons who verified the testing and the calculations, where appropriate; h) a clear statement of approval or rejection (or other status decision) and the dated signature of the designated responsible person. i) references to the equipments and equipment status	
6.21		**Comment:** Analytical procedure can have an impact on the culture media and it can be necessary to check its impact **Proposed change (if any):** Culture media should be prepared in accordance with the manufacturer's	

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		requirements unless scientifically justified. The performance of all culture media should be verified prior to use. The possible impact of the analytical procedure on the culture media should be evaluated.	
6.22		**Comment:** If a in-use shelf life should be established for all Laboratory reagents, solutions, reference standards and culture media, the expiry date should be marked on all of them and not only the unstable one. **Proposed change (if any):** Laboratory reagents, solutions, reference standards and culture media should be marked with the preparation and/or opening date, the expiry date and the signature of the person who prepared them. Their in-use shelf life should be established / documented and scientifically justified. ~~The expiry date of unstable reagents and culture media should be indicated on the label, together with specific storage conditions~~. The specific storage conditions of unstable reagent and culture media should be indicated on the label. In addition, for volumetric solutions, the last date of standardisation and the last current factor should be indicated.	
6.25		**Comment:** Decontamination is a critical point and should be performed according to a standard procedure.	

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		Proposed change (if any): Microbiological media and strains should be decontaminated according to a standard procedure and disposed in a manner to prevent cross-contamination and retention of residues	
6.25 (line 2 & 3)		**Comment:** microbiolocal media can be handled as the other product in 6.22 **Proposed change (if any):** 6.25 Microbiological media and strains should be decontaminated and disposed of in a manner to prevent the cross-contamination and retention of residues. ~~The in-use shelf-life of microbiological media should be established, and documented and scientifically justified.~~ 6.22 Laboratory reagents, solutions, reference standards and culture/microbiological media should be marked with the preparation and opening date and the signature of the person who prepared them.	
6.37		**Comment:** potential issue for review also by the global SME on method transfers	
6.37 (line 1)		**Comment:** in some cases transferring site may not hold comprehensive data/information on the original method (mainly when transferring site is contract acceptor) and therefore the receiving site should also verify compliance of the method.	

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		Proposed change (if any): Prior to transferring a test method the transferring site and/or receiving site as suitable should verify that the test method(s) comply with those as described in the Marketing Authorisation or the relevant technical dossier.	
6.37 (line 4-6)		**Comment:** Guideline should allow for legacy product assay method development and technical transfer that may need revalidation. **Proposed change (if any):** A gap analysis should be performed and documented to identify any supplementary validation that should be performed, prior to or during ~~commencing~~ the technical transfer process.	
6.38 (line 1)		**Comment:** for alignment purpose with the technical transfer section title proposal to replace "test methodology" by" testing methods" **Proposed change (if any): "**The transfer of ~~test methodology~~ testing methods from one laboratory (transferring laboratory to another laboratory (receiving laboratory) ...."	
New Step 6.38		**Comment:** Guideline should include a statement describing the approaches that can be taken for the transfer of a test method (from USP <1224> Transfer of Analytical Procedures) **Rationale**: To define types of analytical transfer	

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		approaches this was missing. **Proposed change (if any):** 6.38 Transfer of the test method can be accomplished by several approaches: comparative testing by the sending and receiving laboratory, co-validation with the receiving laboratory, complete or partial validation of the test method by the receiving laboratory, and transfer waiver, which is an appropriately justified omission of the transfer process. The tests that will be transferred, the extent of the transfer activities, and the implementation strategy should be based on a risk analysis that considers the previous experience and knowledge of the receiving laboratory, the complexity and specifications of the product, and the test method.	
6.39 (bullet point n°2)		**Comment:** type error **Proposed change (if any): "**~~I~~identification of additional training requirements"	
6.39 (bullet point n°5)		**Comment:** testing to be performed are linked to method, it is proposed to merge bullet point 5 and 1. **Proposed change (if any): "**identification of the testing to be performed and the relevant test method(s) undergoing transfer ~~identification of the testing to be performed~~	
6.39 (bullet point n°6)		**Comment:** type error **Proposed change (if any): "**~~I~~identification of additional	

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		training requirements”	

Please add more rows if needed.