EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27th January 2012

Submission of comments on '<Concept paper on Revising Annex 16 of the Guide to Good Manufacturing Practice: Certification by a Qualified Person and Batch Release >' (EMA/INS/GMP/844118/2011)

Comments from:

Name of organisation or individual
European Industrial Pharmacists Group (EIPG)

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)*
	EIPG fully agrees that Annex 16 should be revised, for the reasons given in the Introduction to this Concept Paper. EIPG has already expressed the need for such revision in our comments to the EMA on various documents currently under discussion. In particular, EIPG emphasized the importance of revising Annex 16 when taking a position on the reflection paper on minor deviations. It is essential to revise Annex 16 to allow for the discretionary power of a QP in managing minor deviations. In order to contribute to the preparation of a revised Annex 16, EIPG has prepared some comments on the six fundamental questions that are presented in Chapter 2, Problem Statement.	

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)*
Problem Statement - Question 1		**Question 1**: What is the minimum a QP must personally carry out when certifying a batch ? **Comment**: - Physical presence of the complete batch documentation - Access to the following documents: Registration file Quality/Technical Agreement Validation status Audit reports - Check conformance to quality specs (CoA) - Check that all deviations have been investigated and justified - Signature and date of a summary review checklist, prepared according to an approved procedure	
Problem Statement - Question 2		**Question 2:** What are the prerequisites for relying on statements from persons other than fellow QPs ? **Comment:** - Detailed job description (responsibilities and position in the organization chart)	

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		- Qualification and experience ascertained level - Direct and transparent communication	
Problem Statement - Quesyion 3		**Question 3:** How is the Control Strategy and the batch certification release process linked ? **Comment:** - The control strategy should be defined in the quality system description and reported in the SMF and so should the batch control and release process - As per ICH Q10, the quality system should be documented and defined in terms of its critical components (i.e. the control strategy and the batch control and release process) - Greater emphasis should be placed on the fact that more discretion can be given to the QP only insofar as the control strategy is based around the QP and the quality system is written in such a way as to make this clear to all concerned	
Problem Statement - Question 4		**Question 4:** What are the expectations for QPs reviewing batch records manufactured by third parties in third countries ? **Comment:** - Access to the following documents:	

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		GMP compliance certification of the site, issued by the local Competent Authority or by an EU inspector Import Authorisation in force Quality/Technical Agreement in place Updated APR received Master Batch Record Updated physical audit report by QA - Check of the following documents: Complete batch record (bilingual or in English) Summary of significant deviations with investigation and justification results Inspection of QC samples received Temperature and RH records during transportation Repeated release testing, when an MRA is not present - Presence of a personal practical and actual familiarity with the manufacturing site and the people involved	
Problem Statement - Question 5		**Question 5:** What knowledge should a QP have about the site(s) involved in the manufacturing of a batch ?	

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		Comment: - SMF - Manufacturing Authorization - GMP certificates - Site history - Production Processes - APR/PQR - Quality/Technical Agreement in place - Internal audit reports - Outcome of inspections by Competent Authorities - Supply chain risk assessment - Visit and Audit by him/herself - Direct acquaintance with the people involved	
Problem Statement – Question 6		**Question 6:** What actions are expected from the QP when a batch cannot be certified and therefore released? **Comment:** - Formal and documented decision, notified to the appropriate persons in the company to activate the re-work/re-processing/disposal procedure, as appropriate - Annotate batch records appropriately and ensure that the batch involved is clearly quarantined - Root cause investigation to be performed and a CAPA plan to be implemented	

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		- To assess the possible impact on the batches previously certified to determine the need for a recall procedure - To retain logs and samples from the batch and ensure that it appears in the APR/PQR	

Please add more rows if needed.