EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28th April 2011

Submission of comments on ' Template for the Qualified Person's declaration concerning GMP compliance of the active substance used as starting material and verification of its supply chain "The QP declaration template" ' (EMA/CHMP/CVMP/QWP/696270/2010)

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)*
	The implementation of this QP Declaration Template will provide a harmonized format for a comprehensive declaration and is expected to facilitate the communications with the Competent Authorities. Indeed, the Declaration Template is strictly based on the duties and responsibilities of the QP, in agreement with the Directive 2001/83/EC, and helps clarify the position to be taken by the QP in facing different situations, with reference to API auditing, GMP compliance and supply chain verification. Indeed, this document could be considered an integration to the Annex 16 of EU-GMP, as it discusses extensively and in a more structured format most of the issues which were reported in the 2001 document on QP duties and responsibilities. However, the QP declaration already forms part of the Marketing Authorisation application and it is not believed the proposed template is the appropriate mechanism to demonstrate GMP compliance. Much of the information requested (eg manufacturer name, address and outline description of activities at each site) is already included in the application - thus the template represents duplication of information provision which is against the stated aims of the EU of Better Regulation	

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	On the other hand, some of the requirements of the proposal go beyond what is required in applications e.g. the building number and function to be provided for each of the manufacturing operations in the API supply chain including the starting materials, intermediates and the final API. Such information being requested in the template, such as the audit history of suppliers, risk assessments of the supplier sites and confirmation of the supply chain pedigree are more appropriate to a GMP inspection program rather than inclusion in a regulatory dossier submission.	

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)*
Lines 70-71		Comment: The term “critical raw material”, albeit in use in Part II of the GMP, gives rise to the issue of risk assessments to establish whether a raw material is critical or not. Proposed change (if any): The term “critical raw material” would be better replaced with “active ingredient starting material”.	
Line 192		Comment: Although one can easily find in the document “Compilation of Community Procedures on Inspections and Exchange of Information” (EMA/INS/GMP/459921/2010 Rev 12 Corr) a reference to a re-inspection frequency of 2 to 3 years, it would be better to mention that re-inspection should also be based on a risk assessment, as per emerging practices in the field. Proposed change (if any):	
Lines 74 and 233		Comment: It would be better to state more specifically that the traceability is to be extended backwards to the suppliers of the critical raw materials (active ingredients starting materials), in agreement with the requirements described in Par 6.30 of Part II of the GMP. Moreover, with regards to the supply chain verification and documentation, it is not clear whether an inspection is also to be extended to brokers,	

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		traders, repackers, relabellers, and importers. Finally, how is the supply chain traceability is expected to be documented. Would a presence of Technical Agreements (in compliance with GMP) with all sites (or actors) of the supply chain be sufficient ? Would a declaration of the QP on this basis be acceptable, as a documentation to be produced ? Proposed change (if any):	

Please add more rows if needed.