EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 April 2013

Submission of comments on Risk Assessment for GMP for Excipients

Comments from:

Name of organisation or individual
PDA (The Parenteral Drug Association)

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)*
	PDA welcomes the draft guidance and the implementation of Quality Risk Management. PDA suggests that EMA consider allowing the use of any appropriate QRM tools as is recommended in ICH Q9, rather than recommending specific tools, apparently at the expense of any others.	

2. Specific comments on text

Line number(s) of the relevan t 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 Paragraph 7:		Comment: Mandating a classification of low, medium and high does not seem to be based on a scientific rationale, nor is it mandated by the regulations. The tools provided as examples do not necessarily reflect current industry practice, nor are they the only or necessarily the most appropriate tools. Proposed change: These Quality Risk Management principles should be used to assess the risks presented to the quality, safety and function of each excipient and to classify the level of risk associated with the excipient in question. ~~and to classify the excipient in question as "low risk", "medium risk" or "high risk"~~. Quality risk management tools such as those listed in ICH Q9 ~~(for example, hazard analysis and critical control points – HACCP, etc.)~~ could be used for this purpose.	
Section 2 Paragraph 8		To clarify the list of potential risks or harm, PDA recommends that bullet number 6, "Use of dedicated equipment and/or facilities" be rephrased to read " Potential for any impurities carried over from other processes, in absence of dedicated equipment and/or facilities."	
Section 2 Paragraph 10		Comment: PDA suggests deleting this paragraph as it requires the MAH to establish a rationale whether a regulation is applicable or not. PDA believes this to be the task of the regulators, not the MAH's	

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Section 3 Paragraph 15		Comment: See earlier comment (section 2) pertaining to use of low, medium, high classification. Proposed change: Furthermore, the Manufacturing Authorisation Holder should perform a further risk assessment to determine the level of risk associated with (~~i.e. low risk, medium risk or high risk,~~ that excipient manufacturer).	
Section 4 Paragraph 17		Comment: for enhanced clarity change to read: Once the "appropriate ~~GMP~~ levels of control" for the excipient	

Please add more rows if needed.