PDA Global Headquarters
Bethesda Towers
4350 East West Highway
Suite 150
Bethesda, MD 20814 USA
Tel: +1 (301) 656-5900
Fax: +1 (301) 986-0296
www.pda.org

30 April 2013

European Commission
Health and Consumers Directorate –General, Brussels
sanco-pharmaceuticals-d6@ec.europa.eu

Ref: Guidelines on the Formalised Risk Assessment for Ascertaining the Appropriate GMP for Excipients of Medicinal Products for Human Use

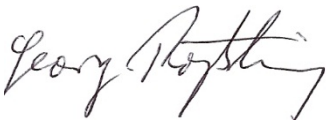
To the Health and Consumers Directorate-General:

PDA is pleased to provide comments on the draft guideline using the template provided for public consultation. PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. Our review was completed by an international group of expert volunteers with experience in investigational medicinal products, regulatory affairs and GMP on behalf of our Regulatory Affairs and Quality Advisory Board.

PDA welcomes the draft guidance and the implementation of Quality Risk Management.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 preferred over others.

If you have any questions, please contact me.

With very best regards,



Georg Roessling, Ph.D.
Senior Vice President,
PDA Europe gGmbH
Adalbertstraße 9
16548 Glienicke/Berlin
Germany
Tel: +49 (33056) 2377 -10
Fax: +49 (33056) 2377 -77
Email: Roessling@pda.org

Information Copy:
David Cockburn
Manufacturing and Quality Compliance
European Medicines Agency
Compliance and Inspections, London
ADM-GMP@ema.europa.eu

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).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsi□ile** +44 (0)20 7418 8416
E-mail info@e□a.europa.eu **Website** www.ema.europa.eu

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	

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 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.