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March 28, 2013

Dr. S. Kopp
Medicines Quality Assurance Programme
World Health Organization
1211 Geneva 27, Switzerland
kopps@who.int

Re: Working Document QAS/13.517; Proposed Updated Text for WHO Good Manufacturing Practices for Pharmaceutical Products: Main Principles

Dear Dr. Kopp,

PDA is pleased to have the opportunity to offer comments on the above-referenced proposal. 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 comments were prepared by a committee of experts with experience in pharmaceutical and biopharmaceutical product issues, including members representing our Regulatory Affairs and Quality Advisory Board. PDA appreciates the opportunity to offer comments on these proposed changes and wishes to thank the WHO for the opportunity to do so.

While PDA supports WHO's revision of the GMP's; in consideration of further global harmonization, in general PDA believes it would be preferable to adopt the wording contained in an existing recognized regulatory standard, specifically the PIC/S GMP.

Having said that, should WHO decide to move forward with the existing proposal, we have provided in the attached table, some specific comments which we believe will clarify and strengthen the proposal.

Again, PDA appreciates the opportunity to comment on this proposal and provides these comments for your consideration. We would be pleased to meet with the WHO to provide clarification of our comments. Should you wish to pursue that opportunity, or if there are any other questions, please do not hesitate to contact me.

Sincerely,

Richard V. Levy
Senior VP, Scientific and Regulatory Affairs

Cc: gaspardm@who.int
Denyse Baker, PDA
Robert Dana, PDA
Rich Johnson, PDA
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Comments on WHO Working Document QAS/13.517
Title of the document: WHO Good Manufacturing Practices for Pharmaceutical Products: Main Principles

Comments submitted by: Richard V. Levy, Parenteral Drug Association
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Date : 28 March 2013
Kindly complete the table without modifying the format of the document - thank you.

Template for comments

General comment(s) if any :	**Originator of the comments**
1. PDA supports WHO's revision of the GMPs. However, in the proposed revisions, we note that there are still many instances where the text is not aligned with global harmonized guidance such as ICH Q10. For example, Chapter 7 continues to refer to "Contract Production and Analysis" rather than adopting the broader ICH terminology of "Outsourced Activities". It is common practice for companies to outsource activities other than production and analytical testing, for example pest control. In consideration of furthering global harmonization, PDA believes that it would be preferable to adopt the PIC/S GMP rather than creating another set of global requirements.	

# section	**# Pararaph If more than one**	**Comment / Rationale**	**Proposed change / suggested text**	**Classification** **L**= low **M**= medium **H**= high	**Originator of the comments (for WHO use)**
1.2		Revise the last sentence to improve wording.	All parts of the PQS should be supported with appropriate resources, including competent personnel, as well as suitable premises, equipment, and facilities.	L	

# section	# Pararaph If more than one	Comment / Rationale	Proposed change / suggested text	Classification **L**= low **M**= medium **H**= high	Originator of the comments (for WHO use)
1.3		There are 2 sections numbered 1.3; one on page 4 following Section 1.2 and one on Section 6 following Section 1.3(s). Clarification is needed as to the actual section reference on page 6.	Provide correct section reference.	H	
1.3		Sections 1.3(b) and 1.3(q) could be combined for simplification and clarification of the purpose of knowledge management.	Product and process knowledge is managed throughout all life cycle stages to facilitate the implementation of quality improvements appropriate to the current level of process and product knowledge.	M	
1.3		The distinction between Sections (m) and (o) is not clear. As written, it may be interpreted as a requirement for 2 distinct activities and that may or may not be necessary, depending on the control strategy for the product in question.	Delete Section (m)	M	
1.3		For clarification, move the effectiveness check language from proposed Section (m) to Section (s) and reword Section (s)	(s) Deviations, suspected product defects and other problems are reported, investigated and recorded. An appropriate level of root cause analysis is applied during such investigations. Most likely root cause(s) should be identified and appropriate corrective actions and/or preventative actions (CAPAs) should be identified and taken. The effectiveness of CAPAs should be monitored.	M	
2.1		Section (h) uses the term "good distribution practice (GDP) without any reference or definition of the term.	Provide a reference to an identified standard, definition or regulation.	M	
2.1		Section (j) should include the need for periodic evaluation and record keeping for complaints.	Deviations are reported, investigated, and recorded; effectiveness checks should be utilized.	L	