PDA
Parenteral Drug Association
Connecting People, Science and Regulation®

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31 May 2010

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Ref: EU Guidelines to Good Manufacturing Practice, Part 1
Medicinal Products for Human and Veterinary Use
Chapter 2, Personnel
Brussels, 18 November 2009, ENTR/F2/MT/AM/jr D (2009) 37672, 18 Nov 2009
Deadline for comments: 31 May 2010

To: Responsible Person: European Medicines Agency, Inspections Sector
Responsible Person: European Commission, Pharm. Unit

PDA is pleased to provide comments on the revised *Chapter 2 of the EU GMP,* dated 18 November 2009. Our comments were prepared by an international group of volunteer experts with experience in GMP and regulatory affairs. Our three specific comments are presented in the attached EMA matrix format.

If you have any questions please contact me, or James Lyda of the PDA staff (lyda@pda.org) who coordinated this project.

With very best regards,

Georg Roessling, Ph.D.
Senior VP, PDA Europe
Roessling@pda.org

cc: S. Mendivil, S. Schmitt, S. Rönninger, J. Lyda, R. Levy, R. Dana,

31 May 2010

Submission of comments on

EU GMP Guide, Part 1, "Chapter 2, Personnel"

ENTR/F/2/MT/AM/jr D (2009) 37672

18 November 2009

Comments from:

Parenteral Drug Association (PDA), Berlin Contact: James C. Lyda, lyda@pda.org

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	NONE	

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)*
2.12		**Comment 1:** We recommend adherence to the wording used in ICH Q10 and by the ICH Q-IWG Q&A. Proposed change (if any): Amend text as follows, "…The Quality management system **elements** and all the measures capable of improving its understanding and implementation should be fully discussed during the training sessions…	
2.22		**Comment 2:** The intent of the opening sentence is a unclear, i.e. the complexity of what? Deletion of the phrase 'consider the complexity and' makes the sentence clearer. The complexity of this situation is inherent in factors (a) and (b) which follow. Proposed change (if any): When product ownership changes, (e.g., through acquisitions) management should ~~**consider the complexity and**~~ ensure: (a) The ongoing responsibilities are defined for each company involved; (b) The necessary information is transferred.	
2.3 (appears 2 times)		**Comment 3:** The chapter number 2.3 appears two times in the text. Proposed change (if any): Correct the numbering sequence.	
		END	