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July 24, 2013

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

Ref: EU Guidelines for GMP for Medicinal Products; Chapter 3: Premises and Equipment

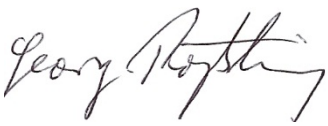
To the Health and Consumers Directorate-General:

PDA is pleased to provide comments on this chapter submitted 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 changes proposed and acknowledges these changes reflect current technologies and controls to protect patients. As a general comment, PDA recommends avoiding the use of absolutes such as "***avoided***" and suggests using the following wording: "cross-contamination should be controlled" since complete avoidance may not be feasible. Please see the attached document for additional specific comments.

If you have any questions, please contact me.

With very best regards,



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cc: Richard Johnson, PDA; Rich Levy, PDA

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Medicinal products – quality, safety and efficacy

18July2013

The Rules Governing Medicinal Products in the European Union

Volume 4

EU Guidelines for

Good Manufacturing Practice for

Medicinal Products for Human and Veterinary Use

Part 1

Chapter 3: Premises and Equipment

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).

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
Name	Comment	Decision to Submit/ withdraw comment
	PDA welcomes the opportunity to comment on the proposed changes. The changes reflect current technologies and controls to protect patients and as such they are welcomed.	
	In general, PDA recommends avoiding the use of absolutes such as "***avoided***" and suggests using the following wording: "cross-contamination should be controlled" since complete avoidance may not be feasible.	

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)*
Exact Line # (s)	Name (First & Last)	Comment: Proposed change (if any):	Decision to Submit/ withdraw comment
3.6		Comment: In line with PDAs comments on the Guideline on setting health based exposure limits, PDA recommends clarifying that the toxicological evaluation referred to in this section could include any health based exposure limit. Also, since the health based limits guideline is referenced later in the paragraph, we recommend deleting the reference here, to avoid duplication. Proposed change (if any): Risk assessment should include among other parameters a toxicological evaluation of the products being manufactured using health based exposure limits ~~(see Guideline...)~~,	
3.6		Comment: Complete avoidance of cross-contamination in a multi-product plant may not be feasible. Proposed change (if any): Cross-contamination should be ~~avoided~~ controlled for all products...	

Please add more rows if needed.