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.