EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<December 29th 2011>

Submission of comments on <Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use>' (EMA/…/…)

Comments from:

Name of organisation or individual
EFG 11 / Dr. Arno Terhechte

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).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*

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)*
Chapter 3 Computerised Systems 3.20 - 3.25		Comment: In this section some relevant aspects (but not all) are listed with regard to the implementation (3.20, 3.21) and the operation (3.22 - 3.25) of a computerised system. Requirements with regard to for example audit trails, change and configuration control, IT-infrastructure, personnel, validation, e-signature are not defined. Proposed change (if any): We would recommend to replace this section as follows: Where a computerised system replaces a manual operation , there should be no resultant decrease in product quality and the integrity of the distribution chain Throughout the distribution process or quality assurance. There should be no increase in the overall risk of the process. The application should be validated; IT infrastructure should be qualified. For further details reference is made to Annex 11 of the EU GMP Guide.	
		Comment: Proposed change (if any):	
		Comment:	

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)*
		Proposed change (if any):	

Please add more rows if needed.