EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2011-12-31

Submission of comments on 'Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use' (SANCO/C8/AM/an D(2010) 380358)

Comments from:

Name of organisation or individual
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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)*
	Background The proposed comments result from a review made with the automation and site engineering point of view. These comments are not exhaustive. General remarks 1. I appreciate the general advocated consistency to the GMP rules. 2. Since Annex 11 has been revised and published in 2011, it would be good to refer to it as well as to Annex 15 regarding the necessity of maintaining compliance for environmental monitoring systems, systems supporting product and distribution traceability as well as complaint management activities. 3. Likewise a consistent reference to Q9 and Q10 (see GMP Part III) will probably set requirements more clearly than rewording some clauses and objectives of these both documents. For example see 1.12 and 1.13.	

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 1		Comment: It would be useful and consistent with the general approach promoted in the EU GMP to define within the context of GDP the roles of Process Owner and System Owner. It could be done in Chapter 1 or, together with the other responsibilities, in Chapter 2. Proposed change (if any): -	
1.9		Comment: Since within the context of GDP, some organisations do not share the same understanding of responsibility than within the GMP context, I would recommend to add the sentence below (or with a similar meaning). Proposed change (if any): Even if some activities are outsourced the license holder remains accountable for the outsourced activities in the same way as if the activities would be performed internally.	

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1.12, 1.13		Comment: Please refer directly Q9 Proposed change (if any): Risk Management (see EU GMP Part III, Q9) should be applied throughout the GDP process, taking into account patient safety, data integrity, and product quality. As part of a risk management system, decisions regarding the extent of compliance and validation effort, the level of formalism as well as of documentation should be based on a justified and documented risk management. Risk management should be applied both proactively and retrospectively (e.g. within the context of CAPA).	
Chapter 2		Comment: See remark on Chapter 1 regarding ownership. Proposed change (if any): -	
Chapter 3		Comment: I would recommend to add to the principle the sentence below. Proposed change (if any): The clauses and the requirements regarding equipment qualification and computerized system compliance as defined	

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		in the EU GMP Annexes 15 and 11 do apply risk-based to premises, equipments and systems supporting GDP activities.	
3.2		Comment: Please refer to the proposed addition for 1.9 Proposed change (if any):	
3.20 – 3.25		Comment: Please refer directly to Annex 11 without repeating or rewording the requirements. See proposal below Proposed change (if any): Computerised systems supporting GDP processes have to comply with and to fulfil the requirements stated in Annex 11. Particular attention should be put on: - System documentation - Data entry - Data integrity - Data availability and security, incl. backup - Business continuity.	
3.26 – 3.29		Comment: I would not put Qualification and Validation in a separate part and especially not at the chapter end. Within the meaning of my comment regarding the principle of Chapter 3, I would recommend to discuss qualification and validation at the beginning of chapter 3 since these	

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		requirements apply in the same way to premises, temperature and environmental controls, equipments, and computerised systems. Proposed change (if any): Please move to principle at the beginning of Chapter 3	
Chapter 4		Comment: Please refer to EU GMP, Chapter 4. Only additional requirements should be mentioned here (please avoid redundancies) Proposed change (if any): -	
Chapter 5		Comment: I would expected that – like as established in Annex 11, 3.4 – information relating to supplier, service provider, and customer qualification should be made available to inspectors on request. Please add to principle at Chapter 5, the sentence below. Proposed change (if any): Information relating to supplier, service provider, and customer qualification should be made available to inspectors on request.	
Chapter 7		Comment: See comment regarding supplier and customer qualification.	

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		Proposed change (if any): -	
Chapter 9 (9.19 – 9.23)		Comment: The recommendation provided for Chapter 3 applies in the same way. I would recommend to add to Chapter 9, Principle, the sentence below. Proposed change (if any): The clauses and the requirements regarding equipment qualification, process validation and computerized system compliance as defined in the EU GMP Annexes 15 and 11 do apply risk-based to transportation processes and to the related equipments and systems.	
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	

Please add more rows if needed.