EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11-July-2013

Submission of comments on ' EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use Part 1: Chapter 5: Production'

Comments from:

Name of organisation or individual
GE Healthcare, Medical Diagnostics

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)*
	The updates to Chapter 5 regarding vendor/supply chain controls for starting materials may not be appropriate to manufacturers of small-scale, specialist medicinal products e.g. PET radiopharmaceuticals. Not only would these additional requirements be unmanageable in terms of resource, it may be that there are only one or two suppliers of certain starting materials and this could be an issue if the starting material manufacturer does not want to accept technical agreements, on-site audits etc	

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)*
5.27		Comment: 5.27 says: "The supply chain and traceability records for each active substance (including active substance starting materials) should be available and be retained by the EEA based manufacturer or importer of the medicinal product." Proposed change: Please clarify in the text if this applies to each batch of materials	
5.33, sub-item e)		Comment: 5.33 requires manufacturers to periodically carry out full testing of all starting materials and compare the results with the supplier's certificate of analysis. The text states that if a discrepancy is identified, then it needs to be investigated. However, there is no guidance in the text as to what is considered to be a discrepancy. There is also no consideration of when this material testing would be carried out – e.g. if full testing is carried out by the manufacturer on a batch of material that is nearing the end of its shelf life, can you expect the results to be consistent with the supplier's certificate of analysis generated at time of release? Also to be considered is the method validation for this additional testing at each manufacturing site (or contract laboratory used by the manufacturer); are the limits of	

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		quantification etc the same as the supplier's? If not, how can you compare the results for consistency? Proposed change: Clarification of the above comments	
5.68		Comment: 5.68 states that the marketing authorisation holder should notify the competent authority if the product ceases to be placed on the market no less than 2 months before the interruption (unless exceptional circumstances apply). Manufacturers of radiopharmaceuticals cannot comply with notifying the CA with more than 2 months due to the short shelf life of such products. Proposed change: Amend text to read "…. otherwise than in exceptional circumstances, such as products with short shelf life (eg radiopharmaceuticals)"	