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 6: Quality Control '

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)*

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)*
6.35		Comment: We would like to challenge the requirement to report every OOS if the manufacturer has been authorised to rework a rejected batch and manufacture a recovery batch. We believe that only if an OOS result affects a batch on the market, then that would be the point at which it should be assessed and reported as per a recall procedure Proposed change: Change to read: Out of specification or significant atypical trends should be investigated. Any confirmed out of specification result, or significant negative trend affecting product batches on the market, should be reported to the relevant competent authorities. The possible impact on batches on the market should be considered in accordance with Chapter 8 of the GMP Guide and in consultation with the relevant competent authorities.	