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 8: Complaints, Quality Defects and Product Recalls'

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)*
8.21		Comment: Chapter 8.21 states that: "Any retrieval of product from the distribution network as a result of a quality defect should be regarded and managed as a recall." Does this include samples returned for complaint investigations? Please clarify that products returned as samples for complaint investigations would be excepted. Does this also mean that product being sent in quarantine (for example under the provisions of GMP Annex 3, 39(a)) that fails QC is considered a recall? If this is the case, then this would mean that the Competent Authority would need to be notified of such events. Please clarify	

Please add more rows if needed.