EU-GMP-Guide
Chapter 8: Complaints, Quality Defects and Recalls

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Chapter 8

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Reasons for changes:

- *…reflect **QRM** principles … investigating **quality defects/complaints** … making decisions … to product **recalls or other risk-mitigating actions**.*
- *… emphasise the **need for the cause(s)** of quality defects/complaints … **appropiate preventative actions** are put in place … against a recurrence*
- *… clarify expectations and responsibilities … **reporting of quality defects to the Supervisory Authority**.*

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Principle:

- *Public and animal health*
- *Procedures in place to record, investigate and review, and effectively and promptly recall*
- *QRM principles applied to investigation and assessment and decision-making process*
- *All concerned competent authorities informed of quality defect which may result in **recall** or **abnormal restriction in the supply***
- *Contract describing role and responsibilities for outsourced activities*

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Personnel and Organisation:

- *Trained and experienced personnel for managing and deciding*
- *These persons should be independent from sales and marketing organisations*
- *If this does not include the QP, the latter should be made formally aware of any investigations, any risk-reducing actions and any recall operations, in a timely manner*
- *Sufficient personnel and resources (investigation, interaction with competent authorities)*
- *Inter-disciplinary teams should be considered*
- *Document roles and responsibilities if complaint and quality defect handling is managed centrally*

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Procedures for handling and investigating complaints including possible quality defects:

- *Written procedures (include investigation for suspected adverse events)*
- *Document all complaints and assess for potential quality defect*
- *Not all complaints may represent a defect, appropriate documentation for non-defects*
- *Consider checking or testing of reference/retention samples and review of batch production record*
- *Request sample for appropriate evaluation*
- *Assess risk posed by the quality defect*
- *Decision making process for risk-reducing actions*
- *Assess impact that any recall may have on availability and need to notify relevant authorities*
- *Internal and external communication*
- *Identification of potential root cause(s) and need for CAPA including assessment of effectiveness of CAPAs*

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Investigation and Decision Making:

- *Record information and assess its validity and extent of defects acc. QRM principles*
- *Consider checking other batches / other products (determine whether they are also affected)*
- *Investigations should include review of previous defect reports for any indication of specific or recurring problems*
- *Decisions should reflect the level of risk as well as seriousness of any non-compliance with marketing authorisation or GMP*
- *Ensure patient and animal safety is maintained*
- *Risk-reducing actions taken at appropriate time-point*
- *All decisions and measures documented*
- *Quality defects reported in a timely manner to all concernced competent authorities in case it may result in a recall or abnormal restriction in supply*

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Root Cause Analysis and Corrective and Preventative Actions:

- *Appropriate level of root cause analysis*
- *If true root cause(s) cannot be determined, identify most likely root cause(s) and address those*
- *Special attention whether a defect relates to falsification*
- *Human error: formal justification and care ! Ensure other errors or problems are not overlooked*
- *CAPAs should be identified and taken, effectiveness of such actions monitored and assessed*
- *Quality defect records reviewed and trend analysis performed regularly for any indication of specific or recurring problems*

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Product Recalls and other potential risk-reducing actions:

- *Written procedures*
- *Any retrieval of product from distribution network as a result of a quality defect is a recall*
- *Recall operations capable of being initiated promptly and at any time*
- *Certain cases may need recall prior to establishing the root cause(s)*
- *Distribution records readily available*
- *IMP: all trial sites and countries identified (Sponsor: rapid unblinding)*
- *Consultation with competent authorities (CA) (extent of recall)*
- *Inform CA also for no-recall for quality defect of expired batch*
- *All CAs informed in advance wherever possible, only for very serious issue recall may be taken in advance of notifying*
- *Consider wether proposed recall may affect different markets in different ways and discuss appropriate action with concerned CAs*
- *Consider risk of shortage for product with no authorised alternative*
- *Any decision not to execute a risk-reduction action which would otherwise be reqired should be agreed with the CA in advance*

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Product Recalls and other potential risk-reducing actions:

- *Recalled products identified and stored separately in a secure area*
- *Formal disposition documented including rationale for disposition or any rework should be discussed with the relevant CA.*
- *Consider extent of shelf-life remaining for any reworked batches*
- *Record progress of recall process and issue a final report (including reconciliation of delivered/recovered quantities)*
- *Evaluate effectiveness of recall procedures periodically (both within office-hour as well as out-of-office hour situations) and consider performing a mock-recall (evaluation should be documented and justified)*
- *In addition to recalls, other potential risk-reducing actions may be considered (e.g. communication to healthcare professionals) on a case-by-case basis and should be discussed with the concerned CA*

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Kommentare,

die die AQPA an die EMA weiterleiten soll ?

(Frist: 18. Juli 2013)