GMP revision chapter 8 (Complaints and Product Recall), Generally we suggest to consider a risk based approach whenever possible	
ORIGINAL TEXT	**BPI's Comments and suggestions**
Complaints and Product Recall	**Complaints, Quality Defects and Product Recalls**
Principle	
All complaints and other information concerning potentially defective products must be reviewed carefully according to written procedures. In order to provide for all contingencies, and in accordance with Article 117 of Directive 2001/83/EC and Article 84 of Directive 2001/82/EC, a system should be designed to recall, if necessary, promptly and effectively products known or suspected to be defective from the market.	In order to protect public and animal health, a system and appropriate procedures should be in place to record, investigate and review complaints including potential quality defects, and if necessary, to effectively and promptly recall medicinal products for human or veterinary use and investigational medicinal products from the distribution network. Quality Risk Management principles should be applied to the investigation and assessment of quality defects and to the decision-making process in relation to product recalls and other risk-reducing actions. Guidance in relation to these principles is provided in Chapter 1. **All concerned competent authorities should be informed in case of a quality defect (faulty manufacture, product deterioration, detection of falsification, non-compliance with the marketing authorisation or product specification file, or any other serious quality problems) with a medicinal or investigational medicinal product which may result in the recall of the product or an abnormal restriction in the supply.** In case of outsourced activities, a contract should describe the role and responsibilities of the manufacturer, the Marketing Authorisation Holder and/ or Sponsor and any other relevant third parties in relation to assessment, decision-making, and dissemination of information and implementation of risk-reducing actions relating to a defective product. Guidance in relation to contracts is provided in Chapter 7.

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Personnel and Organization	
8.1 A person should be designated responsible for handling the complaints and deciding the measures to be taken together with sufficient supporting staff to assist him. If this person is not the Qualified Person, the latter should be made aware of any complaint, investigation or recall. 8.9 A person should be designated as responsible for execution and co-ordination of recalls and should be supported by sufficient staff to handle all the aspects of the recalls with the appropriate degree of urgency. This responsible person should normally be independent of the sales and marketing organisation. If this person is not the Qualified Person, the latter should be made aware of any recall operation.	8.1 Appropriately trained and experienced personnel should be responsible for managing complaint and quality defect investigations and for deciding the measures to be taken to manage any potential risk(s) presented by those issues, including recalls. These persons should be independent of the sales and marketing organisation, unless otherwise justified. If these persons do not include the Qualified Person who is involved in the certification for release of the concerned product, the latter should be made formally aware of any investigations, any risk-reducing actions and any recall operations, in a timely manner. => Marketing and supply shall not be excluded from this chapter

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	8.2 Sufficient personnel and resources should be made available for the handling, reviewing and investigation of complaints and quality defects and for implementing any risk-reducing actions. Sufficient personnel and resources should also be available for the management of interactions with competent authorities.
	8.3 The use of inter-disciplinary teams should be considered, including appropriately trained Quality Management personnel.
	8.4 In situations in which complaint and quality defect handling is managed centrally within an organisation, the relative roles and responsibilities of the concerned parties should be documented. Central management should not, however, result in delays in the investigation and management of the issue
Procedures for handling and investigating complaints including possible quality defects	
8.2 There should be written procedures describing the action to be taken, including the need to consider a recall, in the case of a complaint concerning a possible product defect.	8.5 There should be written procedures describing the actions to be taken upon receipt of a complaint. All complaints should be documented and assessed to establish if they represent a potential quality defect or other issue.
	8.6 As all complaints received by a company may not represent actual quality defect issues, complaints which do not indicate a potential quality defect should be documented appropriately and communicated to the relevant group or person responsible for the investigation and management of complaints of that nature, such as suspected adverse events.
	8.7 There should be procedures in place to facilitate a request to investigate the quality of a batch of a medicinal product to support an investigation into a reported suspected adverse event.

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	8.8 When a quality defect investigation is initiated, procedures should be in place to address at least the following: i. The description of the reported quality defect. ii. The determination of the extent of the quality defect. The checking or testing of reference and/or retention samples should be considered as part of this, and in certain cases, a review of the batch production record should be performed. Risk based, where necessary iii. The need to request a sample of the defective product from the complainant and, where a sample is provided, the need for an appropriate evaluation to be carried out. The distribution information for the batch(es) in question. The assessment of the risk(s) posed by the quality defect. Risk based, where necessary iv. The decision making process that is to be used concerning the potential need for risk-reducing actions to be taken in the distribution network, such **as batch or product recalls**, or other actions. Risk based, where necessary v. The assessment of the impact that any recall action may have on the availability of the medicinal product to patients/animals in any affected market and the need to notify any such impacts to the relevant authorities if life-saving drugs are concerned. vi. The internal and external communications that should be made in relation to a quality defect and its investigation. vii. The identification of the potential root cause(s) of the quality defect. Risk based, where necessary viii. The need for appropriate Corrective and Preventative Actions (CAPAs) to be identified and implemented for the issue, and for the assessment of the effectiveness of those CAPAs. Risk based, where necessary

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Investigation and Decision Making	
8.5 All the decisions and measures taken as a result of a complaint should be recorded and referenced to the corresponding batch records.	
8.6 Complaints records should be reviewed regularly for any indication of specific or recurring problems requiring attention and possibly the recall of marketed products.	
8.3 Any complaint concerning a product defect should be recorded with all the original details and thoroughly investigated. The person responsible for Quality Control should normally be involved in the study of such problems.	8.9 The information reported in relation to possible quality defects should be recorded, including all the original details. The validity and extent of all reported quality defects should be documented and assessed in accordance with quality risk management principles in order to support decisions regarding the degree of investigation and action taken.
8.4 If a product defect is discovered or suspected in a batch, consideration should be given to checking other batches in order to determine whether they are also affected. In particular, other batches which may contain reworks of the defective batch should be investigated.	8.10 If a quality defect is discovered or suspected in a batch, consideration should be given to checking **other batches and in some cases other products**, in order to determine whether they are also affected. In particular, other batches which may contain portions of the defective batch or defective components should be investigated. Risk based, ˆ where necessary
	8.11 Quality defect investigations should include **a review of previous quality defect** reports or any other relevant information for any indication of specific or recurring problems requiring attention and possibly further regulatory action Risk based, where necessary
	8.12 The decisions that are made during and following quality defect investigations should reflect the level of risk that is presented by the quality defect as well as the seriousness of any non-compliance with respect to the requirements of the marketing authorisation/ product specification file or GMP. Such decisions should ensure that patient and animal safety is maintained in a timely manner, in a way that is commensurate with the level of risk that is presented by those issues.
	8.13 As comprehensive information on the nature and extent of the quality defect may not always be available at the early stages of an investigation, the decision-making processes should still ensure that **appropriate risk-reducing actions** are taken at an appropriate time-point during such investigations. All the decisions and measures taken as a result of a quality defect should be documented.

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8.8 The competent authorities should be informed if a manufacturer is considering action following possibly faulty manufacture, product deterioration, detection of counterfeiting or any other serious quality problems with a product	8.14 Quality defects should be reported in a timely manner by the manufacturer to the Marketing Authorisation Holder/ Sponsor and all concerned Competent Authorities in cases where the quality defect may result in the recall of the product or in an abnormal restriction in the supply of the product if life-saving drugs are concerned.
Root Cause Analysis and Corrective and Preventative Actions	
	8.15 An appropriate level of root cause analysis work should be applied during the investigation of quality defects. In cases where the true root cause(s) of the quality defect cannot be determined, consideration should be given to identifying the most likely root cause(s) and to addressing those. Risk based, where necessary
8.7 Special attention should be given to establishing whether a complaint was caused because of counterfeiting.	8.16 Special attention should be given to establishing whether a quality defect relates to falsification. Risk based, where necessary
	8.17 Where human error is suspected or identified as the cause of a quality defect, this should be formally justified and care should be exercised so as to ensure that process, procedural or system-based errors or problems are not overlooked, if present. Risk based, where necessary
	8.18 Appropriate corrective and/or preventative actions (CAPAs) should be identified and taken in response to a quality defect. The effectiveness of such actions should be monitored and assessed. Risk based, where necessary
	8.19 Quality defect records should be reviewed and trend analyses should be performed regularly for any indication of specific or recurring problems requiring attention. Risk based, where necessary
Product Recalls and other potential risk-reducing actions	
8.10 There should be established written procedures, regularly checked and updated when necessary, in order to organise any recall activity.	8.20 There should be established written procedures, regularly reviewed and updated when necessary, in order to undertake any recall activity or implement any other risk-reducing actions.
	8.21 Any retrieval of product from the distribution network as a result of a quality defect should be regarded and managed as a recall. = Risk based, where necessary

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8.11 Recall operations should be capable of being initiated promptly and at any time.	8.22 Recall operations should be capable of being initiated promptly and at any time. In certain cases recall operations may need to be initiated to protect public or animal health prior to establishing the root cause(s) and full extent of the quality defect
8.13 The distribution records should be readily available to the person(s) responsible for recalls, and should contain sufficient information on wholesalers and directly supplied customers (with addresses, phone and/or fax numbers inside and outside working hours, batches and amounts delivered), including those for exported products and medical samples.	8.23 The batch/product distribution records should be readily available to the persons responsible for recalls, and should contain sufficient information on wholesalers and directly supplied customers (with addresses, phone and/or fax numbers inside and outside working hours, batches and amounts delivered), including those for exported products and medical samples.
	8.24 In the case of investigational medicinal products, all trial sites should be identified and the countries of destination should be indicated. In the case of an investigational medicinal product for which a marketing authorisation has been issued, the manufacturer of the investigational medicinal product should, in cooperation with the sponsor, inform the marketing authorisation holder of any quality defect that could be related to the authorised medicinal product. The sponsor should implement a procedure for the rapid unblinding of blinded products, where this is necessary for a prompt recall. The sponsor should ensure that the procedure discloses the identity of the blinded product only in so far as is necessary. Risk based, where necessary
	8.25 Consideration should be given following consultation with the concerned Competent Authorities, as to how far into the distribution network a recall action should extend, taking into account the potential risk to public or animal health and any impact that the proposed recall action may have. The Competent Authority should also be informed in situations in which no recall action is being proposed for a defective batch because the batch has expired (such as with short shelf-life products.).
8.12 All Competent Authorities of all countries to which products may have been distributed should be informed promptly if products are intended to be recalled because they are, or are suspected of being defective.	8.26 All concerned Competent Authorities should be informed in advance in cases where products are intended to be recalled. For very serious issue (i.e. those with the potential to seriously impact upon patient or animal health), rapid risk-reducing actions (such as a product recall) may have to be taken in advance of notifying the Competent Authorities. Wherever possible, attempts should be made to agree these in advance of their execution with the concerned Competent Authorities.

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	8.27 It should also be considered whether the proposed recall action may affect different markets in different ways, and if this is the case, appropriate market-specific risk-reducing actions should be developed and discussed with the concerned competent authorities. The risk of shortage of an essential medicinal product which has no authorised alternative should be considered before deciding on a risk-reducing action such as a recall. Any decisions not to execute a risk-reducing action which would otherwise be required should be agreed with the competent authority in advance.
8.14 Recalled products should be identified and stored separately in a secure area while awaiting a decision on their fate.	8.28 Recalled products should be identified and stored separately in a secure area while awaiting a decision on their fate. A formal disposition of all recalled batches should be made and documented and the rationale for the disposition of recalled products (or any reworked versions of them) should be documented and discussed with the relevant competent authority. The extent of shelf-life remaining for any reworked batches that are being considered for placement onto the market should also be considered.
8.15 The progress of the recall process should be recorded and a final report issued, including a reconciliation between the delivered and recovered quantities of the products.	8.29 The progress of the recall process should be recorded and a final report issued, including a reconciliation between the delivered and recovered quantities of the concerned products/batches.
8.16 The effectiveness of the arrangements for recalls should be evaluated regularly.	8.30 The effectiveness of the arrangements in place for recalls should be periodically evaluated to confirm that they remain robust and fit for use. Such evaluations should extend to both within office-hour situations as well as out-of-office hour situations and, when performing such evaluations, consideration should be given as to whether mock-recall actions should be performed. This evaluation should be documented and justified.
	8.31 In addition to recalls, there are other potential risk-reducing actions that may be considered in order to manage the risks presented by quality defects. Such actions may include the issuance of cautionary communications to healthcare professionals in relation to their use of a batch that is potentially defective. These should be considered on a case-by-case basis and discussed with the concerned competent authorities. Risk based, where necessary