COMPARISION OF MARKET COMPLAINTS AS PER GUIDELINES

Sr.No.	As per EU(MHRA 2007)	As per US (21CFR 211)	As per WHO(TRS 937)	Remarks
1.0	**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 28 of Directive 75/319/EEC, a system should be designed to recall, if necessary, promptly and effectively products known or suspected to be defective from the market.	a) Written procedures describing the handling of all written and oral complaints regarding a drug product shall be established and followed. Such procedures shall include provisions for review by the quality control unit, of any complaint involving the possible failure of a drug product to meet any of its specifications and, for such drug products, a determination as to the need for an investigation in accordance with § 211.192. Such procedures shall include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration in accordance with § 310.305 of this chapter.	14.1 There should be a written procedure in place for the handling of complaints. A distinction should be made between complaints about a product or its packaging and those relating to distribution. In the case of a complaint about the quality of a product or its packaging the original manufacturer and/or marketing authorization holder should be informed as soon as possible.	**OK**
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.	(b) A written record of each complaint shall be maintained in a file designated for drug product complaints. The file regarding such drug product complaints shall be maintained at the establishment where the drug product involved was manufactured, processed, or packed, or such file may be maintained at another facility if the written records in such files are readily available for inspection at that other facility. Written records involving a drug product shall be maintained until at least 1 year after the expiration date of the drug product, or 1 year after the date that the complaint was received, whichever is	14.2 All complaints and other information concerning potentially defective and potentially counterfeit pharmaceutical products should be reviewed carefully according to written procedures describing the action to be taken, including the need to consider a recall where appropriate.	

		longer. In the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under § 211.137, such written records shall be maintained for 3 years after distribution of the drug product.		
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.	(1) The written record shall include the following information, where known: the name and strength of the drug product, lot number, name of complainant, nature of complaint, and reply to complainant.	14.3 Any complaint concerning a material defect should be recorded and thoroughly investigated to identify the origin or reason for the complaint (e.g. repackaging procedure or original manufacturing process).	
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.	(2) Where an investigation under § 211.192 is conducted, the written record shall include the findings of the investigation and followup. The record or copy of the record of the investigation shall be maintained at the establishment where the investigation occurred in accordance with § 211.180(c).	14.4 If a defect relating to a pharmaceutical product is discovered or suspected, consideration should be given to whether other batches of the product should also be checked.	
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.	(3) Where an investigation under § 211.192 is not conducted, the written record shall include the reason that an investigation was found not to be necessary and the name of the responsible person making such a determination.	14.5 Where necessary, appropriate follow-up action should be taken after investigation and evaluation of the complaint.	
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.		Complaints should be handled in accordance with a written procedure. A written report of the complaint, investigation, recommendations for action where relevant, and outcome should be available to the procurement agency.	
8.7	The Competent Authorities should be informed if a manufacturer is considering action following possibly faulty manufacture, product deterioration, or any other serious quality problems with a product.		Any complaint concerning a pharmaceutical product or batch of products supplied by the manufacturer should be thoroughly investigated. The nature of the complaint should be communicated to the manufacturer.	
8.8	The competent authorities should be informed if a manufacturer is considering action following possible faulty manufacturer ,product deteriorations, detection of counterfeiting or any other serious quality problems with product.			
15.10	All quality related complaints ,whether received orally or in writing ,should be recorded and investigated according to a written procedure.			
	Complaint record should include Name and address of complainants ; Name (and where appropriate ,title) and phone number of person submitting the complaint. Complaint Nature(including name and B.No.) Date of complaint is received. Action initially taken (including dates and identity of person taking the action); Any follow up action taken Response provided to the originator of complaint (including date response sent);			

	and Final decision on batch or lot			
	Records of complaints should be retained in order to evaluate trends, product related frequencies, and severity with a view to taking additional, and if appropriate, immediate corrective action.			
		211.192 Production record review. All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed. The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and followup.		

Pink marked phrases are need to include in the SOP as a regulatory compliance.