## How to Handle Customer Complaints For QA / QC

**INSERT DATE HERE**

**By**

**INSERT AUTHOR NAME AND TITLE HERE**

|  | **NAME** | **TITLE** | **SIGNATURE** | **DATE** |
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| **Reviewed By** |  |  |  |  |
| **Approved By** |  |  |  |  |

| **Effective Date** |  |
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# Introduction

1.1 **Purpose**: This Customer Complaint Standard Operating Procedure (SOP) will describe how complaints received are to be handled.

1.2 **Scope:** The SOP applies to all complaints received regarding [COMPANY NAME]’s products and/or services.

1.3 **Responsibilities**:

* All personnel receiving a complaint will record the complaint on the Complaint Record Form
* The Quality Assurance (QA) / Quality Control (QC) department is responsible for issuing a case number to each complaint, maintaining a Complaint Register and a file designated for complaints.
* QA / QC with the help of other departments will perform the necessary investigation regarding the complaint received. [NAME of MANAGER of QA / QC] is responsible for reviewing and ensuring that complaints are appropriately handled, investigated, and appropriate measures are taken in respect of the defective products and to prevent recurrences
* [NAME of DESIGNATED RESPONSIBLE PERSON] will be responsible for notifying any regulatory body involved, if product recall is to be initiated, product deterioration, or any other serious quality problems with a product.   
    
  A summary of action will also be created and stored in [COMPANY NAME]’s internal records as well as furnished to the regulatory bodies, complainant, and anyone else involved.

1.4 **Chief/Principal Investigator:** List the name of the person or people who have authored the SOP

1.5 **Definitions & Abbreviations**: Include all relevant definitions and abbreviations for ready reference here.

1.6 **Materials & Equipment**: Are any specific materials or equipment necessary to comply with the SOP? List them here.

1.7  **Cautions, Warnings, and Dangers**: Should users be aware of any cautions, warnings, and dangers for their own safety? If yes, let readers know and use the labels below to get more specific.

**Caution**: A caution prevents a possible mistake that could result in damage or injury

**Warning**: A warning alerts against potential hazards to life or limb

**Danger**: A danger alerts to immediate danger to life or limb

1.8 **Change History**:

# Procedure

* 1. Complaints may be received from internal or external source and as verbal feedbacks or written feedbacks. Verbal feedbacks may be received in person, through live chat or chatbot, or through a telephone conversation. Written complaints may be received in the form of letters, help desk tickets, e-mails, social media messages, and faxes. Regardless of the means of communication, all complaints will be recorded using the Complaint Record Form.
  2. Complaints can be lodged against either the service or products - appropriate measures should be taken as necessary and all complaints must be reported to [MANAGER NAME of QA / QC].
  3. Complaints against products manufactured and distributed by [COMPANY NAME] may include (but is not limited to) deficiencies of containers, labels, materials, purity, quality of distributed product and adverse product reaction.  
       
     Sometimes customers may also request to return a product. In such instances, assessments will need to be made to determine whether it is due to (or can potentially lead to) product quality issues. The case will be handled as a complaint after proper evaluation.
  4. Upon notification of a complaint, [MANAGER NAME of QA / QC] will document the complaint on a Complaint Record Form with the following information:  
       
     \* Complaint case number  
     \* Customer name  
     \* Customer address  
     \* Customer number  
     \* Product  
     \* Batch number  
     \* Quantity involved  
     \* Nature / reasons for complaint  
       
     If there is insufficient data, additional information from the originating source should be requested.
  5. QA / QC (with the help of other departments if needed) will immediately initiate an investigation of the complaint. The investigation will include review of the existing stock of the same batch and all relevant documents related to the batch of the product.
  6. If a product defect is discovered or suspected in the batch, other batches will also be checked to determine whether they are also affected. In particular, other batches or products that may contain product from the defective batch (e.g. reworked batch) will be investigated.
  7. If the investigation reveals serious product quality problems and/or the product is potentially the cause of adverse reactions, a recall will be initiated in accordance with [SOP on PRODUCT RECALLS].   
       
     All National Regulatory Authorities (including those where products are exported to) will be informed in the event that a recall is activated.
  8. If the investigation reveals a minor defect which will not effect product quality, corrective action should also be proposed to prevent recurrence.
  9. Investigations will be completed within [TIMEFRAME e.g. 3 days] from the date of receiving complaints.
  10. The outcome of the investigation, any decision or measure taken as a result of the complaint, and the corrective action taken to prevent recurrence should be recorded in the Complaint Record Form and referenced to the corresponding batch records.
  11. All Complaint Record Forms shall be maintained in [company knowledge base, wiki, intranet, etc.] so that it can easily be referenced in future cases.
  12. All complaints will be reviewed as part of the Annual Product Quality Review to determine whether there are specific or recurring problems that may require attention and might justify the recall of marketed products.

# 3. Change/Revision History Use table below for any new revisions made, date made, person responsible, and well as description of the change.

| **Revision #** | **Effective Date** | **Person Responsible For Change** | **Description Of Change** |
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# 4. Who Read The SOP Use table below to collect names, the title of the person,signatures, and date read of all people that have read the SOP.

| **Name** | **Title** | **Signature** | **Date** |
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