Procedure: Customer Complaints

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# Purpose

The purpose of this procedure is to describe the requirements for receiving and processing customer complaints at [Company].

# Scope

The scope of this procedure includes all customer complaints, however received, at [Company]. Customer complaints may include, but are not limited to:

**Product Complaints:**

* Efficacy issues
* Non-integrity of primary packing
* Critical batch detail information (legibility or correctness)
* Damage to pack or product (cosmetic to critical)
* Incorrect components
* Missing components / product
* Expiry issues
* Tamper evidence
* Fraud / counterfeiting
* Adverse events

**General Complaints:**

* Shipping / delivery issues
* Communication
* Invoicing

**Regulatory Complaints:**

* Regulatory non-conformities

# Responsibilities

Amend to reflect company structure.

|  |  |
| --- | --- |
| Role | Responsibility |
| Quality Manager | Manages, investigates and resolves, and if necessary, escalates, product related customer complaints. |
| All staff | Inform the Quality Manager if a customer complaint is received or adverse event reported. |

# Procedure

Any complaint concerning a product defect shall be recorded with all of the original details and investigated. If a product defect is reported and substantiated, consideration should be given as to investigation into other batches that may be impacted.

All of the decisions and measures taken as a result of a complaint are recorded and referenced to the corresponding batch records.

Customer complaints are reviewed routinely to identify any trends that may require action. If it is anticipated that any such action may result in an impact to supply then the company must notify the relevant regulatory authority.

## Receiving and logging customer complaints

All after-sales customer communications, whether written, electronic or verbal are to be acknowledged by email or letter to the customer and documented in Form FP808-1 Complaints Register in a timely manner. The information to be recorded in the register comprises:

* consecutive, unique complaint reference number and date complaint received
* identification of the customer / complainant, including contact name, company, address, phone and email
* the product code & description, sales order reference (if applicable), batch numbers (may not be applicable for general complaints)
* complaint type and category (refer to the Glossary for definitions and Section 4.2 Complaints categories)
* description of the complaint
* whether or not formal investigation was initiated and, if not, the reason why not and the name of the person responsible for the decision
* findings from investigations carried out
* response to the complainant
* reference to corrective and preventive action taken (if any)
* status and date signed off.

## Complaints categories

Classify complaints into one of the following categories in the complaints registry:

|  |  |
| --- | --- |
| Complaint category | Description |
| Product complaint | PC1 – labelling and packaging error  PC2 – failure to meet quality specifications  PC3 – performance or efficacy issue (including adverse events) |
| General complaint | GC1 – incorrect product or quantity shipped  GC2 – late delivery  GC3 – inadequate communication or response  GC4 – incorrect (or disputed) invoicing  GC5 – business practices, publicity, etc.  GC6 – regulatory (administrative) |
| Regulatory complaint | RC1 – regulatory non-conformity (product, process and/or quality) |

Add or delete from the above table as required.

## Evaluating and investigating product complaints

All quality related complaints received must be recorded and investigated.

Product complaints are evaluated and, where appropriate, are formally investigated. Formal investigation is required where issues are related to identity (mislabelling), quality or performance of product after release and/or distribution.

The Quality Manager defines the scope and objectives of the investigation. Changes to scope must be justified, documented and authorised.

If conformity of the product with quality standards is found to be an issue during the evaluation and investigation, the Quality Manager is responsible for decisions around the product currently on the market and the immediate future manufacture of the product at the site. These decisions may need escalation to executive management and include consideration of a product recall. Refer to Procedure QP807: Product Recall.

Records of complaint investigations must be kept. The record includes as a minimum:

* date complaint was received
* product details
* name, address and phone number of the complainant
* nature and details of the complaint
* dates and results of the investigation
* reference to any corrective or preventive action taken
* replies to the complainant.

## Evaluating and investigating general complaints

General complaints are classified and recorded in Form FP808-1 Complaints Register. The complaint is evaluated as to:

* who in the company should be informed
* the reply to be forwarded to the complainant
* the requirement for corrective or preventive action

Results of these determinations are recorded in the complaints registry.

## Corrective and preventive action

QA reviews all customer complaints and results of investigations and determines if a:

* *Form FP809-1: CAPA form* is required, or
* *Form FP704-1: Corrective Action Request* is required (for suppliers only)

When a CAPA or CAR is initiated, the number is recorded in the *Form FP808-1 Complaints Register* and the CAPAs and CARs are processed in accordance with Procedure QP809: Corrective and Preventative Action and Procedure QP704: Supplier Evaluation and Monitoring respectively.

When investigation of a customer complaint determines that a supplier or external organisation contributed to the complaint, QA contacts the organisation and provides them with appropriate evidence. When required, QA may issue a formal *Form FP704-1: Corrective Action Request* (CAR) to the responsible supplier. The progress of supplier’s corrective actions must be followed up in a timely manner.

## Records

The complaints register, investigation records and corrective and preventative action records are controlled records and are managed according to Procedure QP403: Control of Records.

**Definitions**

Amend as required or delete.

| Term | Definition |
| --- | --- |
| Product complaint (PC) | A written, electronic or oral communication that alleges deficiencies related to the identity, quality or performance of a product after release and/or distribution. |
| General complaint (GC) | A complaint that is not a product complaint (as definition above). General complaints include advertising, product information, availability, late, lost and wrong deliveries, billing errors and pricing. |
| Regulatory complaint (RC) | A complaint that relates to compliance with a regulatory requirement. |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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Document Information

| Revision History | | | |
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| Revision | Modified by | Change Control No. | Description of Change |
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| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP403 | Control of Records |
| QP704 | Supplier Evaluation and Monitoring |
| QP807 | Product Recall |
| QP809 | Corrective and Preventative Action |
| FP704-1 | Corrective Action Request |
| FP808-1 | Complaints Register |
| FP809-1 | CAPA Form |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
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| Doc. No. | Document Title |
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List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

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