Procedure: Customer Complaints

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Both ISO13485:2016and CFR 820 require complaints handling procedures but the latter is more prescriptive. This procedure satisfies CFR 820.198 and therefore 13485 also. Modify this procedure to reflect how complaints are handled by [Company].

# Purpose

This procedure describes a system, provides instructions and assigns responsibilities for receiving and processing customer complaints at [Company].

# Scope

The scope of this procedure includes all customer complaints, however received.

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| Customer Service Manager |  |
| Quality Manager |  |
|  |  |

Amend roles and responsibilities as applicable for your company processes and structure.

# Definition of terms

These definitions distinguish between complaints subject to regulatory requirements and those that are not. A "product complaint" is the same as a "complaint" in CFR 820.3(b).

|  |  |
| --- | --- |
| Term/Abbreviation | Definition |
| Product complaint | Written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a medical device after release and/or distribution. |
| General complaint | 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. |
| Reportable Complaint | Any complaint that represents an event which must be reported to the regulatory authority under which [Company] operates. |

Edit to reflect the (national) regulations that apply to the company.

# Procedure

## Receiving and logging customer complaints

All after-sales customer communications, whether written, electronic or verbal, are handled by the Customer Service department. Phone calls are documented during or immediately following the call.

Documenting the telephone conversation in an unformatted memo is sufficient but it is preferable to have a standard form or log book for this purpose.

Customer feedback and complaints are recorded in a log maintained by Customer Service. The record includes:

This log (hard copy or electronic) is used to record and track the status of all complaints, whether product, general or regulatory.

* consecutive reference number and date complaint received
* identification of the customer, including:
* contact name
* company
* address
* phone
* email
* the device name and any relevant reference, serial or batch numbers (may not be applicable for general complaints)

Delete those forms of ID that are not relevant to the company.

* complaint type and category (refer to Section 4 and 5.2)
* description of the complaint
* whether the device has been returned
* whether or not formal investigation was initiated and, if not, the reason why not and the name of the person responsible for the decision

If an identical complaint has already been seen and investigated, it is not necessary to carry out another investigation.

* what investigations were carried out
* response to the complainant (refer to Section 5.5)
* reference to corrective and preventive action taken (if any)

## Complaints categories

Customer Service reviews all new complaints and classifies them into one of the following categories.

| Customer Complaint Category | Description |
| --- | --- |
| Product complaint | * PC1 – labelling and packaging error * PC2 – failure to meet quality specifications * PC3 – durability issue * PC4 – reliability issue * PC5 – safety issue * PC6 – effectiveness issue * PC7 – performance issue.   Categories are from CFR 820.3(b). To satisfy CFR 820, it may be preferable to maintain these categories (further sub-divisions may be added) but they are not necessary for ISO 13485. |
| 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)   Processing of General Complaints is not a regulatory requirement. |
| Regulatory Complaint | RC1 – regulatory non-conformity (product, process and/or quality). |

The complaint category identification should be recorded in Form FM809-2: Complaints Register.

## Evaluating and investigating product complaints

Product complaints (refer Section 4) are evaluated and, where appropriate, are formally investigated by QA. The Production and Engineering Managers may assist with the investigation.

Complaints are formally investigated when:

* they involve issues related to identity (mislabelling), quality, durability, reliability, safety, effectiveness or performance of product after release and/or distribution
* they must be reported to the FDA under 21 CFR Part 803 or 804 (unless an investigation has already been performed for a similar complaint and another investigation is not necessary)

Identify the relevant regulatory agency under which [Company] operates.

The Quality Manager defines the scope and objectives of the investigation but may choose not to investigate an issue if it is not appropriate. Changes to scope must be justified, documented and authorised.

Records of complaint investigations are maintained by QA. The record includes as a minimum:

* name of the device
* date complaint was received
* device identification(s) and control number(s)
* 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

These records are specifically required by CFR 820.198(e).

A pre-printed log book or form helps ensure that all this information is captured. Forms should be filed in a logical way so that they are easily retrievable.

## Evaluating and investigating general complaints

General complaints are not regulated and therefore may be handled as the company sees fit. Describe in more detail how you general complaints are handled.

General complaints (refer Section 4 above) are evaluated and processed by Customer Service.

General complaints are classified and recorded in the Complaint Log (refer to Sections 5.1 and 5.2). Customer Service evaluates the complaint and determines:

* who in the company should be informed
* the reply to be forwarded to the complainant
* whether a corrective or preventive action is required

Results of these determinations are recorded in the Complaint Log.

## Evaluating and investigating reportable complaints

When the complaint evaluation (refer Section 5.3) identifies that the complaint represents a reportable event under 21 CFR Part 803 or 804, the Complaint Log entry is marked REPORTABLE to clearly identify this.

Reportable complaints must always be investigated and the results recorded in accordance with Section 5.3 of this procedure.

In addition to Section 5.3reportable complaints must also include a determination of:

These are from CFR 820.198(d).

* whether the device failed to meet specifications
* whether the device was being used for treatment or diagnosis
* the relationship, if any, of the device to the reported incident or adverse effect

## Corrective and preventive action

QA reviews all customer complaints and results of investigations and determines whether a Corrective Action Request (CAR) is required. When a CAR is initiated, the number is recorded in the Complaints Log and the CAR processed in accordance with Procedure *QP810: Corrective and Preventive Actions*.

When investigation of a customer complaint determines that an external organisation contributed to the complaint, QA contacts the organisation and provides them with appropriate evidence. When required, QA may issue a formal CAR to the responsible subcontractor.

## Records

All customer complaints are recorded in *Form FM809-2: Complaints Register* which is maintained by Customer Service department. All documents related to a complaint are identified with the complaint number and then filed.

When complaints are reported to a regulatory authority, both the log entry and the complaint file are marked REPORTABLE.

The Complaints Log and files are maintained by Customer Service.

Appendices

Amend as required or delete.

Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP810 | Corrective and Preventive Actions |
| FM809-2 | Complaints Register |

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

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

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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