Medical Devices: 
Customer Complaints

Authors: 
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Here you will find answers to the following questions:

- What are the requirements for complaint management?
- Who is responsible for complaint management?
- What is necessary for complaint evaluation and investigation?

Manufacturers (including distributors) must maintain complaint files.

Figure 1 contains the definition of a complaint per the U.S. medical device quality system regulation. Complaints may be received from internal or external sources, in written or oral form. It is important to note that oral complaints must be documented upon receipt.

**Figure 1 U.S. Definition for complaint [21 CFR Part 820.3 (b)]**

<table>
<thead>
<tr>
<th>Definition for complaint according to 21 CFR Part 820.3 (b)</th>
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<tbody>
<tr>
<td>Complaint means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.</td>
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</table>

The organization must designate a formal complaint handling unit or group. There is significant variability in how medical device organizations handle complaints. Small organizations may funnel all complaints to a single individual or group while large companies with numerous sites may designate one functional unit within each division or site to handle complaints.

Procedures must be established for receiving, evaluating, investigating and providing follow-up for complaints. Procedures for the complaint process need to include how to:

- assign responsibility
- obtain and document information especially from the complainant
- evaluate and investigate complaints
- handle necessary corrective actions (including a provision when to link into the CAPA system)
- handle material segregation and disposition or reprocessing (especially decontamination) of customer returns
- close a complaint
- respond to the complainant and
- track or trend complaints

All complaints need to be processed in a uniform and timely manner. It can be a challenge to identify and document all complaint information both from internal and external sources. It is important to have good written procedures and well trained personnel to ensure accurate and timely complaint documentation and handling.

Complaint systems can be paper based, electronic or a combination of both depending on the needs of the organization.

The complaint handling unit and the product manufacturing site need to have access to the relevant complaint records. The manufacturing site should be knowledgeable of complaints that are affiliated with product produced at the site especially when the complaint handling unit is located at a different site.
Complaint evaluation

All complaints need to be reviewed and evaluated at a minimum to determine whether an investigation is necessary. This evaluation is not the same as an investigation. The evaluation is completed to determine if the information is truly a complaint and to determine whether or not the complaint needs to be investigated.

Additionally, all complaints must be evaluated to determine whether the complaint represents an event that requires reporting under local vigilance regulations, such as, European Commission, MEDDEV 2.12-1 Guidelines on a Medical Devices Vigilance System or 21 CFR Part 803 Medical Device Reporting. Files related to reportable events should be specifically identified; this can be achieved by segregation, labeling, color coding, electronically tagging, etc.

Many organizations use decision making tools like decision trees or checklists to facilitate decision making during the complaint evaluation process.

Complaint investigation

Most complaints will require some level of investigation at a minimum to determine whether the complaint can be confirmed. Duplicate efforts are not necessary. For investigations of the same issue, the first event can be referenced in subsequent records.

When no investigation will be performed, the records must indicate the reason for not conducting an investigation and identify the name of the individual responsible for the decision (21 CFR 820.198(b)).

There are some specific instances where an investigation is mandated, such as

where the complaint represents an event that must be reported to regulators under vigilance requirements (21 CFR 820.198(d))

Records of complaint investigations need to be maintained. Figure 2 describes the specific information to be retained for U.S. regulated medical device complaints.

Figure 2 Complaint investigation report documentation requirements [21 CFR Part 820.198 (e)]

<table>
<thead>
<tr>
<th>Complaint investigation report documentation requirements according to 21 CFR Part 820.198 (e)</th>
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<tbody>
<tr>
<td>The record of investigation shall include:</td>
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<tr>
<td>(1) The name of the device;</td>
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<tr>
<td>(2) The date the complaint was received;</td>
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<tr>
<td>(3) Any device identification(s) and control number(s) used;</td>
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<tr>
<td>(4) The name, address, and phone number of the complainant;</td>
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<tr>
<td>(5) The nature and details of the complaint;</td>
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<tr>
<td>(6) The dates and results of the investigation;</td>
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<tr>
<td>(7) Any corrective action taken; and</td>
</tr>
<tr>
<td>(8) Any reply to the complainant.</td>
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</tbody>
</table>

When product is to be returned to the organization, consideration must be given to the potential for contamination. Shipping of potentially hazardous materials must be considered as well as handling the materials received. Procedures should describe safe handling and any applicable decontamination methods to be used.

Complaint data should be tracked and trended. This data should be reviewed by management during management review.

Summary:

Manufacturers must have written procedures for receiving, evaluating, investigating and providing follow-up for complaints. A designated unit or group is to be responsible for complaint management.
Most complaints will require some level of investigation.

*This text is an excerpt from Chapter 23 of the GMP MANUAL.*

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