Complaint Management

Examples of Non-conformances
Cited by FDA and an EU Notified Body
This section includes FDA Warning Letter citations based on nonconformances included in FDA 483 Lists of Observations
Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit to **ensure complaints are processed in a uniform and timely manner**.

- Your SOP indicates that a complaint should be documented within [redacted] hours or less of "becoming aware" of the complaint.
- Specifically, we observed time differences that ranged from 4 weeks to 11 1/2 months after you first became aware of the complaint.
Your firm failed to establish and implement complaint handling procedures as required by 21 CFR 820.198(a). Your Complaint Report **form fails to include the need for review** and/or **investigation**, **who** would conduct the investigation, their **conclusions** and **any response** back to the complainant.
Failure to analyze complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. 21 CFR 820.100(a)(1). Your firm fails to conduct an appropriate analysis of complaints and reports of nonconforming product in that:

A. You **fail to examine complaints by failure mode**, and **multiple failures** reported for devices from a single lot are **not individually analyzed**.
Failure to review, evaluate, and investigate any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications.

- Patient's nurse contacted your company to report the [diabetes meter] was reading high and patient was taken to the Emergency Room. This **complaint was closed without performing an investigation**.

- Patient's daughter contacted your company to report the OneTouch Ultra was set in the **wrong units of measurement**. Complaint was **closed without performing an investigation**.
Your firm received two oral user reports that alleged the possible failure of two AC defibrillators occurring during surgery. You explained to the FDA investigators that the devices "burned up" due to user error. However, your firm failed to:

(a) conduct and document a formal complaint investigation;
(b) document the nature and details of the incidents;
(c) document your follow-up with the users;
(d) document your justification for why you did not consider the oral user reports as complaints; and
(e) document your determination of whether any adverse medical event had occurred during surgery.
Failure to establish, maintain, and implement procedures for receiving, reviewing, and evaluating complaints, as required by 21 CFR 820.198(a).

For example, the following service reports received by the firm and classified as complaints were not evaluated to determine if the complaints represented events which were required to be reported to FDA as MDRs:
Failure to establish and maintain adequate procedures for receiving, reviewing and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). Your "Complaint Procedure" does to ensure:

1) complaints are processed in a **uniform and timely manner**;

2) **oral complaints** are documented upon receipt; and

3) complaints are **evaluated** to determine whether they are **reportable under 21 CFR 803**.
Failure to maintain complaint files, to comply with 21 CFR 820.198.
For example:

a) Your firm did not consider any of the following events to be complaints; no complaint records were created and no investigations were performed: [several examples of injuries and malfunctions]

b) Your firm has not adequately established and maintained procedures for receiving, reviewing and evaluating complaints by a formally designated unit. “Policy 1.4. Complaint Process” is not being followed. The policy states that the employee receiving a complaint or praise shall complete a Company Complaint Form. No Company Complaint Forms have been completed. This policy is not adequate because it does not describe a method for determining if an investigation is necessary, how corrective and preventive actions are implemented and evaluated, and how to determine if a complaint must be reported to FDA.

The adequacy of your firm's response dated June 15, 2011, cannot be determined at this time. Your firm's response did not include objective evidence (b)(4)
Failure to investigate complaints involving the possible **failure of labeling to meet any of its specifications** as required by 21 C.F.R. § 820.198(c). Specifically, your firm did not investigate several complaints to determine a root cause for the complaint and/or the determination whether the issues described in the complaint(s) extended to other lot(s) of product.

For example your firm did not perform a root cause investigation for the following complaints that dealt with mislabeling: [four specific instances of mislabeling are listed].
Your firm failed to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit to ensure that complaints are documented and investigated as required by 21 CFR 820.198.

For example, your firm did not document the investigation of complaints that involve devices that customers return for repair. Also, your firm failed to establish a procedure to ensure that complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR Part 803 or 804, Medical Device Reporting.
Failure to adequately establish and maintain complaint files, including procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a).

For example:

a. (b)(4) of a sample of (b)(4) Return Material Authorizations reviewed (b)(4) communicated alleged deficiencies related to quality, reliability, or performance of [brand name] electric breast pumps. These communications were not recognized as complaints by your firm’s customer service representatives or servicing technicians nor documented as complaints on customer complaint/issue form (b)(4).

b. Complaint files do not document the complete nature and details of complaints or an explanation of the efforts made to ascertain the information. Complaint File Nos. (b)(4) document alleged pain and injury events yet do not document the patient outcome including whether medical intervention was necessary or your firm’s efforts to ascertain this information. (CHI-DO)
This section includes examples of nonconformances on a Notified Body List of Findings
Notified Body Audit Findings
Lack of Timeliness for Complaint Closure

- The following finding is quite common and is in regard to a lack of timeliness in closing complaints and specifically failure to follow the company’s own procedures.

**Requirement:**

Complaint System, SOP-xxx, Rev. x, 7.8 Complaint File Closure: Product Complaint files should be closed […], but no later than 90 days from receipt of the product.

**Description of Nonconformity:**

The timeline for complaint closure was not followed for Customer Complaint Report, RGA # XXX.

**Supporting Audit Evidence:**

Customer Complaint Report, RGA # XXX, Product, 6/9/2012 – complaint not closed within the required 90 days
Notified Body Audit Findings
Lack of a Rationale for Not Opening a Corrective Action

- The following finding is quite common and is in regard to a failure to provide rationale for not opening a corrective action.

**Requirement:**

8.5.1 General

If any customer complaint is not followed by corrective and/or preventive action, the reason shall be authorized (see 5.5.1) and recorded (see 4.2.4).

**Description of Nonconformity:**

There are no rationales provided within the complaint documentation why corrective / preventive actions are not necessary.

**Supporting Audit Evidence:**

Customer Complaint Number XXX
Notified Body Audit Findings
Failure to Use Complaint Data as an Input to Assess the QMS

- The following finding is in regard to not using complaints as an input for assessing whether any changes are needed to assure suitability and effectiveness of the quality management system.

Requirement:
- EN ISO 13485, clause 8.5 “Improvement”.
- The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

Description of Nonconformity:
- Complaint # XXX: The identified problem was not analyzed for impact on the risk analysis (should be part of the final incident report).

Supporting Audit Evidence:
- Customer Complaint Numbers XXX and YYY
Requirement:
EN ISO 13485:2012/AC2012 - 8.5.1 Improvement - General
If national or regional regulations require notification of adverse events that meet specified reporting criteria, the organization shall establish documented procedures to such notification to regulatory authorities.

MEDDEV 2.12-1 rev 8:
IMMEDIATELY (without any delay that could not be justified) after the MANUFACTURER established a link between the device and the event but not later than 30 elapsed calendar days following the date of awareness of the event.
If after becoming aware of a potentially reportable INCIDENT there is still uncertainty about whether the event is reportable, the MANUFACTURER must submit a report within the timeframe required for that type of INCIDENT.

Description of Nonconformity:
Several vigilance reports were submitted late to the competent authorities, exceeding the 30 calendar day requirement.

Supporting Audit Evidence:
XXX, awareness date: Apr 3, 2013, initial MDV report to MHRA May 7, 2013
Notified Body Audit Findings
Failure to Meet Vigilance Reporting Timeliness Requirements

**Requirement:**

8.5.1 Customer Complaints - The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

**Description of Nonconformity:**

- There is no overall summary of the current status of open complaints. Several complaints are open for well over a year without justification.
- Complaints do not include a risk impact evaluation to establish priorities.
- Complaint data are not provided in normalized view (complaints vs. number of devices sold).

**Supporting Audit Evidence:**

Varies:

- Complaint #s – AAA, BBB, CCC ..... JJJ
- Compliant #s – LLL, MMM, NNN, OOO, PPP
- Example of complaint data report
Leadership at All Levels of the Organization

Training: Tailored to all Company Employees

Standardized Complaint Reporting and Handling Processes

Cross-Functional Complaint/CAPA Quality Improvement Teams

Periodic Reviews of System Performance

Clear Published Metrics to Instill Awareness

Effective Means for Returning Complaint-Related Devices