Complaints and Complaint Investigations

Presented by:
Graham N. Giesen, Supervisory Investigator
Food and Drug Administration
Office of Regulatory Affairs
Dallas District Office

Definition: Complaint

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

21 CFR 820.3(b)

Complaint Files & Procedures

- Maintain complaint files
- Establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit
- Process all complaints in a uniform and timely manner
- Document oral complaints upon receipt

21 CFR 820.198(a)

The Preamble on Documenting Oral Complaints

A December 1986 General Accounting Office report entitled “Medical Devices: Early Warning of Problems is Hampered by Severe Underreporting,”…showed that approximately 83 percent of the hospitals report complaints orally. FDA believes that these oral complaints must be captured in the complaint handling process.

QS Preamble, Comment 191

MDR Reportable Complaints

Evaluate complaints to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting

21 CFR 820.198(a)(3)

Complaints Not Investigated

- Review and evaluate all complaints to determine whether investigation is necessary
- When no investigation is made, maintain a record that includes the reason no investigation was made and the name of individual responsible for the decision not to investigate

21 CFR 820.198(b)

Preamble on Initial Complaint Review

Section 820.198(b) discusses the initial review and evaluation of the complaints in order to determine if the complaints are “valid.” …this evaluation is not the same as a complaint investigation. The evaluation is performed to determine whether the information is truly a complaint or not and…whether the complaint needs to be investigated or not. If the evaluation decision is not to investigate, the justification must be recorded.

QS Preamble, Comment 190

Complaint Investigations

Review, evaluate and investigate any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications, unless such investigation has already been performed for a similar complaint and another investigation is not necessary

21 CFR 820.198(c)

The Preamble on Duplicate Investigations

In cases where an investigation would be duplicative, a reference to the original investigation is an acceptable justification for not conducting a second investigation.

QS Preamble, Comment 190

Documenting Complaint Investigations

Record of investigation made under 820.198 shall include:

1. The name of the device
2. The date the complaint was received
3. Any device identification(s) and control number(s) used
4. The name, address, and phone number of the complainant

More . . .

21 CFR 820.198(e)

Complaint Investigations

Record of investigation made under 820.198 shall include:

5. The nature and details of the complaint
6. The dates and results of the investigation
7. Any corrective action taken
8. Any reply to the complainant

21 CFR 820.198(e)

The Preamble on Complaint Investigations

Section 820.198(e)(1) through (e)(5) are considered to be basic information essential to any complaint investigation. If there is some reason that the information described in 820.198(e) cannot be obtained, then the manufacturer should document the situation and explain the efforts made to ascertain the information. This will be considered acceptable as long as a reasonable and good faith effort was made.

QS Preamble, Comment 190

Additional Information for MDRs

When investigating MDR reportable complaints, include in records a determination of:

1. Whether device failed to meet specifications
2. Whether device was being used for treatment or diagnosis
3. Relationship, if any, of device to reported incident or adverse event

21 CFR 820.198(d)

How do you investigate complaints when samples are not available or returned?

- Test any reserve samples or products manufactured around the time of the manufacture of the device in question
- Analyze the Device History Records
- Analyze any related Service Records
- Analyze any CAPA data and Nonconforming data that is related to the device in question

Failure investigation and what documentation would you maintain?

- Investigate to root cause where possible
- Do not take the easy road and stop at the quick fix
- Make sure the proposed fix will not cause unexpected results or other adverse problems

Complaint Record Accessibility

When the formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.

21 CFR 820.198(f)

Complaint Retention Requirements

- The complaint files shall be maintained in accordance with the general record keeping requirements of 820.180. All complaint files are to be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer.

The Preamble on Complaints Not Maintained at Manufacturing Site

A manufacturer's procedures must ensure that the manufacturing site is alerted to complaints concerning devices produced at that site.

QS Preamble, Comment 196

Foreign Complaint Records

If the formally designated complaint unit is outside the U.S., required complaint records shall be reasonably accessible in the U.S. at either:

- A location in U.S. where manufacturer's records are regularly kept
- The location of the initial distributor

21 CFR 820.198(g)

Effectiveness of Complaint Systems

- Careful about what matrix you use to analyze effectiveness.
- Common Pitfalls
  - How many complaints?
  - How many are opened and closed?
  - Too many problem codes?

Complaint Handling System in a Risk-Based Environment?

- Remember – risk management tools may be helpful in deciding what actions to take BUT be careful NOT to use risk management tools to try and justify away doing an action!

Feedback Loop

- Complaints and complaint investigations are integral to an effective CAPA system as they provide a source of external data post-market

- One single complaint may lead a company to take remedial action or it may require ongoing analysis of numerous complaints to identify a trend that may necessitate remedial action

FDA Expectations

- Procedures defining complaint and complaint investigation process
- Complaints handled in a timely and uniform manner
- Appropriate questions are asked and information collected to support decision(s)
- Risk is considered

FDA-483 Observations and Warning Letter Citations Related to Complaints

- Complaint handling procedures for [receiving][reviewing][evaluating] complaints have not been [established][defined][documented][completed][implemented].

FDA-483 Observations and Warning Letter Citations Related to Complaints

- Complaints involving the possible failure of a device to meet any of its specifications were not evaluated and investigated where necessary.

FDA-483 Observations and Warning Letter Citations Related to Complaints

- Your firm classified incoming customer calls as non-complaints without conducting and documenting further follow-up with the patients or justifying the reason why.

FDA-483 Observations and Warning Letter Citations Related to Complaints

- Your firm does not always obtain nor document adequate details of the incoming calls.

Thank You!