According to 2012 FDA statistics, drug company’s Product Complaint handling systems (21 CFR 211.198) were cited in 142 Turbo EIR observations for their deficiencies representing almost 4% of all observations. Medical device companies were cited 512 times for similar deficiencies to 21 CFR 820.198 or nearly 11% of all observations. The most frequent cause of these observations is that systems do not exist for receiving, reviewing, or evaluating complaints, or that the current procedures do not include provisions for adequate assessment of the complaints.

Maintaining an adequate complaint handling system is more than just a requirement, it is a good quality practice that can help assure your product continues to meet quality attributes after it leaves your control. Key parts of a complaint handling program include:

- Written procedures
- Collection and triage of complaints
- Evaluation of complaints
- Reporting and Trending

**Written Procedures**

All processes impacting GMP systems must be documented in controlled procedures and approved by the Quality Unit.

**Collection and Triage**

It is best to have a single point of contact for collecting complaints. Consider utilizing the same reporting system as for adverse events at this point because there is generally overlap in the evaluation of complaints for adverse events and vice-versa because some complaints may indicate quality issues (e.g., Lack of Efficacy). Each product complaint should be prioritized based on the possible implications. Complaints that may require
FDA Field Alerts should receive the highest priority. Those that could indicate serious quality issues or impact patient safety should also be classified highly.

### Evaluation of Complaints

The Quality Unit determines if investigation of the complaint is required and if so, how the complaint will be investigated. Written justification of the decision is documented with appropriate rationale. Whether or not return samples can be obtained is documented, as well as a review of retain samples, if appropriate. A decision to quarantine any material not already distributed should be made and documented. Critical complaints such as those that may require expedited reporting such as for certain adverse events or quality issues are expected to be reviewed immediately and possible root causes assessed.

Investigation should also include possible impact to other batches/units, the complaint history for the particular batch/unit, and a review of the manufacturing and laboratory records for possible deviations that could have led to the complaint.

Product complaint investigations should be completed within a standard timeline, generally 30 calendar days, from the time the company received the complaint. Some complaints, such as those involving third-party manufacturers, may require longer timelines. If the investigation cannot be completed on time, an interim report approved by the Quality Unit should be issued.

### Reporting and Trending

Completed investigation and remediation reports should be distributed as necessary to internal groups and the company should respond appropriately to the customer/complainant. The final report should indicate if the complaint is confirmed or unconfirmed, including a documented rationale.

Appropriate corrective and preventive actions should be documented and completed for each confirmed complaint.

Complaints should be categorized so they may be tracked and trended. Categories may include defect type, system(s) impacted, product, dose, equipment, etc. Trend reports should be prepared for management review on a regular basis to identify trends and assure management is aware of issues that potentially impact product quality. The analysis should include a statistical evaluation, identification of outliers, and identify trends that indicate a need for process change or improvement.

When developing or assessing your product complaint system, consider the points above and assure your program does not end up as a statistic.

Photo via Wall Street Journal Blog